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

NONRESIDENT STERILE COMPOUNDING PERMIT APPLICATION FOR

Nonresident Pharmacies

FEBRUARY 2015

DH5003-MQA-02/15
Rule 64B16-28.100 F.A.C.

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a permit in the State of Florida. A Nonresident Sterile Compounding Permit as authorized by Section 465.0158, *Florida Statutes* is required in order to ship, mail, deliver, or dispense in any manner, a compounded sterile product into Florida.

We welcome nonresident pharmacies (currently registered under s. 465.0156, F.S.) seeking mandatory Nonresident Sterile Compounding Permits. Your assistance in providing all required information below will enable the Florida Board of Pharmacy (the Board) to process your application as quickly as possible. You are encouraged to apply as early as possible in order to avoid any undue delays.

Florida Statutes require the Board to receive a completed application and all applicable fees before reviewing an application. So please read this application carefully and fully before submission. Keep a copy of the completed application for your records. When mailing the completed application and fees, use the address noted in the instructions and on the application form.

Fees will be deposited upon of the receipt of your application. Board staff will notify you of the receipt and deposit at this time. If you need to contact the Board, email us at info@floridaspharmacy.gov, or call us at (850) 245-4292. Phone calls are returned within 24 hours and emails within 48 hours during normal business hours.

Our staff is committed to providing prompt and reliable information to our customers. Customer service is important to us and while we strive to process your application as quickly as possible, we welcome your comments on how our services may be improved.

Sincerely,

The Florida Board of Pharmacy

APPLICATION SUBMISSION; PROCESSING ; AND PERMITTING

Failure to attach any required documentation or a failure to submit a completed application with the required application fee is considered an incomplete application. A submitted application will expire after one year.

1) Mail completed applications along with a $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, FL 32314-6320

2) Along with the application, **Nonresident Pharmacies** must submit the following:

a. A letter of licensure verification for both the facility and the Pharmacy Manager or Pharmacist in Charge from their local state, territory or district regulatory or licensing agency. The letter must include the original licensure date, the expiration date, and current licensure status.

b. A copy of the most recent inspection conducted by the state, territory, or district regulatory or licensing agency or the entity responsible for conducting inspections in the state where they are physically located and a **current inspection** conducted by the state, territory, or district regulatory or licensing agency is also required. The current inspection must display compliance with Chapter 797, of the United States Pharmacopeia. An inspection report is current if the inspection was conducted within 6 months before the date of submitting the application for the initial permit. If you are unable to submit a current inspection report displaying compliance with USP Chapter 797 due to acceptable circumstances as established by rule, or if no current inspection has been performed, the department shall:

- Conduct or contract with an entity to conduct, an onsite inspection for which all costs shall be borne by the applicant; *or*
- Accept a current and satisfactory inspection report from an entity approved by the board.

c. A copy of the applicant's existing policies and procedures for sterile compounding**.** The policies and procedures must comply with pharmaceutical standards in chapter 797 of the United States Pharmacopoeia and any standards for sterile compounding required by board rule.

d. Any and all other documentation requested or mandated within this application**.**

3) Once an application is complete and approved, board staff will issue the applicant a new permit number. The "hard copy" permit should arrive at the applicant's listed address within 7 days of the issue date.

All pharmacies must answer the following questions. The questions will help our inspectors understand more about your pharmacy's approach to USP Chapter 797. Please answer the following questions as completely and legibly as possible. Attach additional pages if needed.

1. These questions relate to your primary engineering controls.

a. How many primary engineering controls do you have? _____

b. What kind are they? (select all that apply)

- ☐ Laminar Airflow Workbench (LAFW)
- ☐ Compounding Aseptic Isolator (CAI)
- ☐ Biological Safety Cabinet (BSC)
- ☐ Compounding Aseptic Containment Isolator (CACI)
- ☐ Integrated vertical clean bench
- ☐ Other: please describe _____

c. Where are your primary engineering controls located? (select all that apply)

- ☐ Positive Pressure ISO Class 7 buffer room with walls/doors
- ☐ Negative Pressure ISO Class 7 buffer room with walls/doors
- ☐ Positive Pressure ISO Class 7 anteroom
- ☐ Positive Pressure ISO Class 8 anteroom
- ☐ Non-ISO classed segregated compounding area for non-hazardous compounding
- ☐ Non-ISO classed containment segregated compounding room with 12 ACPH/negative pressure
- ☐ Other: please describe _____

d. What was the date of the last certification your primary and secondary engineering controls?

_____

e. Did the certification of the primary and (if applicable) secondary engineering controls include testing of non-viable particle counts and airflow pattern smoke testing ***under dynamic operating conditions*** (while pharmacy staff are working or simulating work in the area being tested)?

☐ Yes ☐ No

2. What kind of gloves and alcohol are in use at your pharmacy for sterile compounding activities?

Describe briefly:

3. If your pharmacy uses isolators (Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators), describe how gloves are donned before compounding in your isolator/s.

☐ Not applicable because we do not use isolators for sterile compounding.

Describe briefly:

4. Primary engineering controls must be disinfected at frequent intervals with sterile 70% IPA during use but they also must be part of the daily cleaning routine. Briefly describe how the inside of your primary engineering controls are cleaned and disinfected (as well as the agents used) daily during your pharmacy's daily cleaning routine.

Describe briefly:

5. Before pharmacy staff or outsourced cleaning staff are allowed to perform daily and monthly cleaning activities, they must receive (at minimum) training and competency verification in which two areas?

1. 2.

6. USP 797 requires that each compounding staff member successfully complete some training and testing before they are allowed to make compounded sterile preparations for human use. Briefly describe this type of training and testing at your facility.

Describe briefly:

7. These questions relate to viable air sampling. Please provide a short answer to each.

a. How often does your pharmacy perform viable air sampling? _____

b. Where is viable air sampling performed?_____

_____

c. How large are the samples of air you are sampling?_____

d. What are your action levels?_____

8. Surface sampling is a personnel metric that is required "periodically" by USP Chapter 797. How is it performed at your pharmacy? Briefly describe under what conditions it is performed, how often, with what and where it is performed.

Describe briefly:

9. USP Chapter 797 requires Gloved fingertip sampling. Briefly describe how and when your pharmacy performs gloved fingertip sampling.

Describe briefly:

10. What activities would occur at your pharmacy if the results (number of colony forming units) of one of your Environmental Sampling samples exceeded the preselected Action Levels for that area.

Describe briefly:

11. Please explain how the concept of “first air” is critical to executing sterile compounding with proper aseptic technique.

Describe briefly:

12. If a pharmacy uses a 0.22 micron filter for the purposes of sterilization, what test is required before that batch may be released?

_____

13. According to USP Chapter 797, is sterility testing required if a beyond-use date of 30 days refrigerated is assigned to a medium risk level batch?

Answer Yes or No and then briefly explain your rationale:

14. During a compounding process, the pharmacy removes the vial stopper from a product purchased from an FDA registered manufacturer. Does this change the risk level that should be assigned to the final CSP made from that product and what risk level would you assign it?

Answer: Yes or No then indicate the risk level you would assign this CSP and your rationale:

15. Please provide us with a description of your practice of Lyophilization involving sterile compounding (“freeze drying” solutions to make lyophilized powder).

Describe your practice of Lyophilization below including its use in pharmacy:

16. If a pharmacy has performed sterility testing on a batch (or outsourced it to a vendor who performs sterility testing in compliance with USP Chapter 71 on their behalf) and the batch fails, is it acceptable practice to retest that batch?

Answer Yes or No and then briefly describe your rationale:

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(850) 245-4292 | www.floridaspharmacy.gov

NONRESIDENT STERILE COMPOUNDING PERMIT APPLICATION FOR NONRESIDENT PHARMACIES

Application Type:

☐ **New Establishment $255 fee (1020)** ***(New applicants must also apply for the Nonresident Pharmacy Permit)***

☐ **Change of Location $100 fee (3012)** _____ **Existing Sterile Compounding Permit Number**

☐ **Change of Ownership* $255 fee (1023 create new file)** _____**Existing Nonresident Permit Number**

***New permit number will be issued**

Federal Employer Identification Number (FEIN)

1. Corporate Name | **Telephone Number**

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

3. Mailing Address

City | State | Zip

4. Physical Address

City | State | Zip

5. Prescription Department Manager (PDM) or Pharmacist In Charge (PIC)

Name | License No. | Start Date | Signature

6. Contact Person | **Telephone Number**

7. DEA Registration Number (If applicable)

8. Do you have 24-hr access to patient records?
___ Yes ___ No (If no explain on separate sheet)

9. Date of last inspection: Day _____ Month _____Year _____ Inspecting Authority_____

10. Was this inspection structured to ensure compliance with USP 797 standards? (Attach a copy of the inspection report, the floor plan and your policies and procedures manual).

_____Yes _____No

11. Prescription Department Operating Hours

Monday-Friday: Open _____Close: _____

Saturday: Open _____Close: _____

Sunday: Open _____Close: _____

11a. Toll-Free Telephone Number
(available 6 days a week for 40 hours)

(_____) _____- _____

12. Ownership Information

a. Type of Ownership

_____Individual _____Corporation _____Partnership _____Other:_____

CORPORATIONS & LIMITED PARTNERSHIPS: INCLUDE A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE STATE WHERE THE FACILITY IS LOCATED.

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

Yes _____ No _____

c. Persons 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. ***Attach a separate sheet if necessary.***

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

Questions 13 through 20 are required pursuant to Section 456.0635(2) *Florida Statutes*. Please explain any "yes" answered to the following questions on a separate sheet, providing as much detail as possible. Please also provide copies of any relevant supporting documentation.

13. 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? (If "*yes,*" provide court documents concerning this conviction)

Yes_____ No _____

If "yes" to 13: **For felonies of the second and first degree, is the date of application more than 15 years from the date of plea, sentence, and completion of any subsequent probation?** Yes _____ No _____

***If "yes" to 13*: For felonies of the third degree, is the date of application 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_____

***If "yes" to 13*: 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_____

***If "yes" to 13*: 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 _____

14. 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?

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

***If "yes"*: Is the date of application more than 15 years after the sentence and any subsequent period of probation ended?**

Yes_____ No_____

15. 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 16.)

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

16. 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)

17. 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 18 and 19.)

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

18. 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)

19. 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)

20. 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)

21. 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

22. Has the applicant, affiliated persons, partners, officer, directors, or PDM or Pharmacist in Charge 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.

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

Pharmacy Name	State	Status

23. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors, PDM or Pharmacist in Charge 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)

24. Has the applicant, affiliated persons, partners, officer, directors, PDM or Pharmacist in Charge ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

Yes _____ No _____ (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.)

25. 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)

26. Does the applicant, affiliated person, partner, officer, director, PDM, or Pharmacist in Charge have any outstanding fines, liens or overpayments assessed by a final order of the department?

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

If "yes" to 26: **Does the applicant, affiliated person, partner, officer, director or Pharmacist in Charge have a repayment plan approved by the department?**

Yes _____ No _____

APPLICANT SIGNATURE PAGE

Florida law requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application that 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 of board.

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I, the undersigned, 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. I do authorize the Florida Board of Pharmacy and the Department to make any investigations that they deem appropriate and to secure any additional information concerning the applicant or me. 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. I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be denied, 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.

I, the undersigned, hereby acknowledge that proving false information in relation to this application, may result in denial of licensure, discipline, and/ or criminal penalties pursuant to sections 456.067, 465.015 (5), 775.082, 775.083, and 775.084, *Florida Statutes*.

I, the undersigned, have completely reviewed and read the foregoing document and state that the facts stated in it are true.

SIGNATURE _____ TITLE _____ DATE_____
Owner/Officer

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FLORIDA BOARD OF PHARMACY
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Phone: (850) 245-4292
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APPLICANT ATTESTATION FORM FOR NONRESIDENT PHARMACIES

Section 465.0158(3) (c), F.S., requires that applicants submit a written attestation by an owner or officer of the applicant and by the applicant's Prescription Department Manager, (PDM) or Pharmacist In Charge (PIC).

I hereby by attest and affirm that I have read and understand the laws and rules governing sterile compounding in the State of Florida, and that any sterile compounded product shipped, mailed, delivered, or dispensed into the State of Florida from our facility meets or exceeds the standards for sterile compounding set by the State of Florida and has not been compounded in violation of the laws and rules of the state, territory, or district in which our facility is located.

Under Penalties of Perjury, I declare that I have read the foregoing Attestation Form and that the facts stated in it are true

SIGNATURE _____ TITLE _____DATE_____
(Owner/Officer)

SIGNATURE _____ TITLE _____DATE_____
(PDM/PIC)

If the owner or office who executed this attestation is no longer an owner or officer, another or new owner or officer shall execute a new attestation within 10 days of the change.

If there is a change in the PDM or PIC who executed this attestation, the new supervising pharmacist shall execute a new attestation within 10 days of the change.