

AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
STERILE COMPOUNDING COMMITTEE
August 9, 2016
St. Petersburg Marriott Clearwater
12600 Roosevelt Boulevard, North
St. Petersburg, Florida 33716

Committee Members:

Michele Weizer, PharmD, BCPS, Chair

Mark Mikhael, PharmD

Debra Glass, BPharm

Board Counsel:

David Flynn, Assistant Attorney General

Lawrence Harris, Assistant Attorney General

Board Staff:

Allison Dudley, Executive Director

Alexandra Meredith, Regulatory Supervisor

PLEASE TURN OFF ALL CELL PHONES, PAGERS AND BEEPERS DURING THE MEETING. THANK YOU.

Tuesday August 9, 2016; Immediately Following Rules Committee

1. Rule 64B16-27.797, the Standards of Practice for Compounding Sterile Products

- Draft language
- Discussion re need for additional changes

2. Rule 64B16-28.802, Special Sterile Compounding Permits

- Draft language

3. Rule 64B16-28.905, Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities

- Discussion re Inspection Entities for Outsourcing Facilities

4. In-state outsourcing facility requirements

- Discussion

5. FDA Guidance Documents (Informational)

5. Future meetings

6. New business/old business

7. Public Comment

Participants in this public meeting should be aware that these proceedings are being recorded.

Proposed Amendment

Rule 64B16-27.797, Fla. Admin. Code. (Oct. 1, 2014)

Amendment Origination: The proposed amendment is being placed before the Sterile Compounding Committee based on discussion and direction at the June 2016 Board meeting. Specifically, the main issue involves the caulking of the perimeters of ceiling tiles located in the compounding area.

Coding: The insertion of text to the existing rule will be coded with underlining. And, the deletion of existing rule language will be coded by a ~~strike through~~.

PROPOSED AMENDMENTS TO EXISTING LANGUAGE

There are not any changes being proposed to the rule number, title, opening paragraph, or subsections (1) through (3).

Subsection (4):

Insert a new subsection (4) to read as follows: (4) Registered Outsourcing facilities: For any pharmacy registered as an outsourcing facility, the minimum standards of practice for sterile compounding shall be the current good manufacturing practices as adopted in subsection (3).

Current Subsection (4):

Renumber to subsection (5) and amend as follows:

(5) ~~(4)~~ Clarifications, Variances, or Exceptions Specific to the United States Pharmacopeia:

(a) no change

(b) no change

(c) no Change

(d) USP Chapter 797 provides in part that the compounding facility's ceiling tiles located in the ante-area, buffer area, and clean room that consist of inlaid panels "shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame." A pharmacy shall not be required to caulk the inlaid ceiling tiles to the perimeter of the support frame if the following are met:

1. The ceiling tiles are specifically manufactured to be utilized in a facility that must meet and maintain an airborne particulate cleanliness of ISO Class 5.

Proposed Amendment

Rule 64B16-27.797, Fla. Admin. Code. (Oct. 1, 2014)

2. The core of the ceiling tiles are sealed on the front, back, and all four edges to render them impervious and hydrophobic, so they can be properly maintained and cleaned as required by this rule.

3. The ceiling tiles are inlaid or installed using a gasket grid sealing system, which is manufactured for use in facilities that must meet and maintain an airborne particulate cleanliness of ISO Class 5. The sealing system must create and maintain a positive seal between the ceiling tile and the support frame.

64B16-28.802 Special Sterile Compounding Permits for Pharmacies and Outsourcing Facilities.

(1) A Special Sterile Compounding Permit (SSCP) is required before any pharmacy may engage in the preparation of compounded sterile products. For purposes of this rule, an outsourcing facility shall be deemed a pharmacy.

(2) An SSCP shall be issued by the department as an additional permit with a separate permit number that differs from the permit number of the pharmacy obtaining the SSCP.

(3) All sterile compounding shall be done in strict compliance with the standards set forth in Rules 64B16-27.700 and 64B16-27.797, F.A.C.

(4) An outsourcing facility shall comply with current good manufacturing practices as adopted and incorporated in Rule 64B16-27.797, F.A.C.

(a) If a pharmacy is not registered as an outsourcing facility at the time the pharmacy applies for an SSCP, the applicant shall amend the application within 7 business days if the pharmacy becomes a registered outsourcing facility before the SSCP is issued.

(b) If a pharmacy is issued an SSCP and later becomes registered as an outsourcing facility, the pharmacy will not be required to obtain a new or additional SSCP. However, the pharmacy applicant shall comply with current good manufacturing practices to be eligible to retain the issued SSCP and the pharmacy shall notify the department in writing within 7 business days of becoming a registered outsourcing facility.

(c) An outsourcing facility that does not engage in patient specific sterile compounding and dispensing pursuant to such prescription shall only be required to obtain the SSCP. However, if the outsourcing facility engages in patient-specific sterile compounding, in addition to the SSCP, the outsourcing facility shall be required to obtain a pharmacy permit specific to the type of patient dispensing that the pharmacy will be engaged in (i.e., community pharmacy permit or institutional pharmacy permit).

(5) The SSCP is not required for a Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope pharmacy if that pharmacy holds no other pharmacy permit and is not registered as an outsourcing facility.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History—New 6-18-13, Amended 10-20-13, 5-8-16.

64B16-28.905 Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities.

All applicants for a nonresident sterile compounding permit must have and present a current and satisfactory inspection report, and all nonresident sterile compounding permit holders seeking biennial renewal of the permit must have and present a current and satisfactory inspection report, as mandated by Section 465.0158, F.S.

(1) **Current and Satisfactory Inspection Report:** An inspection report is current if the inspection report establishes that the inspection took place within the time frames established in Section 465.0158(3)(e), F.S. An inspection report will be deemed satisfactory when the report reflects that the applicant or permit holder compounds all sterile products in compliance with minimum practice and quality standards (minimum standards). The minimum standards are different for those who are only registered as a nonresident pharmacy pursuant to Section 465.0156, F.S., and for those who are registered as an outsourcing facility pursuant to Section 21 U.S.C. 353b.

(2) **Minimum Standards:** Applicants for an initial permit or applicants for biennial renewal that are both a registered nonresident pharmacy and a registered outsourcing facility must meet the minimum standards applicable to a registered outsourcing facility.

(a) **Registered Outsourcing Facility:** The minimum standards for a registered outsourcing facility are the Current Good Manufacturing Practices (cGMP) that are adopted and incorporated by reference in subsection 64B16-27.797(3), F.A.C.

(b) **Registered Nonresident Pharmacies:** The minimum standards for a registered nonresident pharmacy are Chapters 797, 71, 85, and 731 of the United States Pharmacopeia that are adopted and incorporated by reference in subsection 64B16-27.797(1), F.A.C.

(3) **Mandatory State Inspection Report:** The current and satisfactory inspection report must be generated from an inspection that is performed by the regulatory or licensing authority of the state, territory, or district (hereinafter "state") where the applicant is geographically located, unless the applicant meets the acceptable circumstances established herein. The board hereby deems the following as acceptable circumstances for the department's acceptance of a current and satisfactory inspection report performed pursuant to Sections 465.0158(3)(e)1.-3., F.S., in lieu of the state inspection report:

(a) In the event that state or federal law prohibits the submission of the state inspection report;

(b) In the event that the state refuses to perform the inspection or generates an inspection report after completion of the inspection;

(c) In the event that the state is unable to perform an inspection within a reasonable time period from the date requested. Reasonable time period means within 180 days from the date that the applicant requested an inspection be performed. A failure by the applicant to request an inspection within 180 days from the date of permit renewal is deemed not to be an acceptable circumstance;

(d) In the event that the state inspection report documents that the applicant fails to meet the minimum standards adopted in this rule or when the inspection report merely lists an overall pass or fail and does not have the minimum standards enumerated within the inspection report with an appropriate indication of pass, fail, or not applicable, next to each enumerated standard;

(e) In the event the state inspection report would not be admissible in an administrative proceeding pursuant to the provisions of Chapter 120, F.S., or when state or federal inspectors advise they will not testify to the contents, results thereof, or authentication of the state inspection report;

(f) In the event that the applicant is able to submit a current inspection report from the United States Food and Drug Administration that concludes or establishes the applicant is in compliance with cGMP.

(4) **Approved Inspection Entities for Registered Nonresident Pharmacies:** This section is not applicable to inspection reports for registered outsourcing facilities. The board must approve entities for which the department will accept a current and satisfactory inspection report in lieu of an onsite inspection by the department or an inspection by the licensing or regulatory authority of the state, territory, or district where the applicant is located. An entity that wants to be approved as an inspection entity must submit an Approval Request with attached documentation to the board office. The Approval Request, and attached documentation, shall demonstrate compliance with the following requirements:

(a) The entity must be a legally recognizable business entity that possesses a separate existence for tax purposes. An Approval Request must be submitted with business formation documents that establish compliance with this paragraph;

(b) The entity is formed, established, or created to avoid a reoccurring conflict of interest between the entity and those whom the entity will be inspecting. A conflict of interest is a real or seeming incompatibility between the entity's private interests and the entity's duty to conduct an impartial inspection;

(c) The entity will not conduct any inspection in which the entity or an employed inspector of the entity has a conflict of interest;

(d) The entity must have a customized inspection report. The inspection report must enumerate all minimum standards of each of the chapters of the United States Pharmacopeia that are listed in paragraph (2)(b) of this rule. Each enumerated minimum standard must have a place for the inspector to mark compliant or yes; non-compliant, deficient or no; and not applicable. Each enumerated minimum standard must also have room for the inspector to document observations or comments. An Approval Request must be submitted with a copy of the customized inspection report;

(e) The entity must submit any completed inspection report with digital photography capturing each enumerated minimum standard if the enumerated minimum standard is subject to being captured by photography;

(f) With the Approval Request, the entity must submit an inspection history report. The inspection history report must reflect that the applicant has experience performing inspections for compliance with the required minimum standards. To be approved, an entity must have a minimum of 2 years' experience performing inspections and must have performed a minimum of 20 inspections. The required inspection experience may be demonstrated through the experience of the employed inspectors, if the entity has not been in existence for 2 years prior to submitting an Approval Request;

(g) The entity must agree in writing that the entity will not make a recommendation for the granting, denial, or discipline of a permit;

(h) The entity shall have a written policies and procedures manual. The policies and procedures shall at a minimum address the timely completion and proper performance of inspections and must establish protocols and procedures to ensure compliance with this rule. The policy and procedures manual must be submitted with the Approval Request. The policies and procedures shall require the inspections to be unannounced and that the costs of any inspection shall not be based on or differ in the amount based on the results of the inspection;

(i) The entity must agree in writing that it will testify to the contents of the inspection report in any civil, criminal, or administrative proceeding and that the entity agrees that it and any employed inspectors will not request an expert witness fee (Section 92.231, F.S.) for the testimony of the inspector who performed the inspection;

(j) The entity shall maintain all inspection reports and related records for a period of no less than 4 years from the date inspection was concluded;

(k) The entity shall, within 60 days prior to closing, notify the department or the board when it will close or cease performing inspection services and make arrangements with the department for preserving inspections records that are still within the 4 year retention requirement.

(5) Employed Inspectors: The entities' employed inspectors must meet the following criteria:

(a) Any employed inspector must hold an active license to practice pharmacy in any state, territory or district of the United States. Proof of the license shall be submitted with the Approval Request. The employed inspectors may not have any disciplinary history related to the practice of a health profession within 5 years prior to the Approval Request and may have never been disciplined for an offense related to compounding. This provision shall not prohibit the entity from retaining or employing any person that does not hold a pharmacy license for the purposes of assisting the inspectors. For example, it is acceptable to hire a microbiologist or chemist to assist the inspectors in completing the inspection and inspection report;

(b) Any employed inspector must have a minimum of 4 years' experience in the practice of sterile compounding. At least 2 of the 4 years of experience must be obtained through the active practice of compounding sterile products in all risk categories (low, medium, and high risk sterile compounding). The other 2 years may be obtained by one or more of the following: 1) Being employed by a state or federal agency to perform inspections of pharmacies or pharmaceutical manufacturers to determine compliance with minimum sterile compounding standards or current good manufacturing practices standards; 2) Being employed as a full-time instructor at an accredited university for the purpose of instructing students in didactic and clinical instruction on sterile compounding; 3) Being employed to conduct research related to sterile compounding; or 4) Being published in a peer review journal when the article is related to sterile compounding. Three months of credit will be awarded for each published article related to sterile compounding;

(c) At least one of the employed inspectors must have a minimum of 1 year, of the 4 years required, supervisory experience related to the practice of sterile compounding. Supervisory experience is being employed as a supervisor of other pharmacists, not just technicians, in a pharmacy setting that engaged in sterile compounding;

(d) Those employed inspectors which do not have at least 6 months of experience in performing inspections related to sterile compounding must first attend 2 inspections, as a subordinate inspector in training, before being allowed to perform an inspection independently;

(e) The entity must submit a copy of each inspector's employment history and a copy of the each inspector's curriculum vitae (CV) with the Approval Request. The CV must demonstrate that the inspectors are compliant with the experience requirements of this rule;

(f) During the period of employment as an inspector for the entity, the inspectors must have documented training related to sterile compounding and performing sterile compounding inspections. At a minimum, the training must consist of at least 10 clock hours of training annually. The training documentation shall be made available to the board upon written request.

(6) Once an entity is approved by the board, the applicant will be required to maintain compliance with the provisions of this rule or the approval is subject to revocation in compliance with the provisions of Chapter 120, F.S. The department will randomly require documentation of each approved entity to ensure continued compliance with the provision of this rule.

(7) All approved entities shall be listed on the Department's website.

Rulemaking Authority 465.0158 FS. Law Implemented 465.0158 FS. History--New 12-24-15.

**DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292**



**SPECIAL STERILE COMPOUNDING PERMIT APPLICATION
AND INFORMATION FOR OUTSOURCING FACILITIES**

August 2016

Special Sterile Compounding Permit for Outsourcing Facilities

Pursuant to Rule 64B16-28.100, F.A.C., any establishment that is engaged in sterile compounding must be permitted by the Florida Board of Pharmacy. If the establishment is registered as an outsourcing facility with the Secretary of the U.S. Department of Health and Human Services and is solely engaged in non-patient-specific compounding, the establishment must obtain this special permit but is not required to obtain any other permits offered by the Board of Pharmacy. The compounding of sterile products must be in strict compliance with Current Good Manufacturing Practices (cGMP).

If engaged in any patient-specific compounding the applicant must also obtain a community pharmacy permit.

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of \$255.00.

Application Processing

Please read all application instructions before completing your application.

- 1) Please mail the application and the \$255.00 application fee (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

OR, use the following address if you are using express mail:

Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

Within 7-14 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. Please do not contact the board office concerning your inspection date, and allow 30 days for the inspector to contact you. If the inspector has not contacted you within 30 days, then notify the board. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

- 2) Submit fingerprint results-

Failure to submit fingerprints will delay your application. All officers, officers and prescription department managers are required to submit a set of fingerprints unless the corporation is exempt under the Section 465.022, Florida Statutes for corporations having more than \$100 million of business taxable assets in this state. These corporations are only required to have the prescription department manager or consultant of record to submit fingerprints. The statute allows the prescription department manager for a corporation having more than \$100 million of business taxable assets in this state to submit results from AHCA if the results were also available to the Department and are within one year of the receipt date of the application.

Applicants can use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

How do I find a Livescan vendor in order to submit my fingerprints to the department?

The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at <http://www.doh.state.fl.us/mqa/background.html>

What information must I provide to the Livescan vendor I choose?

- a) If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, **including your Social Security number**. The Department will not be able to process a submission that does not include your Social Security number.
- b) You must provide the correct ORI number.

Where do I get the ORI number to submit to the vendor?

The ORI number for the pharmacy profession is EDOH4680Z

- 3) Attestation for Business Taxable Assets- For new establishments only.

If the applicant has more than \$100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business attesting the corporation has more than \$100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

Licensure Process- For new establishments only.

Once the application is deemed complete, the board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 10 days. **Please wait 15 days from your satisfactory inspection before checking on the status of your permit.** You may lookup your license number on our website at <http://www.doh.state.fl.us/mqa> under "Look up Licensee."

Drug Enforcement Administration (DEA)

The DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit.

If controlled substances will be involved in your pharmacy practice, you must make an Application for Registration under the Controlled Substance Act of 1970 with the DEA. If possible, you are encouraged to use the on-line form system provided by the DEA. Information is available by visiting their website at <http://www.DEAdiversion.usdoj.gov>.

IMPORTANT NOTICE: The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(e) Has obtained a permit by misrepresentation or fraud.

(f) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(g) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(h) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. [465.003\(14\)](#) or s. [893.02](#) when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

If applicable to you, please provide the documentation to the Florida Board of Pharmacy.



**FLORIDA BOARD OF
 PHARMACY**
 P.O. Box 6320
 Tallahassee, FL 32314-6320
 Telephone (850) 245-4292
 www.floridaspharmacy.gov

**SPECIAL STERILE COMPOUNDING PERMIT APPLICATION FOR
 OUTSOURCING FACILITIES**

Application Type – Please choose one of the following: ____ New Establishment \$255 fee (1020) ____ Change of Location \$100 fee (3011) _____ Existing Sterile Compounding Permit Number ____ Change of Ownership (a new permit number will be issued) \$255 fee (1022 create new file)			
Will the Pharmacy Dispense Schedule II and/or III Controlled Substances? ____Yes ____No			
Please list your Federal Employer Identification Number _____			
1. Corporate Name		Telephone Number	
2. Doing Business As (d/b/a)		E-Mail Address	
3. Mailing Address			
City	State	Zip	
4. Physical Address			
City	State	Zip	
5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record (ie. Supervising Pharmacist)			
Name	License No.	Start Date	Signature
6. Contact Person		Telephone Number	
7. DEA Registration Number		8. Date ready for inspection (must be within 90 days of the date of the application)	
9. Operating Hours		10. Provide Toll-Free Telephone Number (If applicable.)	
Monday-Friday: Open _____ Close: _____ Saturday: Open: _____ Close: _____ Sunday: Open: _____ Close: _____		(_____) _____ - _____	

11. Ownership Information

a. Type of Ownership: _____ Individual _____ Corporation _____ Partnership
_____ Other: _____

NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE FLORIDA SECRETARY OF STATE'S OFFICE

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes _____ No _____

c. Does the corporation have more than \$100 million of business taxable assets in this state?

Yes _____ No _____ If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax Return (F-1120). If no, continue to 12d.

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5 percent or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 12c. If 12c is yes, please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 12c is yes and the prints are on file with DOH or AHCA and available to the Board of Pharmacy the requirement to submit the prints for this person is met. *Attach a separate sheet if necessary.*

Owner/Officer-Title	Date of Birth	Mailing Address, City State, Zip Code	% of Ownership
	/ /		%
	/ /		%
	/ /		%

12. Has anyone listed in 12.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years?

Yes _____ No _____ If yes, please provide a signed affidavit disclosing the reason the entity was closed.

13. Has anyone listed in 12.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years?

Yes _____ No _____ If yes, please provide a signed affidavit disclosing the reason the entity was closed.

14. Has anyone listed in 12.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes _____ No _____ If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2) and 465.022(5), Florida Statutes, questions 15 through 23 are being asked. If you answer yes to any of the following questions, explain on a separate sheet

providing accurate details and submit copies of supporting documentation.

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes; or a similar felony offense in another state or jurisdiction since July 1, 2009? (If yes, provide court documents concerning this conviction)

Yes _____ No _____

15a. If “yes” to 15, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).

Yes _____ No _____

15b. If “yes” to 15, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes _____ No _____

15c. If “yes” to 15, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If “yes”, please provide supporting documentation).

Yes _____ No _____

16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication to a felony under 21 U.S.C. ss.801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

16a. If “yes” to 16, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?

Yes _____ No _____

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 18.)

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

18. If the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been terminated, has the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

19. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program? (If no, do not answer 20 and 21)

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

20. Has the applicant been in good standing with a state Medicaid program for the most recent five years?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

21. Did the termination occur at least 20 years prior to the date of this application?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

22. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant listed on the United States Department of Health Human Services Office of Inspector General’s List of Excluded Individuals and Entities?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

23. I have been provided and read the statement from the Florida Department of Law Enforcement regarding sharing, retention, privacy and right to challenge incorrect criminal history records and the “Privacy Statement” document from the Federal Bureau of Investigation. (Found on Page 9 of this application.)

Yes _____ No _____

24. Are you currently registered or permitted in any other states? If yes, provide the state, permit type, and permit number for each permit. Attach a separate sheet if necessary.

Yes _____ No _____

State	Permit Type	Permit Number

25. Has the applicant, affiliated persons, partners, officer, directors, or PDM or Consultant Pharmacist of Record ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.

Yes _____ No _____ (If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

26. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or Consultant Pharmacist of Record in this state or any other?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)

27. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

Yes _____ No _____ (You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

28. Is there any other permit issued by the Department of Health located at the physical location address on this application?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

29. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes, please answer 29a.

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

29a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?

Yes _____ No _____

30. Is the policy and procedure manual for preventing controlled substance dispensing based on fraudulent representation or invalid practitioner-patient relationship available for inspection by DOH?

Yes _____ No _____

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ TITLE _____ DATE _____
Owner/Officer

PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete. Faxed applications will not be accepted.

- _____ **Application completed (all questions answered)**
- _____ **Application signed**
- _____ **Consultant Pharmacist of Record/Prescription Department Manager Listed with Signature**
- _____ **\$255.00 Fee Attached (Fee required for new establishments only)**

- _____ **Copy of Articles of Incorporation from the Secretary of State's Office (Required for new establishments)**
- _____ **Fingerprints have been submitted via live scan for all officers and owners and the prescription department manager or consultant pharmacist of record. (Required for new establishments)**
- _____ **Attach proof from AHCA of fingerprint results if applicable for prescription department manager or consultant pharmacist of record. (Required for new establishments)**
- _____ **Attestation for Business Taxable Assets of \$100 million if applicable**
- _____ **Bill of Sale is required for Change of Ownership**

Electronic Fingerprinting

Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the live scan method;
- You can find a Livescan service provider at: <http://www.doh.state.fl.us/mqa/background.html>;
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, **including your Social Security number (SSN)**;
- If you do not have a SSN you will need to contact the Board office for a fingerprint card then return the card to the Board office;
- The ORI number for the Board of Pharmacy is EDOH4680Z
- Typically, background-screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo, you may be required to be reprinted by another agency in the future.

Name: _____ Social Security Number: _____

Aliases: _____

Date of Birth: _____ Place of Birth: _____
(MM/DD/YYYY)

Citizenship: _____ Race: _____ (W-White/Latino (a); B-Black; A-Asian;
NA-Native American; U-Unknown)

Sex: _____ Weight: _____ Height: _____
(M=Male; F=Female)

Eye Color: _____ Hair Color: _____

Address: _____ Apt. Number: _____

City: _____ State: _____ Zip Code: _____

Transaction Control Number (TCN#): _____
(This will be provided to you by the Live Scan Service provider.)

Keep this form for your records.

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.

Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C-8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.
US Department of Justice, Federal Bureau of Investigation,
Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as may be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

**DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292**



**SPECIAL STERILE COMPOUNDING PERMIT APPLICATION
AND INFORMATION**

May 2013

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the board) staff to process your application as soon as possible. You are encouraged to apply as early as possible, to avoid delays due to a large volume of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting the application. You should keep a copy of the completed application and all other materials sent to the board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you in approximately 7-14 days if any materials are incomplete.

If you need to communicate with the board staff, you are encouraged to email the board staff at info@floridaspharmacy.gov , or you may at call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

Special Pharmacy Permit Application Information

A special sterile compounding permit is a type of special permit, which is required before any permitted pharmacy may engage in the preparation of compounding sterile products. The compounding of sterile products must be in strict compliance with the standards set forth in rules 64B16-27.797 and 64B16-27.700.

All permittees, with the exception of stand alone Special Parenteral/Enteral and Special Parenteral/Enteral Extended Scope, that are currently compounding sterile products are required to submit this application and will be issued a new Special Sterile Compounding permit number (in addition to your usual pharmacy permit).

This permit is not required for those that hold an individual Special Parenteral & Enteral Pharmacy permit or a Special Parenteral & Enteral Extended Scope permit.

Non-Resident pharmacies are not required to obtain this permit at this time.

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of \$255.00. The application must have the original signatures of the owner or officer of the establishment and the Prescription Department Manager (PDM) or Consultant Pharmacist of Record.

Chapter 465, F.S., requires Special Pharmacies to be under the professional supervision of the PDM or Consultant Pharmacist of Record licensed in the State of Florida. A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs.

Community/Special Parenteral & Enteral, and Special Closed/ Parenteral & Enteral permit holders are required to submit this application and will be issued a new Special Sterile Compounding permit number.

Sterile Compounding Pharmacy Permit Frequently Asked Questions

Q. Who is required to apply for the new permit?

A. The only exceptions to this new permitting requirement are: 1) Stand-alone Special Parenteral/Enteral pharmacies; 2) Special Parenteral/Enteral Extended Scope pharmacies; 3) pharmacies that only perform non-sterile compounding; and 4) non-resident pharmacies

(Note: Modified II B Institutional Pharmacies who are mixing/compounding strictly for immediate use are not required to obtain this permit.)

Q. What is the deadline to obtain this permit?

A. The new **Special Sterile Compounding Permit** must be obtained on or before March 21, 2014 in order to continue sterile compounding.

Q. Where do I find the application for the Special Sterile Compounding Permit?

A. The application can be found online at <http://www.floridaspharmacy.gov/licensing/>

Q. Is there an online application available?

A. No, paper applications must be submitted at this time.

Q. Can the pharmacy continue compounding sterile products during the application process?

A. Pharmacies that are compounding sterile products under their current pharmacy permit may continue to do so, but must obtain the new **Special Sterile Compounding Permit** on or before March 21, 2014 in order to continue sterile compounding.

Q. What is the fee for the Sterile Compounding Pharmacy permit?

A. There will be no fee required for existing licensees. New establishments are required to submit \$255.00 with the application.

Q. Will the pharmacy be issued a new license number?

A. If you currently hold a combined Community/Special Parenteral & Enteral, or a combined Special Closed/Parenteral & Enteral permit you will also be required to apply for the Special Sterile Compounding Permit and maintain two separate permits. Your current permit will become your Community Permit or your Special Closed Pharmacy Permit. Upon approval of your application, you will be issued a separate **Special Sterile Compounding Permit**. When you renew your existing permit it will be reprinted with just Community or Special Closed Pharmacy.

Q. Can I submit a copy of the policy & procedure manual instead of answering the 36 questions listed in the application?

A. Do not send the policy and procedure manual to the board office. The board office will approve the policy and procedure manual based upon answers submitted for the questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

Q. Will a background check be required to obtain a Sterile Compounding Pharmacy permit?

A. Fingerprints are not required for existing licensees, however new establishments will be required to submit fingerprints via Live Scan pursuant to [Chapter 465.022 Florida Statutes](#)

Q. Is a separate pharmacy manger required for the new permit?

A. No, the existing pharmacy manager will be listed as PIC for both permits.

Q. Is an inspection required in order for the permit to be issued?

A. An inspection is not required for pharmacies that currently hold a combined Community/Special Parenteral & Enteral or a combined Special Closed/Parenteral & Enteral permit. If applying for a new establishment an inspection is required and an inspector will contact you to set up an inspection date. Upon completion of a passing inspection, a new permit number will be issued.

Q. Will I need a new DEA permit for this license?

A. For information regarding DEA registration, please contact the DEA at 1-800-667-9752 or 954-306-4654. You may also visit the DEA website at <http://www.DEAdiversion.usdoj.gov>

Application Processing

Please read all application instructions before completing your application.

- 1) Please mail the application and the \$255.00 application fee (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

OR, use the following address if you are using express mail:

Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

*** There is no fee required for existing pharmacies that are currently engaged in the preparation of sterile products from a period of 180 days of adoption of Rule 64B16-28.100, F.A.C.**

Within 7-14 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. Please do not contact the board office concerning your inspection date, and allow 30 days for the inspector to contact you. If the inspector has not contacted you within 30 days, then notify the board. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

- 2) Submit fingerprint results- **For new establishments only.**

New Applicants - Failure to submit fingerprints will delay your application. All officers, officers and prescription department managers are required to submit a set of fingerprints unless the corporation is exempt under the Section 465.022, Florida Statutes for corporations having more than \$100 million of business taxable assets in this state. These corporations are only required to have the prescription department manager or consultant of record to submit fingerprints. The statute allows the prescription department manager for a corporation having more than \$100 million of business taxable assets in this state to submit results from AHCA if the results were also available to the Department and are within one year of the receipt date of the application. **If fingerprints were previously submitted to DOH they are not required to submit them again.**

Applicants can use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

1. How do I find a Livescan vendor in order to submit my fingerprints to the department?

The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at <http://www.doh.state.fl.us/mqa/background.html>

2. What information must I provide to the Livescan vendor I choose?

a) If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, **including your Social Security number**. The Department will not be able to process a submission that does not include your Social Security number.

b) You must provide the correct ORI number.

3. Where do I get the ORI number to submit to the vendor?

The ORI number for the pharmacy profession is EDOH4680Z

3) Attestation for Business Taxable Assets- For new establishments only.

If the applicant has more than \$100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business attesting the corporation has more than \$100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

All Applicants Must Complete the Following Questions.

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection. Do not send the policy and procedure manual to the board office. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

List the following:

Firm Name:

Doing business as (d/b/a):

Telephone number:

Address:

Permit number:

- 1) Explain the practice setting of the proposed facility.
- 2) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 3) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 4) What is the ratio of supportive personnel to each pharmacist? How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 5) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 6) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 7) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 8) What are the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions? If this type of dispensing will not be performed, please state so accordingly.
- 9) What is the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 10) What is the procedure for the annual review and updating of the policy and procedure manual?
- 11) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 12) Include a sample copy of a patient profile.
- 13) What aseptic techniques are utilized?
- 14) Describe the Quality Assurance Program.
- 15) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 16) What are the policy and procedures for handling waste and returns?
- 17) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 18) Describe the refrigerator/freezer to be used.
- 19) Describe appropriate waste containers for:
 - a. Used needles and syringes.
 - b. Cytotoxic waste including disposable apparel used in preparation.

- 20) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 21) How will you utilize the following reference material to ensure patient safety?
 - a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.
 - b. Authoritative Therapeutic Reference.
 - c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
- 22) What steps will be taken to ensure safe handling of cytotoxic drugs related to the Occupational Safety and Health Administration guidelines.
- 23) Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.
- 24) What are the protocols for the maintenance of patient profiles and the offer to counsel if dispensing to outpatients?
- 25) Describe the system for the maintenance of compounding records.
- 26) What percentage of your business is related to sterile compounding?
- 27) Describe the types of sterile products you will compound.
- 28) Are the products you will be compounding:
 - a. be pursuant to a patient-specific prescription
 - b. be prepared in bulk (compounding multiple doses from a single source or batch)
 - c. be prepared in bulk for office use.
- 29) Will your pharmacy ship sterile compounded products to other states?
If yes, provide a list of states to which your pharmacy will ship.
- 30) Provide the total number of pharmacy staff and indicate how many will be preparing sterile products;
 - a. Pharmacists
 - b. Pharmacy Interns
 - c. Pharmacy Technicians
- 31) Provide the number of clean rooms in your pharmacy.
- 32) Provide the number of laminar flow hoods in your pharmacy.
- 33) When was the last time your clean room was certified by an independent contractor for National Sanitation Foundation Standard 49? Provide a copy of the most recent inspection and the name and address of the independent contractor.
- 34) When was the last time your laminar flow hood was certified by an independent contractor for National Sanitation Foundation Standard 49? Provide a copy of the most recent inspection and the name and address of the independent contractor.
- 35) Has your company ever recalled a sterile compounded product due to a compounding error? If yes, list the name (s) of the drug and the reason for the recall.

Licensure Process- For new establishments only.

Once the application is deemed complete, the board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 10 days. **Please wait 15 days from your satisfactory inspection before checking on the status of your permit.** You may lookup your license number on our website at <http://www.doh.state.fl.us/mqa> under “Lookup Licensee.”

Drug Enforcement Administration (DEA)

The DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit.

If controlled substances will be involved in your pharmacy practice, you must make an Application for Registration under the Controlled Substance Act of 1970 with the DEA. If possible, you are encouraged to use the on-line form system provided by the DEA. Information is available by visiting their website at <http://www.DEAdiversion.usdoj.gov>. DEA Form 224 may be obtained in paper form by writing to:

Drug Enforcement Administration
Attn: ODR
PO Box 2639
Springfield, VA 22152-2639

Form 224 should be completed and mailed via U.S. Postal service to the address listed on the form.

Contact DEA at 1-800-667-9752 or 954-306-4654 for information on change of location or change of name.

If your pharmacy does change locations, you are required to have a pharmacy inspection prior to operating in the new location.

For Existing Permittees Only

Applicants must complete and submit answers to the policy and procedure questions beginning on page 4 of the application. The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection. Do not send the policy and procedure manual to the board office. The board office will approve the policy and procedure manual based upon answers submitted for the questions, where applicable, by using excerpts or summaries from the policy and procedure manual. Once the application is deemed complete, the board staff will issue the new license number. The actual copy of your license should arrive within 7 days of the issue date.

PRE-INSPECTION CHECKLIST FOR NEW ESTABLISHMENTS

_____ Is there an adequate sink in workable condition that is easily accessible to the prescription counter that will be available during the hours when the prescription department is normally open for business pursuant to Rule 64B16-28.102, F.A.C.?

_____ Is the pharmacy department equipped an area suitable for private patient counseling if applying for a community pharmacy permit pursuant to Rule 64B16-28.1035, F.A.C.?

_____ Are all required signs displayed?

- Daily operating hours pursuant to Rule 64B16-28.1081, F.A.C.
- “Consult your pharmacist regarding the availability of a less expensive generically equivalent drug and the requirements of Florida law” pursuant to Section 465.025(7), F.S.
- Prescription Department Closed pursuant to Rule 64B16-28.109, F.A.C.
- Pharmacist meal breaks pursuant to Rule 64B16-27.1001(6), F.A.C.
- Patient Consultation Area pursuant to Rule 64B16-28.1035, F.A.C.

_____ Is your pharmacy compliant with Standards for Compounding Sterile Preparations pursuant to Rule 64B16-27.797, F.A.C.?

You may download a copy of the inspection form from the website at http://doh.state.fl.us/mqa/enforcement/enforce_forms.html

IMPORTANT NOTICE: The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

- (a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.
- (b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.
- (c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.
- (d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.
- (e) Has obtained a permit by misrepresentation or fraud.
- (f) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.
- (g) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.
- (h) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.
- (i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.
- (j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. [465.003](#)(14) or s. [893.02](#) when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

If applicable to you, please provide the documentation to the Florida Board of Pharmacy.



**FLORIDA BOARD OF
PHARMACY**
 P.O. Box 6320
 Tallahassee, FL 32314-6320
 Telephone (850) 245-4292
 www.floridaspharmacy.gov

STERILE COMPOUNDING PHARMACY PERMIT APPLICATION

Application Type – Please choose one of the following:

- New Establishment \$255 fee (1020)
 Existing Permit (\$255 fee) (1024) _____ Existing Permit Number
 Change of Location \$100 fee (3011) _____ Existing Sterile Compounding Permit Number
 Change of Ownership (a new permit number will be issued) \$255 fee (1022 create new file)
 _____ Existing Sterile Compounding Permit Number

Will the Pharmacy Dispense Schedule II and/or III Controlled Substances? Yes No

Please list your Federal Employer Identification Number _____

1. Corporate Name	Telephone Number

2. Doing Business As (d/b/a)	E-Mail Address

3. Mailing Address

City	State	Zip

4. Physical Address

City	State	Zip

5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record								
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 30%;">Name</th> <th style="width: 15%;">License No.</th> <th style="width: 15%;">Start Date</th> <th style="width: 40%;">Signature</th> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </table>	Name	License No.	Start Date	Signature				
Name	License No.	Start Date	Signature					

6. Contact Person	Telephone Number

7. DEA Registration Number	8. Date ready for inspection (must be within 90 days of the date of the application)

9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor. If not available, you may write in pending.						
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%;">Name</th> <th style="width: 20%;">Telephone Number</th> <th style="width: 30%;">Permit Number</th> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </table>	Name	Telephone Number	Permit Number			
Name	Telephone Number	Permit Number				

Street Address	City	State	Zip

--	--	--	--

13. Has anyone listed in 12.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years?

Yes _____ No _____ If yes, please provide a signed affidavit disclosing the reason the entity was closed.

13a Has anyone listed in 12.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years?

Yes _____ No _____ If yes, please provide a signed affidavit disclosing the reason the entity was closed.

14. Has anyone listed in 12.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes _____ No _____ If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2) and 465.022(5), *Florida Statutes*, questions 15 through 23 are being asked. If you answer yes to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes; or a similar felony offense in another state or jurisdiction since July 1, 2009? (If yes, provide court documents concerning this conviction)

Yes _____ No _____

15a. If “yes” to 15, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).

Yes _____ No _____

15b. If “yes” to 15, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes _____ No _____

15c. If “yes” to 15, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If “yes”, please provide supporting documentation).

Yes _____ No _____

16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless

of adjudication to a felony under 21 U.S.C. ss.801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

16a. If “yes” to 16, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?

Yes _____ No _____

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 18.)

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

18. If the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been terminated, has the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

19. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 20 and 21)

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

20. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

21. Did the termination occur at least 20 years prior to the date of this application?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

22. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant listed on the United States Department of Health Human Services Office of Inspector General’s List of Excluded Individuals and Entities?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

23. I have been provided and read the statement from the Florida Department of Law Enforcement regarding sharing, retention, privacy and right to challenge incorrect criminal history records and the “Privacy Statement” document from the Federal Bureau of Investigation. (Found on Page 9 of this application.)

Yes _____ No _____

24. Are you currently registered or permitted in any other states? If yes, provide the state, permit type, and permit number for each permit. *Attach a separate sheet if necessary.*

Yes _____ No _____

State	Permit Type	Permit Number
25. Has the applicant, affiliated persons, partners, officer, directors, or PDM or Consultant Pharmacist of Record ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.		
Yes _____ No _____ (If yes, please list them below, you may provide additional sheet)		
Pharmacy Name	State	Status
26. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or Consultant Pharmacist of Record in this state or any other?		
Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)		
27. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?		
Yes _____ No _____ (You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is <u>NOT</u> a minor traffic offense for the purposes of this question.)		
28. Is there any other permit issued by the Department of Health located at the physical location address on this application?		
Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)		
29. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes, please answer 29a.		
Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)		
29a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?		
Yes _____ No _____		
30. Is the policy and procedure manual for preventing controlled substance dispensing based on fraudulent representation or invalid practitioner-patient relationship available for inspection by DOH?		
Yes _____ No _____		

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ TITLE _____ DATE _____
Owner/Officer

PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete. Faxed applications will not be accepted.

- _____ **Application completed (all questions answered)**
- _____ **Application signed**
- _____ **Consultant Pharmacist of Record/Prescription Department Manager Listed with Signature**
- _____ **\$255.00 Fee Attached (Fee required for new establishments only)**

- _____ **Copy of Articles of Incorporation from the Secretary of State's Office (Required for new establishments)**
- _____ **Fingerprints have been submitted via live scan for all officers and owners and the prescription department manager or consultant pharmacist of record. (Required for new establishments)**
- _____ **Attach proof from AHCA of fingerprint results if applicable for prescription department manager or consultant pharmacist of record. (Required for new establishments)**
- _____ **Attestation for Business Taxable Assets of \$100 million if applicable**
- _____ **Bill of Sale is required for Change of Ownership**
- _____ **Policy & Procedure Questions Answered**

Electronic Fingerprinting

Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the live scan method;
- You can find a Livescan service provider at: <http://www.doh.state.fl.us/mqa/background.html>;
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, **including your Social Security number (SSN)**;
- If you do not have a SSN you will need to contact the Board office for a fingerprint card then return the card to the Board office;
- The ORI number for the Board of Pharmacy is EDOH4680Z
- Typically, background-screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo, you may be required to be reprinted by another agency in the future.

Name: _____ Social Security Number: _____

Aliases: _____

Date of Birth: _____ Place of Birth: _____
(MM/DD/YYYY)

Citizenship: _____ Race: _____ (W-White/Latino (a); B-Black; A-Asian;
NA-Native American; U-Unknown)

Sex: _____ Weight: _____ Height: _____
(M=Male; F=Female)

Eye Color: _____ Hair Color: _____

Address: _____ Apt. Number: _____

City: _____ State: _____ Zip Code: _____

Transaction Control Number (TCN#): _____
(This will be provided to you by the Live Scan Service provider.)

Keep this form for your records.

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.

Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C-8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.
US Department of Justice, Federal Bureau of Investigation,
Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as may be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Sara Rothman (CDER) at 301-796-3110.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OU DLC**

**July 2016
Compounding and Related Documents**

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:

Office of Communications

Division of Drug Information, WO51, Room 2201

Center for Drug Evaluation and Research

Food and Drug Administration

10903 New Hampshire Ave., Silver Spring, MD 20993

Phone: 301-796-3400; Fax: 301-847-8714

druginfo@fda.hhs.gov

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OU DLC**

July 2016

Compounding and Related Documents

Contains Nonbinding Recommendations

Draft — Not for Implementation

TABLE OF CONTENTS

I.	INTRODUCTION AND SCOPE	1
II.	BACKGROUND	2
A.	Section 503A of the FD&C Act	2
B.	Compounding, Generally	2
C.	Risks Associated with Compounded Drug Products	3
D.	Compounded Drugs That Are Essentially Copies of Commercially Available Drug Products.....	3
III.	POLICY	4
A.	Commercially Available Drug Product.....	5
B.	Essentially a Copy of a Commercially Available Drug Product.....	5

Contains Nonbinding Recommendations

Draft — Not for Implementation

Guidance for Industry¹

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed in the title page.

I. INTRODUCTION AND SCOPE

To qualify for exemptions under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), a drug product must be compounded by a licensed pharmacist or physician who does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product, among other conditions. This guidance sets forth the FDA's policies regarding this provision of section 503A, including the terms *commercially available*, *essentially a copy of a commercially available drug product*, and *regularly or in inordinate amounts*.²

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

² This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For proposed policies pertaining to compounding drug products from bulk drug substances for use in animals, see FDA's draft guidance, *Compounding Animal Drugs from Bulk Drug Substances*. For proposed policies pertaining to mixing, diluting, and repackaging biological products, see FDA's draft guidance, *Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*. For proposed policies pertaining to repackaged drug products, see FDA's draft guidance, *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*.

All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Contains Nonbinding Recommendations

Draft — Not for Implementation

32 **II. BACKGROUND**

33

34 **A. Section 503A of the FD&C Act**

35

36 Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act
37 in 1997 and amended by the Drug Quality and Security Act in 2013, describes the conditions that
38 must be satisfied for human drug products compounded by a licensed pharmacist in a State-
39 licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from
40 the following three sections of the FD&C Act³:

41

42 • Section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP)
43 requirements)

44 • Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use)

45 • Section 505 (concerning the approval of drugs under new drug applications (NDAs) or
46 abbreviated new drug applications (ANDAs))

47

48 One of the conditions that must be met for a compounded drug product to qualify for the
49 exemptions under section 503A of the FD&C Act is that it must be compounded by a licensed
50 pharmacist or a licensed physician that “does not compound regularly or in inordinate amounts
51 (as defined by the Secretary) any drug products that are essentially copies of a commercially
52 available drug product.”⁴

53

54 The statute further states that “[t]he term ‘essentially a copy of a commercially available drug
55 product’ does not include a drug product in which there is a change, made for an identified
56 individual patient, which produces for that patient a significant difference, as determined by the
57 prescribing practitioner, between the compounded drug and the comparable commercially
58 available drug.”⁵

59

60 A complete list of the conditions that must be met for a compounded drug product to qualify for
61 the exemptions in section 503A appears in the FDA’s guidance, *Pharmacy Compounding of*
62 *Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.

63

64 **B. Compounding, Generally**

65

66 Compounded drug products serve an important role for patients whose clinical needs cannot be
67 met by an FDA-approved drug product, such as a patient who has an allergy and needs a
68 medication to be made without a certain dye, an elderly patient who cannot swallow a pill and
69 needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a
70 strength that is lower than that of the commercially available product. Drug products for
71 identified individual patients can be compounded by licensed pharmacists in state-licensed

³ In addition, under section 581(13) of the FD&C Act, the term “product,” for purposes of pharmaceutical supply chain security requirements, does not include a drug compounded in compliance with section 503A.

⁴ See section 503A(b)(1)(D).

⁵ See section 503A(b)(2).

Contains Nonbinding Recommendations

Draft — Not for Implementation

72 pharmacies and Federal facilities and by licensed physicians operating under section 503A of the
73 FD&C Act. Drug products can also be compounded by outsourcing facilities under section 503B
74 of the FD&C Act for identified individual patients pursuant to prescriptions or for distribution to
75 health care practitioners without first receiving a prescription.⁶ Both sections 503A and 503B
76 restrict compounding drug products that are essentially a copy of a commercially available drug
77 product (section 503A) or an approved drug product (section 503B).

C. Risks Associated with Compounded Drug Products

81 Although compounded drugs can serve an important need, they also pose a higher risk to patients
82 than FDA-approved drugs. Compounded drug products are not FDA-approved, which means
83 they have not undergone FDA premarket review for safety, effectiveness, and quality. In
84 addition, licensed pharmacists and licensed physicians who compound drug products in
85 accordance with section 503A are not required to comply with CGMP requirements.
86 Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed
87 physicians who compound drug products and seek to qualify for the exemptions under section
88 503A of the FD&C Act for the drug products that they compound because these compounders
89 are not licensed by FDA and generally do not register their compounding facilities with FDA.
90 Therefore, FDA is often not aware of potential problems with their compounded drug products
91 or compounding practices unless it receives a complaint such as a report of a serious adverse
92 event or visible contamination.

94 FDA has investigated numerous serious adverse events associated with compounded drug
95 products that were contaminated or otherwise compounded improperly, including the adverse
96 events associated with the 2012 fungal meningitis outbreak in which contaminated injectable
97 drug products resulted in more than 60 deaths and 750 cases of infection. FDA has also
98 identified many pharmacies that compounded drug products under insanitary conditions whereby
99 the drug products may have been contaminated with filth or rendered injurious to health and that
100 shipped the compounded drug products made under these conditions to patients and health care
101 practitioners across the country, sometimes in large amounts.

D. Compounded Drugs That Are Essentially Copies of Commercially Available Drug Products

106 Section 503A provides exemptions from new drug approval, labeling with adequate directions
107 for use, and CGMP requirements of the FD&C Act, so that drug products can be compounded as
108 customized therapies for identified individual patients whose medical needs cannot be met by
109 commercially available drug products. The restrictions on making drugs that are essentially
110 copies ensure that pharmacists and physicians do not compound drug products under the
111 exemptions for patients who could use a commercially available drug product. Such a practice
112 would create significant public health risks because patients would be unnecessarily exposed to

⁶ Section 503B of the FD&C Act describes the conditions that must be met for a human drug product compounded by an outsourcing facility to qualify for exemptions from sections 505, 502(f)(1), and 582 (concerning drug supply chain security requirements) of the FD&C Act. The conditions applicable to outsourcing facilities are discussed in separate guidances applicable to those facilities.

Contains Nonbinding Recommendations

Draft — Not for Implementation

113 drug products that have not been shown to be safe and effective and that may have been prepared
114 under substandard manufacturing conditions. FDA has investigated serious adverse events in
115 patients who received contaminated compounded drugs when a comparable approved drug, made
116 in a facility subject to CGMP requirements, was available.

117
118 In addition to these immediate public health risks, section 503A’s limitations on producing a
119 drug product that is essentially a copy of a commercially available drug product protects the
120 integrity and effectiveness of the new drug and abbreviated new drug approval processes that
121 Congress put in place to protect patients from unsafe, ineffective, or poor quality drugs.
122 Furthermore, sponsors may be less likely to invest in and seek approval of innovative, life-saving
123 medications if a compounder could, after a drug is approved, compound “substitutes” that have
124 not had to demonstrate safety and effectiveness and are not produced in accordance with CGMP
125 requirements or labeled with adequate directions for use.

126
127 Sponsors might also be less likely to seek approval of an ANDA for a generic drug if
128 compounders were permitted to compound drugs that are essentially copies of commercially
129 available drugs without going through the ANDA process. An ANDA must include data to
130 demonstrate that the drug has the same active ingredient and is bioequivalent to an approved
131 drug. FDA also conducts a premarketing inspection of proposed manufacturing facilities before
132 approving the application.

133
134 The copies restriction also protects FDA’s drug monograph process. FDA has an ongoing
135 process for evaluating the safety and effectiveness of certain over-the-counter (OTC)
136 medications, and if the Agency determines that an OTC drug meets certain conditions and is
137 generally recognized as safe and effective, it will publish a final monograph specifying those
138 conditions. Products that comply with a final monograph may be marketed, but manufacturers
139 are required to meet CGMP standards. Restrictions in section 503A prevent compounders from
140 producing drugs without having to comply with monograph standards, or CGMP requirements.

141 142 **III. POLICY**

143
144 As stated above, to qualify for the exemptions under section 503A of the FD&C Act, a drug must
145 be compounded by a licensed pharmacist or a licensed physician that does not compound
146 regularly or in inordinate amounts (as defined by the Secretary) any drug products that are
147 essentially copies of a commercially available drug product.⁷ In other words, a compounded
148 drug product is not eligible for the exemptions in section 503A if it is both 1) essentially a copy
149 of a commercially available drug product, and it is 2) compounded regularly or in inordinate
150 amounts. Accordingly, and as discussed below, when evaluating whether a drug product meets
151 the condition in section 503A regarding essentially copies, FDA intends to determine first
152 whether a compounded drug product is *essentially a copy of a commercially available drug*
153 *product*, and if it is, FDA intends to determine second whether the drug product was
154 compounded regularly or in inordinate amounts.

155

⁷ See section 503A(b)(1)(D).

Contains Nonbinding Recommendations

Draft — Not for Implementation

156 FDA’s policies with regard to the terms (1) *commercially available drug product*, (2) *essentially*
157 *a copy of a commercially available drug product*, and (3) *regularly or in inordinate amounts*, are
158 as follows:

159

A. Commercially Available Drug Product

160

161
162 For purposes of this guidance, a drug product is commercially available if it is a marketed drug
163 product.

164

165 We do not consider a drug product to be commercially available if

166

167 • the drug product has been discontinued and is no longer marketed⁸) or

168

169 • the drug product appears on the FDA drug shortage list in effect under section 506E
170 of the FD&C Act.⁹ A drug “appears on the drug shortage list in effect under section
171 506E” if the drug is in “currently in shortage” status (and not in “resolved” status) in
172 FDA’s drug shortage database.

173

174 Commercially available drugs are available on the market, and they are generally subject to
175 FD&C Act requirements relating to approval, labeling, and CGMP requirements, and the copies
176 restriction applies to all such drugs because section 503A is not intended to provide a means for
177 compounders to produce compounded drugs exempt from the Act’s requirements that are
178 essentially copies of commercially available drug products.

179

B. Essentially a Copy of a Commercially Available Drug Product

180

181

1. What is Essentially a Copy?

182

183
184 FDA intends to consider a compounded drug product to be essentially a copy of a commercially
185 available drug product if:

186

- 187 • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as
188 the commercially available drug product;
- 189 • the API(s) have the same, similar, or an easily substitutable dosage strength; and
- 190 • the commercially available drug product can be used by the same route of administration
191 as prescribed for the compounded drug,

192

⁸ FDA maintains a list of approved drug products that sponsors have indicated are not marketed in the discontinued section of the list of Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). See <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Specifically, the list includes approved drug products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or have had their approvals withdrawn for reasons other than safety or effectiveness subsequent to being discontinued from marketing.

⁹ See <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

Contains Nonbinding Recommendations

Draft — Not for Implementation

193 unless a prescriber determines that there is a change, made for an identified individual patient,
194 which produces for that patient a significant difference from the commercially available drug
195 product.

196
197 The limitations in section 503A(b)(1)(D) apply to the compounding of drug products that are
198 *essentially* copies of a commercially available drug product – not only to drugs that are exact
199 copies or even to drugs that are nearly identical. This is to ensure that compounders do not evade
200 the limits in this section by making relatively small changes to a compounded drug product and
201 then offering the drug to the general public without regard to whether a prescribing practitioner
202 has determined that the change produces for the patient a significant difference. For example,
203 Congress contemplated that a compounded drug may be essentially a copy of a commercially
204 available drug if “minor changes in strength (such as from .08% to .09%) are made that are not
205 known to be significant . . .” for the patient for whom the drug was prescribed.¹⁰

a. Same API

206
207
208
209 With regard to the characteristics listed above, an API is the substance in a drug product that
210 is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure,
211 mitigation, treatment, or prevention of disease or to affect the structure or function of the
212 body.¹¹ When a compounded drug product offers the same API as a commercially available
213 drug product, in the same, similar, or easily substitutable dosage strength and for use through
214 the same route of administration, we generally intend to consider such a drug product
215 *essentially a copy*, unless a prescriber determines that there is a change, made for an
216 individual patient, that will produce a significant difference for that patient.

217
218 We recognize that, for some patients, a drug product that has the same API, strength, and
219 route of administration may include a change that produces a significant difference for a
220 particular patient. For example, a drug product compounded without a particular inactive
221 ingredient may produce a significant difference for a patient who has an allergy to the
222 inactive ingredient in the commercially available drug product. However, for other patients,
223 this change may produce no difference at all. Congress did not intend for compounders to
224 use, for example, the fact that some patients may have allergies as a basis to compound a
225 drug without the inactive ingredient for other patients who do not have the allergy under the
226 exemptions in section 503A (i.e., without meeting requirements for premarket approval,
227 labeling with adequate directions for use, or CGMP requirements).¹² In the context of
228 compounding and consistent with the statute, we intend to consider such a drug essentially a

¹⁰ U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

¹¹ Section 503A refers to bulk drug substances. A *bulk drug substance* is defined as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances (21 CFR 207.3(4)).

¹² See note 10.

Contains Nonbinding Recommendations

Draft — Not for Implementation

229 copy, unless a prescriber determines that there is a change that will produce a significant
230 difference for the patient for whom it is prescribed.

b. Same, Similar or Easily Substitutable Strength

233
234 FDA generally intends to consider two drugs to have a similar dosage strength if the dosage
235 strength of the compounded drug is within 10% of the dosage strength of the commercially
236 available drug product.

237
238 With regard to the concept of easily substitutable strength, in some cases, the same or similar
239 dosage strength can be achieved by administration of fractional or multiple doses of a drug
240 product. For example, if FDA-approved Drug X tablets have a dosage strength of 25 mg and
241 a patient needs 50 mg of Drug X, FDA would generally consider a compounded Drug X 50
242 mg tablet to have an easily substitutable strength because the patient could take two Drug X
243 25 mg tablets to achieve the required dose.

c. Same Route of Administration

244
245
246
247 Route of administration is a way of administering a drug to a site in a patient (e.g., topical,
248 intravenous, oral).¹³ In general, FDA does not intend to consider a compounded drug
249 product with the same API and similar or easily substitutable strength to be essentially a copy
250 of a commercially available drug product if the compounded drug product and the
251 commercially available drug product have different routes of administration (e.g., if the
252 commercially available drug product is oral and the compounded drug product is topical).
253 However, if the compounded drug product has the same API and similar or easily
254 substitutable strength as the commercially available drug product and the commercially
255 available drug product can be used (regardless of how it is labeled) by the route of
256 administration prescribed for the compounded drug, FDA generally intends to consider the
257 compounded drug to be essentially a copy of the commercially available drug. In this case,
258 the compounded drug product generally would not produce a significant difference for an
259 identified individual patient relative to the commercially available drug product.

260
261 For example, if the commercially available drug is an injectable drug sold in a vial that is
262 labeled for intra-muscular use, but the drug also can be drawn from the vial by a smaller
263 needle for subcutaneous administration, a compounded drug product with the same API and
264 similar or easily substitutable strength prescribed for sub-cutaneous administration would
265 generally be considered to be essentially a copy, unless the prescriber documents on the
266 prescription that the compounded drug product produces a significant difference for the
267 identified individual patient.

Same Characteristics as Two or More Commercially Available Drug Products

¹³ See

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071667.htm>.

Contains Nonbinding Recommendations

Draft — Not for Implementation

270
271 FDA intends to consider a compounded drug product to be essentially a copy of a
272 commercially available drug product if the compounded drug product contains the same APIs
273 as two or more commercially available drug products in the same, similar, or easily
274 substitutable strength and if the compounded drug product and the commercially available
275 drug products have the same route of administration, unless there is documentation as
276 described in section III.B.2. Such drug products present the same kinds of concerns as drug
277 products that have a single API and in some respects may be more dangerous because of the
278 potential for unintended drug interactions. For example, if drug X and drug Y are
279 commercially available oral drug products, FDA intends to consider a compounded oral drug
280 product that combines drug X and drug Y in strengths that are within 10% of the strengths of
281 the respective commercially available products to be essentially a copy of the commercially
282 available drug product, unless a prescriber determination of a significant difference has been
283 documented.

2. Statement of Significant Difference

284
285
286 Pursuant to section 503A(b)(2) of the FD&C Act, a compounded drug product is not essentially a
287 copy of a commercially available drug product if a change is made for an identified individual
288 patient, and the prescribing practitioner has determined that the change will produce a significant
289 difference for that patient. If a compounder intends to rely on such a determination to establish
290 that a compounded drug is not essentially a copy of a commercially available drug product, the
291 compounder should ensure that the determination is documented on the prescription.
292

293
294 FDA does not believe that a particular format is needed to document the determination, provided
295 that the prescription makes clear that the prescriber identified the relevant change and the
296 significant difference produced for the patient. For example, the following would be sufficient:
297

- 298 • “No Dye X, patient allergy” (if the comparable drug contains the dye)
- 299 • “Liquid form, patient can’t swallow tablet” (if the comparable drug is a tablet)
- 300 • “6 mg, patient needs higher dose” (if the comparable drug is only available in 5 mg dose)

301
302 However, if a prescription identifies only a patient name and drug product formulation, this
303 would not be sufficient to establish that the prescriber made the determination described by
304 section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be
305 produced by the change the compounder will make to a commercially available drug product
306 (i.e., a change in drug product formulation). Other factors, such as a lower price, are not
307 sufficient to establish that the compounded drug product is not essentially a copy of the
308 commercially available drug product.¹⁴

¹⁴ Congress noted that “where it is readily apparent, based on the circumstances, that the ‘significant difference’ is a mere pretext to allow compounding of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, minor changes in strength (such as from .08% to .09%) are made that are not known to be significant or instances in which the prescribing physician is receiving financial remuneration or other incentives to write

Contains Nonbinding Recommendations

Draft — Not for Implementation

309

310 If a prescription does not make clear that the prescriber made the determination required by
311 section 503A(b)(2), or a compounded drug is substituted for the commercially available drug
312 product, the compounder can contact the prescriber and if the prescriber confirms it, make a
313 notation on the prescription that the compounded drug product contains a change that makes a
314 significant difference for the patient. The notations should be as specific as those described
315 above, and the date of the conversation with the prescriber should be included on the
316 prescription.

317

318 It is not possible to offer comprehensive guidance about when a difference will be “significant”
319 to an identified individual patient. FDA generally does not intend to question prescriber
320 determinations that are documented in a prescription or notation. However, we do intend to
321 consider whether a prescription or notation relied upon by a compounder to establish that a drug
322 is not essentially a copy documents that the determination was made.

323

3. Documentation of shortage

324

325

326 If the drug was compounded because the approved drug product was not commercially available
327 because it was on the FDA drug shortage list, the prescriber or compounder should include a
328 notation on the prescription that it was on the drug shortage list and the date the list was checked.

329

4. Regularly or in Inordinate Amounts

330

331

332 A drug product is not eligible for the exemptions in section 503A if it is prepared by a
333 pharmacist or physician who compounds “regularly or in inordinate amounts (as defined by the
334 Secretary)” any drug products that are essentially copies of a commercially available drug
335 product.¹⁵ FDA interprets this to mean that to be compounded in accordance with section 503A,
336 a drug product that is essentially a copy of a commercially available drug product cannot be
337 compounded regularly – i.e., it cannot be compounded at regular times or intervals, usually, or
338 very often. Nor can the amounts compounded be inordinate, in light of the purpose of section
339 503A.

340

341 Section 503A is intended to protect patients from the public health risks of providing
342 compounded drugs to patients whose medical needs could be met by commercially available
343 drug products and to protect the integrity and efficiency of the drug approval process. Under the
344 statutory scheme, only very rarely should a compounded drug product that is essentially a copy
345 of a commercially available drug product be offered to a patient. For example, a compounded
346 drug product that has the same API, dosage strength, and route of administration as a drug
347 product on FDA’s shortage list would not be considered essentially a copy of a commercially
348 available drug because a drug product is not considered *commercially available* if it is on FDA’s
349 drug shortage list. In addition, a compounded drug product is not essentially a copy of a

prescriptions for compounded products.” See the U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

¹⁵ See section 503A(b)(1)(D).

Contains Nonbinding Recommendations

Draft — Not for Implementation

350 commercially available drug product if a prescriber has determined that the compounded drug
351 has a change that produces a significant difference for a patient. We conclude, therefore, that a
352 drug product that is essentially a copy of a commercially available drug product is compounded
353 regularly or in inordinate amounts if it is compounded more frequently than needed to address
354 unanticipated, emergency circumstances or in more than the small quantities needed to address
355 unanticipated, emergency circumstances.

356
357 Once it has been determined that a compounded drug is essentially a copy of a commercially
358 available drug product as described above, the following are examples of factors that may be the
359 basis for concluding that it has been compounded regularly or in inordinate amounts:

- 360
- 361 • The compounded drug product amounts to more than a small number of prescriptions or a
362 small percentage of the compounded drug products that a physician or prescriber prepares
363 or provides to patients.
 - 364 • The compounder routinely substitutes compounded drugs that are essentially copies of
365 commercially available drugs upon receiving prescriptions for patients.
 - 366 • The compounder offers pre-printed prescription pads that a prescriber can use to write a
367 prescription for the drug product that is essentially a copy without making a
368 determination that there is a change that will produce a significant difference for a
369 patient.
 - 370 • The compounded drug product is not compounded on an as-needed basis, but on a routine
371 or pre-set schedule.

372
373 The foregoing list is not intended to be exhaustive. Other factors may be appropriate for
374 consideration in a particular case.

375
376 To focus enforcement on the most significant cases, as a matter of policy, at this time FDA does
377 not intend to take action against a compounder for compounding a drug product that is
378 essentially a copy of a commercially available drug product regularly or in inordinate amounts if
379 the compounder fills four or fewer prescriptions for the relevant compounded drug product in a
380 calendar month.¹⁶ Be aware that a prescription would not be considered to be for a drug that is
381 essentially a copy of a commercially available drug product and would not be counted towards
382 the four prescriptions if the prescription documents that the compounded drug product makes a
383 significant difference for the patient as described above.

384 385 *5. Recordkeeping*

386
387 A licensed pharmacist or physician seeking to compound a drug product under section 503A
388 should maintain records to demonstrate compliance with section 503A(b)(1)(D). For example,
389 records should be kept of notations on prescriptions for identified individual patients that a
390 prescriber has determined that the compounded drug has a change that produces a significant
391 difference for the identified patient.

¹⁶ For purposes of this policy, a prescription does not include additional refills. FDA intends to consider each refill of a prescription as an additional prescription.

Contains Nonbinding Recommendations

Draft — Not for Implementation

392
393 Compounders under section 503A should also maintain records of the frequency in which they
394 have compounded drug products that are essentially copies of commercially available drug
395 products and the number of prescriptions that they have filled for compounded drug products that
396 are essentially copies of commercially available drug products to document that such
397 compounding has not been done regularly or in inordinate amounts.

Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Sara Rothman (CDER) at 301-796-3110.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OU DLC**

**July 2016
Compounding and Related Documents**

Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:

Office of Communications

Division of Drug Information, WO51, Room 2201

Center for Drug Evaluation and Research

Food and Drug Administration

10903 New Hampshire Ave., Silver Spring, MD 20993

Phone: 301-796-3400; Fax: 301-847-8714

druginfo@fda.hhs.gov

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OU DLC**

July 2016

Compounding and Related Documents

Contains Nonbinding Recommendations

Draft — Not for Implementation

TABLE OF CONTENTS

I.	INTRODUCTION AND SCOPE	1
II.	BACKGROUND	2
	A. Section 503B of the FD&C Act	2
	B. Compounding, Generally	3
	C. Compounded Drugs that are Essentially Copies of Approved Drug Products	3
	D. Compounded Drugs that are Essentially Copies of Unapproved Non-Prescription Drug Products.....	4
III.	POLICY	4
	A. Definition of <i>Essentially a Copy of an Approved Drug</i>.....	4
	B. Recordkeeping.....	12
	APPENDICES A & B.....	13

Contains Nonbinding Recommendations

Draft — Not for Implementation

Guidance for Industry¹

**Compounded Drug Products That Are Essentially Copies of
Approved Drug Products Under Section 503B of the Federal Food,
Drug, and Cosmetic Act**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed in the title page.

I. INTRODUCTION AND SCOPE

For a drug product compounded by an outsourcing facility to qualify for the exemptions under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act), it must not be “essentially a copy of one or more approved drug products,”² and must meet the other conditions in section 503B.³ This guidance sets forth the FDA’s or policies concerning the *essentially a copy* provision of section 503B.⁴

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance was prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

² See section 503B(a)(5).

³ See section 503B(a)(11).

⁴ This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For proposed policies pertaining to compounding drug products from bulk drug substances for use in animals, see FDA’s draft guidance *Compounding Animal Drugs from Bulk Drug Substances*. For proposed policies pertaining to mixing, diluting, and repackaging biological products, see FDA’s draft guidance *Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*. For proposed policies pertaining to repackaged drug products, see FDA’s draft guidance *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*.

All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Contains Nonbinding Recommendations

Draft — Not for Implementation

29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

II. BACKGROUND

A. Section 503B of the FD&C Act

In 2013, the Drug Quality and Security Act created a new section 503B of the FD&C Act, which describes a new category of compounders called *outsourcing facilities*.⁵ Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from the following three sections of the FD&C Act:

- Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use)
- Section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs))
- Section 582 (concerning drug supply chain security requirements).

In contrast to drug products compounded under section 503A of the FD&C Act, drug products compounded by outsourcing facilities under section 503B cannot qualify for exemption from current good manufacturing practice (CGMP) requirements in section 501(a)(2)(B) of the FD&C Act. Outsourcing facilities are also subject to FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that help to mitigate the risks of the drug products they compound.

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503B of the FD&C Act is that “the drug is not essentially a copy of one or more approved drugs.”⁶ Section 503B(d)(2) defines *essentially a copy of an approved drug* as —

- A drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing (section 503B(d)(2)(A)); or
- A drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) and is not subject to approval in an application submitted under section 505, unless there is a change that produces for an individual patient a clinical difference, as determined

⁵ See Pub.L. No.113-54, §102(a), 127 Stat. 587, 587-588 (2013). Under section 503B(b), a compounder can elect to register with FDA as an outsourcing facility. Section 503B(d)(4) defines an *outsourcing facility* as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B. An outsourcing facility is not required to be a licensed pharmacy, although compounding must be by or under the direct supervision of a licensed pharmacist. In addition, an outsourcing facility may or may not obtain prescriptions for identified individual patients.

⁶ See section 503B(a)(5).

Contains Nonbinding Recommendations

Draft — Not for Implementation

66 by the prescribing practitioner, between the compounded drug and the comparable
67 approved drug (section 503B(d)(2)(B)).
68

69 A compounded drug product only qualifies for the exemptions in section 503B if it is
70 compounded by an outsourcing facility that compounds all of its drugs, both sterile and non-
71 sterile, in accordance with all of the conditions of section 503B.⁷ A complete list of the
72 conditions that must be met for a drug product to qualify for the exemptions in section 503B
73 appears in the guidance *For Entities Considering Whether to Register As Outsourcing Facilities*
74 *Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.
75

B. Compounding, Generally

76
77
78 Compounded drug products serve an important role for patients whose clinical needs cannot be
79 met by an FDA-approved drug product such as for a patient who has an allergy and needs a
80 medication to be made without a certain dye contained in an FDA-approved drug product, or an
81 elderly patient or a child who cannot swallow a pill and needs a medicine in a liquid form that is
82 not available in an approved product. Drug products for identified individual patients can be
83 compounded by licensed pharmacists in State-licensed pharmacies and Federal facilities and by
84 licensed physicians operating under section 503A of the FD&C Act.⁸ Drug products can also be
85 compounded by outsourcing facilities for identified individual patients pursuant to prescriptions
86 or for distribution to health care practitioners without receiving prescriptions. Sections 503A and
87 503B restrict compounding drug products that are essentially copies of commercially available
88 (section 503A) or approved drug products (section 503B).
89

C. Compounded Drugs that are Essentially Copies of Approved Drug Products

90
91
92 Although compounded drugs can serve an important need, they also pose a higher risk to patients
93 than FDA-approved drugs. Drug products compounded by outsourcing facilities in accordance
94 with the conditions of section 503B are exempt from FDA drug approval requirements and the
95 requirement to be labeled with adequate directions for use. Because they are not FDA-approved,
96 they have not undergone FDA premarket review for safety, effectiveness, and quality. Although
97 outsourcing facilities must comply with CGMP requirements and are inspected by FDA
98 according to a risk-based schedule, their drugs also lack a premarket inspection and finding of
99 manufacturing quality that is part of the drug approval process. Because they are subject to a
100 lower regulatory standard, drugs compounded by outsourcing facilities should only be distributed
101 to health care facilities or dispensed to patients to fulfill the needs of patients whose medical
102 needs cannot be met by an FDA-approved drug.
103

⁷ See sections 503B(a)(11) and 503B(d)(4)(A)(iii).

⁸ Section 503A of the FD&C Act describes the conditions that must be met for a human drug product compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act. The conditions applicable to compounders seeking to operate under section 503A are discussed in separate guidance documents applicable to these entities.

Contains Nonbinding Recommendations

Draft — Not for Implementation

104 The restrictions on compounding drugs that are essentially copies of approved products ensure
105 that outsourcing facilities do not compound drug products under the exemptions in section 503B
106 for use in patients who could use an approved product. Compounding copies of these products
107 would unnecessarily expose patients to drug products that have not been shown to be safe and
108 effective.

109
110 In addition to these immediate public health risks, section 503B’s prohibition on producing a
111 drug product that is essentially a copy of an approved drug product protects the integrity and
112 effectiveness of the new drug and abbreviated new drug approval processes. Sponsors would be
113 less likely to invest in and seek approval of innovative, life-saving medications if an outsourcing
114 facility could, after a drug is approved, compound “substitutes” that may be less expensive
115 because they have not gone through the drug approval process.

116
117 Sponsors would also be less likely to seek approval of an ANDA for a generic drug if
118 outsourcing facilities were permitted to compound drugs that are essentially copies of approved
119 drugs without going through the ANDA process. An ANDA must include data to demonstrate
120 that the drug has the same active ingredient and is bioequivalent to an approved drug. FDA also
121 conducts a premarketing inspection of proposed manufacturing facilities before approving the
122 application. Section 503B’s restrictions on producing a drug product that is essentially a copy of
123 an approved drug product protect the integrity of both the new drug and the abbreviated new
124 drug approval processes.

125

D. Compounded Drugs that are Essentially Copies of Unapproved Non-Prescription Drug Products

126

127

128

129 The definition of *essentially a copy of an approved drug* in section 503B(d)(2) also refers to drug
130 products that are not subject to section 503(b) (i.e., non-prescription drug products) and that are
131 not subject to approval in an application submitted under section 505. Congress did not provide
132 exemptions under section 503B for such drugs, which ensures that outsourcing facilities do not
133 compound unapproved over-the-counter drug products under the exemptions in section 503B.
134 Such products may be produced only under the same requirements that apply to other drug
135 manufacturers. Section 503B also protects FDA’s drug monograph process. FDA has an
136 ongoing process to evaluate the safety and effectiveness of over-the-counter (OTC) medications,
137 and if the Agency determines that an OTC drug meeting certain conditions is generally
138 recognized as safe and effective, it will publish a final monograph specifying those conditions.
139 Compounding copies of such drug products would undermine the process that drug
140 manufacturers must comply with, which includes a set of specific regulatory requirements that
141 limit the formulation of the drug product, and both the content and format of its labeling.

142

III. POLICY

143

144

145 Under section 503B(a)(5) of the FD&C Act, a compounded drug must not be essentially a copy
146 of one or more approved drugs.

147

148

A. Definition of *Essentially a Copy of an Approved Drug*

149

Contains Nonbinding Recommendations

Draft — Not for Implementation

150 The definition of *essentially a copy of an approved drug* has two components, specified in
151 sections 503B (d)(2)(A) and 503B(d)(2)(B) of the Act. Section 503B (d)(2)(A) applies to a
152 compounded drug that is “identical or nearly identical” to an approved drug or an unapproved
153 non-prescription drug. All other compounded drugs are evaluated under section 503B (d)(2)(B).
154 FDA applies these provisions as depicted in the diagrams in Appendices A and B.

155
156 The definition of *essentially a copy of an approved drug* in section 503B(d)(2) addresses both
157 drug products approved under section 505 and marketed drug products that are not subject to
158 section 503(b) and that are not subject to approval in an application submitted under section 505.

159
160 For purposes of this provision:

- 161
- 162 • *Approved drug* means a drug product that is approved under section 505 of the FD&C
163 Act and does not appear on the list described in subsection 503B(a)(4) of drugs that have
164 been withdrawn or removed from the market because such drugs or components of such
165 drugs have been found to be unsafe or not effective.
 - 166 • *Marketed drug not subject to section 503(b) and not subject to approval in an application*
167 *submitted under section 505* means any non-prescription drug product marketed without
168 an approved application.⁹ We refer to these products as *covered OTC drug products*
169 throughout the remainder of this guidance document.
 - 170 • A drug appears on the drug shortage list in effect under section 506E if the drug is in
171 “currently in shortage” status (and not in “resolved” status), as indicated in FDA’s drug
172 shortage database.¹⁰

173
174 In the discussion that follows, in subsection 1, we explain how we intend to apply the definition
175 of *essentially a copy of an approved drug* in section 503B(d)(2) when the compounded drug is
176 compared to an approved drug, and then in subsection 2, we explain how we intend to apply this
177 definition when the compounded drug is compared to a covered OTC drug product.

- 178
- 179 1. *Application of the “Essentially a Copy” Definition in Section 503B(d)(2) When the*
180 *Compounded Drug Is Compared to an Approved Drug (see Appendix A)*
 - 181 a. Compounded drugs that are identical or nearly identical to an approved drug (section
182 503B(d)(2)(A))

183
184
185 Under section 503B(d)(2)(A), a compounded drug is essentially a copy of an approved
186 drug if the compounded drug is identical or nearly identical to an approved drug unless
187 the approved drug appears on the drug shortage list in effect under section 506E at the
188 time of compounding, distribution, and dispensing.

189

⁹ This includes unapproved OTC drugs whether they are marketed under FDA’s OTC Drug Monograph Review program or outside the monograph system.

¹⁰ See <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

Contains Nonbinding Recommendations

Draft — Not for Implementation

190 i. Identical or nearly identical (Appendix A, box 1)

191
192 FDA intends to consider a compounded drug product to be identical or nearly identical to
193 an approved drug if the compounded drug product and the FDA-approved drug have the
194 same:

- 195 • active ingredient(s),
- 196 • route of administration,
- 197 • dosage form,
- 198 • dosage strength, and
- 199 • excipients.¹¹

200
201 A compounded drug product that has all of these characteristics in common with an
202 FDA-approved drug product is essentially a copy of an approved drug, unless the
203 approved drug appears on FDA’s drug shortage list at the time of compounding,
204 distribution, and dispensing. If a compounded drug product is identical or nearly
205 identical to an approved drug that is *not* on FDA’s drug shortage list at the time of
206 compounding, distribution, and dispensing, the compounded product is essentially a copy
207 and an outsourcing facility may not produce it under section 503B.

208
209 In establishing this policy, FDA considered the following. Under section 503B(d)(2)(A),
210 the identical or nearly identical compounded product cannot be exempted from the
211 copying restriction by a prescriber determination that there is a change to the
212 compounded product that produces a clinical difference for an individual patient.
213 Compounded products meeting the criteria outlined above are not expected to contain
214 changes from an approved drug that would produce such a difference.

215
216 A compounded drug that is identical or nearly identical to an approved drug is not
217 considered essentially a copy if the approved drug is in shortage at the time of
218 compounding, distribution, and dispensing.¹² In such a case, the outsourcing facility can
219 compound the drug provided that it complies with the other conditions of 503B. It is
220 important to patients and prescribers that compounded drugs prepared to address a
221 shortage closely resemble the drug in shortage, and for that reason, the statute seeks to
222 allow compounders to compound drugs that are as close as possible to the drug in
223 shortage.¹³ A compounded drug product with the characteristics described in our policy
224 would be the same as the approved drug in several important respects. The active
225 ingredient is the substance in a drug product that is intended to furnish pharmacological

¹¹ In some cases, information about the excipients contained in an approved drug is not publicly available and not known to the outsourcing facility. In such cases, FDA does not intend to consider whether the compounded drug has the same excipients that the approved drug is labeled to contain in determining whether a compounded drug is identical or nearly identical to an approved drug.

¹² *Distribution* means that a compounded human drug product has left the facility in which the drug was compounded. Distribution includes delivery or shipment to a physician’s office, hospital, or other health care setting for administration and dispensing to an agent of a patient or to a patient for the patient’s own use.

¹³ See footnote 11.

Contains Nonbinding Recommendations

Draft — Not for Implementation

226 activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention
227 of disease or to affect the structure or function of the body. Dosage form is the way of
228 identifying the drug in its physical form, and route of administration describes the way a
229 drug is administered to the body. Inactive ingredients (also known as “excipients”) may
230 include preservatives, dyes, and flavorings. The dosage strength of a drug product
231 indicates the amount of the active ingredient that is present in each dosage.
232

233 If the outsourcing facility compounds a product that differs on one or more of these
234 characteristics, we generally would not consider the product to be identical or nearly
235 identical. As described below, if the compounded drug product is not considered
236 identical or nearly identical under section 503B(d)(2)(A), it would then be evaluated
237 under section 503B(d)(2)(B).
238

239 Outsourcing facilities seeking to compound drugs under this provision should also take
240 note that other provisions of the FD&C Act contain requirements for drug product
241 formulation and packaging that are important for patient safety. In particular, drug
242 products compounded in accordance with section 503B remain subject to adulteration
243 and misbranding provisions of the FD&C Act including, but not limited to, section
244 501(b) (concerning drug products that are recognized in an official compendium and
245 whose strength differs from, or whose quality or purity falls below, the standards set forth
246 in such compendium) and section 502(g) (concerning drug products that are recognized
247 in an official compendium and that are not packaged and labeled as prescribed therein).
248

249 ii. Compounded drugs that are identical or nearly identical to an approved
250 drug on FDA’s drug shortage list after the shortage is resolved (Appendix
251 A, box 2)
252

253 As explained above, under section 503B (d)(2)(A), a compounded drug is not essentially
254 a copy of an approved drug if the approved drug appears on FDA’s drug shortage list at
255 the time of compounding, distribution, and dispensing. However, FDA recognizes that
256 there may be circumstances in which a drug product is in shortage when the outsourcing
257 facility compounds the drug, but the shortage is resolved before the outsourcing facility
258 distributes it. FDA does not intend to take action against an outsourcing facility for
259 filling orders that it received for a compounded drug that is identical or nearly identical to
260 an approved drug that was on FDA’s drug shortage list at the time that the outsourcing
261 facility received the order, provided the drug also appeared on the FDA drug shortage list
262 within 60 days of the outsourcing facility distributing or dispensing the drug.¹⁴

¹⁴ An outsourcing facility may not be able to predict when a drug shortage will be resolved, and the facility may have orders for a compounded drug in-house that were in progress when the drug was removed from FDA’s drug shortage list (e.g., the outsourcing facility may have compounded a drug while it was in shortage, but the shortage ended while the outsourcing facility awaited the results of sterility testing before release). This policy provides some regulatory flexibility when an outsourcing facility fills orders that it received for a compounded drug while the drug was in shortage. FDA may take regulatory action, however, if an outsourcing facility continues to fill new orders for the compounded drug after the approved drug is removed from FDA’s drug shortage list, or if it continues to fill orders more than 60 days after the drug has been removed from FDA’s drug shortage list.

Contains Nonbinding Recommendations

Draft — Not for Implementation

263
264
265
266
267
268
269
270
271
272
273
274
275
276
277
278
279
280
281
282
283
284
285
286
287
288
289
290
291
292
293
294
295
296
297
298
299
300

- b. Compounded drugs that contain a bulk drug substance that is a component of an approved drug (see Appendix A, boxes 3 and 4)

Under section 503B(d)(2)(B), a compounded drug product is essentially a copy of an approved drug if a component of the compounded drug product is a bulk drug substance¹⁵ that is also a component of an approved drug, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

- i. Using the same bulk drug substance (Appendix A, box 3)

If a component of the compounded drug is a bulk drug substance that is also a component of an approved drug, the compounded drug product is essentially a copy of an approved drug and cannot be compounded under section 503B, unless there is a prescriber determination of clinical difference, as described below.¹⁶ This provision applies to a compounded drug whether it was compounded from bulk drug substances or from drugs in finished form.

- ii. Prescriber determination of clinical difference (Appendix A, box 4)

If an outsourcing facility compounds a drug, the component of which is a bulk drug substance that is a component of an approved drug, there must be a change that produces a clinical difference for an individual patient as determined by the prescribing practitioner. If an outsourcing facility intends to rely on such a determination to establish that a compounded drug is not essentially a copy of an approved drug, the outsourcing facility should ensure that the determination is on the prescription or order (which may be a patient-specific prescription or a non-patient specific order) for the compounded drug.

FDA is aware that a health care practitioner who orders a compounded drug from an outsourcing facility for office stock will not know the identity of the individual patients who will receive the compounded drug at the time of the order. In that case, the outsourcing facility should obtain a statement from the practitioner that specifies the change between the compounded drug and the comparable approved drug and indicates that the compounded drug will be administered or dispensed only to a patient for whom the change produces a clinical difference, as determined by the prescribing practitioner for that patient. Such assurances should be provided by a person able to make the representation for the health care practitioner.

¹⁵ Title 21, section 207.3(4) of the Code of Federal Regulations defines the term *bulk drug substance* to mean “any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.”

¹⁶ FDA expects that if a compounded drug has the same bulk drug substance as an approved drug, the two drugs have the same active ingredient.

Contains Nonbinding Recommendations

Draft — Not for Implementation

301
302 For example, a hospital may need an FDA-approved drug combined with a particular
303 diluent in infusion bags to administer to patients during surgery. The pharmacy manager
304 for the hospital could order the compounded drug from an outsourcing facility and
305 document on the order that the compounded drug will only be administered to patients for
306 whom the prescriber determines that this formulation will produce a clinical difference
307 from the comparable approved drug. Similarly, a physician who regularly treats patients
308 with an allergy to an inactive ingredient in a particular approved injectable drug product
309 could order a compounded version of the drug for office use from an outsourcing facility
310 provided that he or she includes a statement on the order that removing the particular
311 inactive ingredient produces a clinical difference for his or her individual patients and
312 that he or she will provide the drug only to patients with that particular clinical need.

313
314 Many outsourcing facilities compound non-sterile drugs in addition to sterile drugs.¹⁷ All
315 drugs compounded by an outsourcing facility must be compounded in accordance with
316 section 503B, including the prohibition on compounding drug products that are
317 essentially copies of approved drug products in order for any of them to qualify for the
318 exemptions provided in section 503B.¹⁸ For example, a hospice may need a compounded
319 liquid formulation of a drug that is only approved in capsules to treat elderly patients who
320 cannot swallow capsules. The pharmacy manager for the hospice could order the
321 compounded drug from an outsourcing facility and document on the order that the liquid
322 formulation produces a clinical difference for hospice patients who are unable to swallow
323 capsules and that the compounded drug will be dispensed only to a patient whose
324 prescribing practitioner determines that the liquid formulation will produce this clinical
325 difference for the patient.

326
327 FDA does not believe that a particular format is needed, provided that an order for office
328 stock (i.e., not patient-specific) clearly identifies the relevant change and the clinical
329 difference produced for patient(s), as determined by the prescriber. For example, the
330 following would be sufficient:

- 331
- 332 • “Liquid form, compounded drug will be prescribed to patients who can’t swallow
333 tablet” (if the comparable drug is a tablet)
 - 334 • “Dilution for infusion solution to be administered to patients who need this
335 formulation during surgery” (if the comparable drug is not available at that
336 concentration, pre-mixed with the particular diluent in an infusion bag)
 - 337 • “1 mg, pediatric patients need lower dose” (if the comparable drug is only
338 available in 25 mg dose)
- 339

¹⁷ An entity that *only* compounds non-sterile drugs does not meet the statutory definition of an outsourcing facility in section 503B(d)(4) of the FD&C Act. The definition states, in part, that an outsourcing facility “is engaged in the compounding of sterile drugs” (section 503B(d)(4)(i)).

¹⁸ Under section 503B(a)(11), a compounded drug can qualify for the exemptions from section 503B only if all of the facility’s compounded drugs are compounded in accordance with section 503B.

Contains Nonbinding Recommendations

Draft — Not for Implementation

340 An order that only identifies the product formulation, without more information, would
341 not be sufficient to establish that the determination described by section 503B(d)(2)(B)
342 has been made.

343
344 Many outsourcing facilities also compound drug products based on prescriptions for
345 identified individual patients. The following are examples of statements on a patient-
346 specific prescription that could be used to document the prescriber’s determination that a
347 compounded drug has a change that produces a clinical difference for a particular patient:
348

- 349 • “No Dye X, patient allergy” (if the comparable drug contains the dye)
- 350 • “Liquid form, patient can’t swallow tablet” (if the comparable drug is a tablet)
- 351 • “150 mg drug X in 120 ml cherry-flavored Syrup USP, patient needs alcohol-free
352 preparation (if the comparable drug is only available in formulations that contain
353 alcohol)

354
355 However, if a prescription identifies only a patient name and product formulation, this
356 would not be sufficient to establish that the determination described by section
357 503B(d)(2)(B) has been made.

358
359 Note also that the clinical difference identified on either a patient-specific prescription or
360 order, or non-patient specific order, must be produced by the “change” between the
361 outsourcing facility’s product and the approved drug (i.e., a change in product
362 formulation). Other factors such as a lower price are not sufficient to establish that the
363 compounded product is not essentially a copy of the approved drug.

364
365 If a prescription or order does not make clear that the determination required by section
366 503B(d)(2)(B) has been made, the outsourcing facility may contact the prescriber or
367 health care facility, and if the prescriber or health care facility confirms it, make a
368 notation on the prescription or order that the prescriber has determined that the
369 compounded product contains a change that produces a clinical difference for patient(s).
370 The notations should be as specific as those described above, and the date of the
371 conversation with the health care facility or prescriber should be included on the
372 prescription or order.

373
374 FDA generally does not intend to question the determinations of clinical difference that
375 are documented in a prescription or order as described above. However, we do intend to
376 consider whether a prescription or order relied upon by an outsourcing facility to
377 establish that a drug is not essentially a copy documents that the determination was made.

- 378
- 379 iii. Essentially a copy of one or more approved drug products

380
381 Under section 503B(a)(5), a compounded drug product must not be essentially a copy of
382 **one or more** (emphasis added) approved drug products. When applying section
383 503B(d)(2)(B), FDA intends to consider a compounded drug product that has bulk drug
384 substances that are components of one or more approved drugs to be essentially a copy of

Contains Nonbinding Recommendations

Draft — Not for Implementation

385 an approved drug product, unless the prescribing practitioner determines that there is a
386 change that produces a clinical difference for an individual patient between the
387 compounded drug product and the comparable approved drug. For example, if there are
388 two approved drug products that are tablets, one containing 5 mg of active ingredient A
389 and the other containing 10 mg of active ingredient B and the outsourcing facility
390 compounded a tablet that offered both active ingredients in the same dosage strengths, the
391 compounded drug would be essentially a copy absent a prescriber determination of
392 clinical difference.

393

394 2. *Application of the “Essentially a Copy” Definition in Section 503B(d)(2) When the*
395 *Compounded Drug Is Compared to a Covered OTC Drug Product (Appendix B)*

396

397 a. Compounded drugs that are identical or nearly identical to a covered OTC drug
398 product (section 503B(d)(2)(A)) (Appendix B, box 1)

399

400 Under section 503B(d)(2)(A), a compounded drug is not considered essentially a copy of
401 an approved drug if it is identical or nearly identical to **an approved drug** that appears on
402 FDA’s drug shortage list at the time of compounding, distribution, and dispensing. The
403 statute does not provide a similar exemption from the definition in section 503B(d)(2) if
404 the compounded drug is identical or nearly identical to a **covered OTC drug** on FDA’s
405 drug shortage list. Therefore, FDA intends to apply the same policy described above in
406 section III.A.1.a to OTC monograph drugs, with one exception.

407

408 If a compounded drug is identical or nearly identical to a covered OTC drug under
409 section 503B(d)(2)(A), the compounded drug is essentially a copy of an approved drug,
410 and the appearance of the covered OTC drug on FDA’s shortage list does not change that
411 result; the drug cannot be compounded under section 503B.¹⁹ If the compounded drug is
412 not identical or nearly identical to a comparable drug, it must be evaluated under section
413 503B(d)(2)(B), as described below.

414

415 b. Compounded drugs that contain a bulk drug substance that is a component of an
416 covered OTC drug product (section 503B(d)(2)(B)) (Appendix B, box 2)

417

418 Under section 503B(d)(2)(B), a compounded drug product is essentially a copy and
419 cannot be compounded under section 503B if a component of the compounded drug
420 product is a bulk drug substance²⁰ that is also a component of a covered OTC drug,
421 unless there is a change that produces for an individual patient a clinical difference, as
422 determined by the prescribing practitioner, between the compounded drug and the
423 comparable **approved** drug. A clinical difference between the compounded drug and an
424 unapproved drug (such as a covered OTC drug) does not exempt the compounded drug
425 from the definition in section 503B(d)(2)(B).

¹⁹ The compounded drug would not be essentially a copy if it was also identical or nearly identical to an approved drug on FDA’s drug shortage list, but this would be a very rare case.

²⁰ See footnote 15.

Contains Nonbinding Recommendations

Draft — Not for Implementation

426
427
428
429
430
431
432
433
434
435
436
437
438
439
440
441
442
443
444
445
446
447
448
449
450
451
452
453
454
455
456
457
458
459

c. Essentially a copy of one or more approved drug products²¹

Under section 503B(a)(5), a compounded drug product must not be essentially a copy of **one or more** approved drug products. When applying section 503B(d)(2)(B), FDA intends to consider a compounded drug product that has bulk drug substances that are components of one or more approved drugs to be essentially a copy of an approved drug product unless the prescribing practitioner determines that there is a change that produces a clinical difference for an individual patient between the compounded drug product and the comparable approved drug. For example, if there are two approved drug products that are tablets, one containing active ingredient A and the other containing active ingredient B, and the outsourcing facility compounded a tablet that offered both active ingredients, the compounded drug containing active ingredients A and B would be essentially a copy absent a prescriber determination of clinical difference.

If a bulk drug substance is a component of a covered OTC drug *and* an approved drug, the bulk drug substance can be evaluated as a component of an approved drug, as described in section III.A.1 of this guidance.

B. Recordkeeping

Outsourcing facilities should maintain records to demonstrate compliance with the essentially a copy provision in section 503B(a)(5). For example, where an outsourcing facility has compounded a drug that is evaluated under 503B(d)(2)(B) and a component of the compounded drug is a bulk drug substance that is a component of an approved drug, the outsourcing facility should maintain prescription or order records of a prescriber's determination of clinical difference as described above in section III.A.1.b.ii.

In addition, if the outsourcing facility compounded a drug that is identical or nearly identical to an approved drug product that appeared on FDA's drug shortage list, the outsourcing facility should maintain documentation (e.g., a notation on the order for the compounded drug) regarding the status of the drug on FDA's drug shortage list at the time of compounding, distribution, and dispensing.

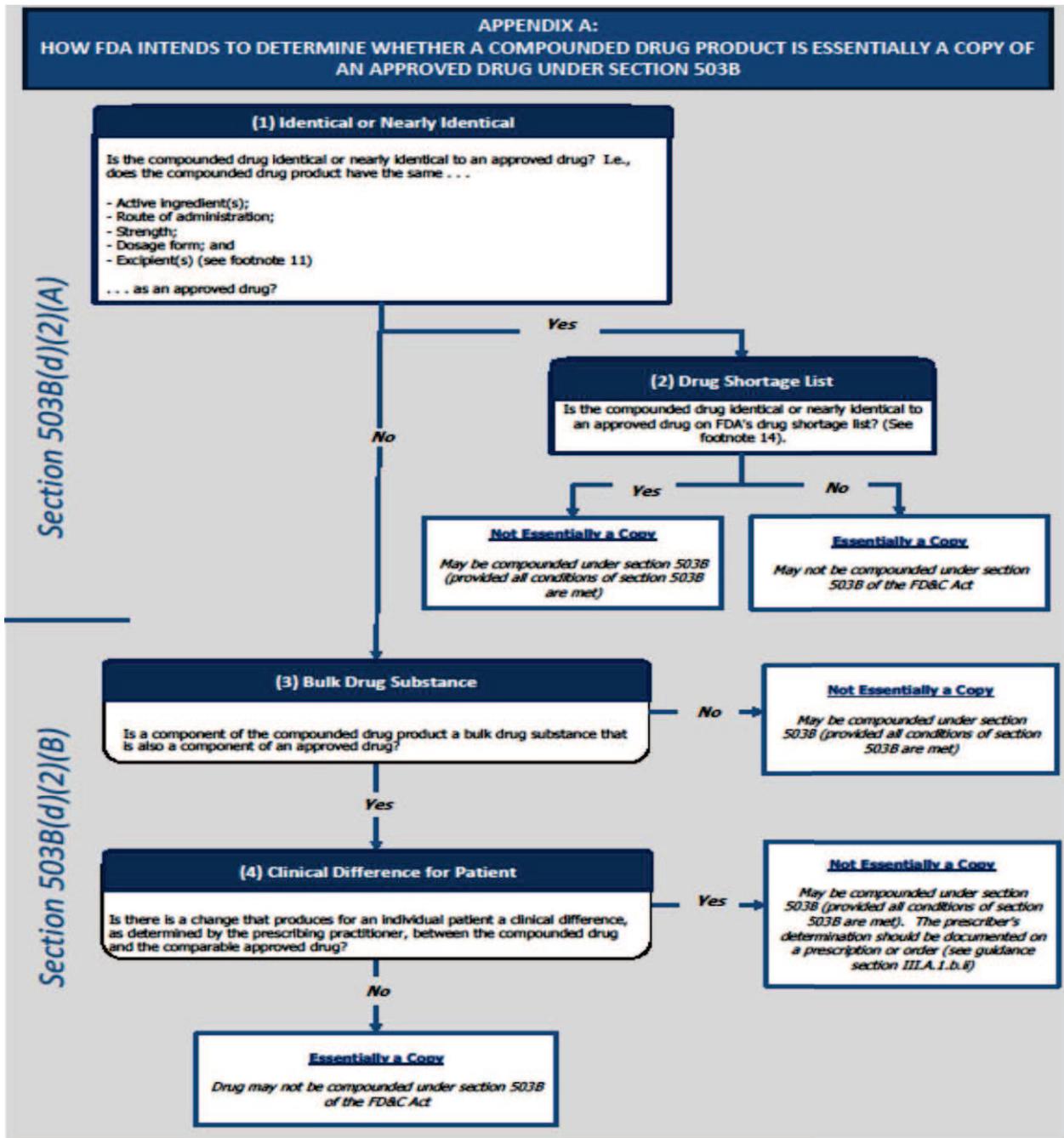
²¹ This scenario is not depicted in the diagrams in the appendices.

Contains Nonbinding Recommendations

Draft — Not for Implementation

460

APPENDICES A & B

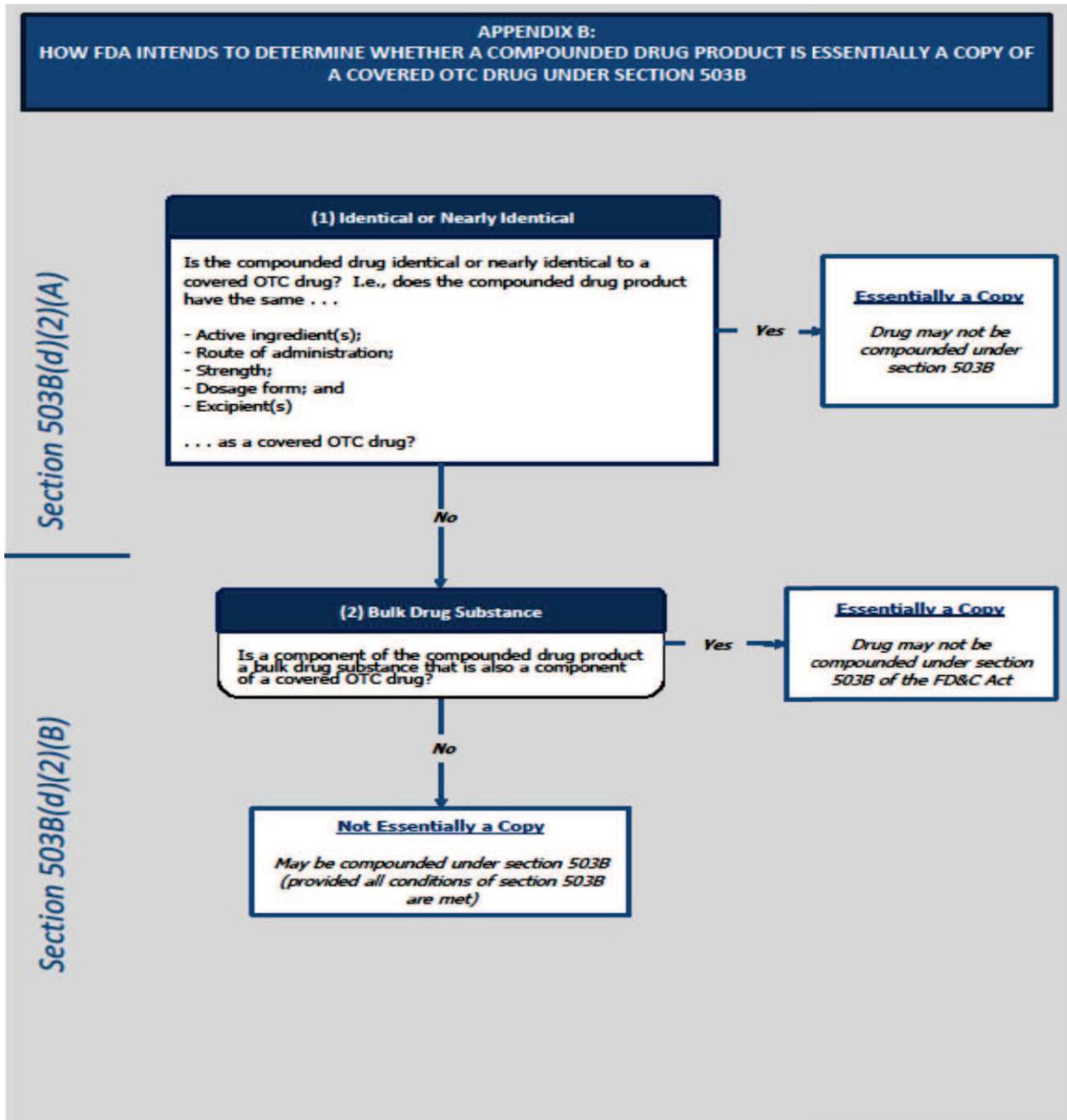


461

462

Contains Nonbinding Recommendations

Draft — Not for Implementation





Notice

This notice is to advise of a change in the U.S. Food and Drug Administration (FDA)'s procedure for inspections of entities that are seeking to compound human drugs in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (i.e., human drug compounders that are not registered with FDA as outsourcing facilities under section 503B).

Effective August 1, 2016, FDA investigators will make a preliminary assessment of whether such entities are compounding their human drugs in accordance with certain conditions of section 503A before closing the inspection. If the investigator issues a "Form FDA-483"¹ list of inspectional observations to the firm, the investigator will *not* include observations that represent deviations solely from FDA's current good manufacturing practice (CGMP) requirements unless it appears, based on the investigator's preliminary assessment, that the firm compounds drugs that do not qualify for the exemptions under section 503A.

Section 503A of the FD&C Act describes the conditions that must be met for a drug product compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from provisions of the FD&C Act requiring pre-market FDA approval of drugs (section 505), labeling with adequate directions for use (section 502(f)(1)), and compliance with CGMP requirements (section 501(a)(2)(B)). If a drug is not compounded in accordance with the conditions in section 503A, it does not qualify for the exemptions in that section and is subject to the approval, labeling with adequate directions for use, and CGMP requirements.

Because a Form FDA-483 does not represent a final Agency determination regarding a firm's compliance, formerly, FDA investigators have been identifying deviations from drug production practices on Forms FDA-483 that could lead to quality problems without regard to whether the observations related to CGMP deficiencies or other deficiencies, such as those relating to the prohibition in section 501(a)(2)(A) of the FD&C Act on preparing, packing, or holding drugs under insanitary conditions whereby they may be contaminated with filth or rendered injurious to health.

After the inspection, when determining whether to pursue regulatory action, such as a warning letter, FDA has considered a number of factors, including evidence concerning compliance with the conditions of section 503A. When FDA has issued a warning letter, FDA has only cited compounders that were not registered as outsourcing facilities for violations of CGMP requirements when the agency had evidence that at least some of their drugs were not compounded in accordance with the conditions of section 503A. Our experience was that in the substantial majority of cases, inspected human drug compounders not registered as outsourcing facilities were compounding at least some of their drugs not in accordance with section 503A,

¹ A Form FDA-483 is issued to firm management at the conclusion of an inspection when an investigator has observed conditions that in the investigator's judgment may constitute violations of the FD&C Act and related Acts.

subjecting their drugs to CGMP requirements. Nevertheless, FDA has received input from stakeholders that they would like inspectional evidence regarding section 503A to be reviewed earlier, prior to the close of an inspection, and to be taken into consideration in decisions about what to include in any Form FDA-483.

In response to stakeholder input, and as noted above, FDA investigators now will make a preliminary assessment regarding the firm's compliance with certain conditions of section 503A before closing an inspection, and if a Form FDA-483 is issued to the firm it will *not* include observations that represent deviations only from CGMP requirements unless the investigator's preliminary assessment is that the firm compounds drugs that do not qualify for the exemptions under section 503A. After the inspection, FDA will conduct a thorough review of the evidence to evaluate whether the firm compounds all of its drugs in accordance with certain conditions of section 503A and other applicable provisions of Federal law. When FDA's more thorough post-inspection review differs from the FDA investigators' preliminary assessment and reveals that a facility fails to produce drugs in accordance with the conditions of section 503A, FDA intends to consider citing CGMP violations in any regulatory action it decides to pursue.

Importantly, although drug products compounded in accordance with the conditions of section 503A are exempt from certain requirements in the FD&C Act, as described above, they remain subject to all other provisions of the FD&C Act that apply to conventional drug manufacturers, including, but not limited to, the prohibition on preparing, packing, or holding drugs under insanitary conditions. Because section 503A does not provide an exemption from the prohibition on insanitary conditions, FDA investigators will continue to include observations on Forms FDA-483 that appear to constitute insanitary conditions without regard to the investigator's preliminary assessment of a firm's status under section 503A. Investigators may similarly include on Forms FDA-483 observations that appear to violate other legal requirements from which section 503A does not provide an exemption.

Since the 2012 fungal meningitis outbreak in which contaminated injectable drug products compounded by a pharmacy resulted in over 60 deaths and 750 cases of infection, FDA has investigated numerous serious adverse events, including infections and deaths, associated with poor quality (e.g., contaminated or superpotent) sterile and non-sterile compounded drugs. Many compounders have recalled drug products and temporarily or permanently ceased sterile operations as a result of FDA's inspectional findings. FDA intends to continue to inspect compounding facilities and to take action, as appropriate, when the Agency identifies violations of Federal law that could put patients at risk.