

AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
COMPOUNDING RULES COMMITTEE

JUNE 9, 2014

Embassy Suites – Lake Buena Vista
4955 Kyngs Heath Road
Kissimmee, FL 34746
(407) 597-4000

Committee Members:

Michele Weizer, PharmD, Boca Raton, Chair
Leo “Lee” Fallon, BPharm, PhD The Villages
Debra Glass, BPharm, Tallahassee
Mark Mikhael, PharmD, Orlando

Board Staff:

Patrick Kennedy, Executive Director
Tammy Collins, Program Operations Administrator
Jay Cumbie, Regulatory Specialist II

Board Counsel:

David Flynn, Assistant Attorney General
Lynette Norr, Assistant Attorney General

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

Call to order by Dr. Weizer at 3:07p.m.

Dr. Weizer welcomed members of the audience and requested Mr. Flynn introduce the first proposed language change to Rule 64B16-27.797.

Mr. Flynn presented the recommended language changes to Rule 64B16-27.797(3) that shall read as follows: “**Current Good Manufacturing Practices:** The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with Current Good Manufacturing Practices per 21 U.S.C. § 501 (2012), adopted and incorporated herein by reference and 21 C.F.R. Parts 210 and 211 (2011), adopted and incorporated herein by reference.”

Dr. Weizer then requested a vote on the above referenced change.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, to approve the proposed language change to Rule 64B16-27.797. Motion carried.

Dr. Weizer then moved to the next recommended change to 64B16-27.797 which included the striking of section 5 and 6 from the rule.

Motion: by Dr. Mikhael, seconded by Dr. Fallon, to approve the striking of section 6 & 7 from Rule 64B16-27.797. Motion carried.

Michael Glazer approached the Committee to discuss a possible grandfathering provision in regards to the placement of an air return system as long as the pharmacy is still meeting all standards and requirements of USP 797.

Dr. Mikhael stated that he would be in support of the provision if there were a smoke study that showed there wasn't a return coming back into the pharmacy.

Motion: by Dr. Mikhael, seconded by Dr. Fallon, to allow grandfathering provision in regards to the placement of a an air return system as long as the pharmacy is still meeting all standards and requirements set by USP797. Motion carried.

Larry Gonzalez (Florida Society of Health System Pharmacists) approached the Committee to state that FSHP would be in support of the exemption as proposed by Mr. Glazer.

Motion: by Dr. Fallon, Seconded by Mrs. Glass, that there will be no negative economic impact resulting from the 3 proposed changes to Rule 64B16-27.797. Motion carried.

Mr. Flynn then introduced the Annual Regulatory Plan and proceeded to illustrate how it is mostly dominated by the numerous rules that will be affected by HB323 and HB7077.

Bob Hoye approached the committee to request confirmation that June 22, 2014 is the day pharmacies can no longer compound sterile human medications for office use.

Mr. Flynn stated that June 22, 2014 is the day the Board has determined that the Federal provisions are applicable.

Dr. Weizer opened the floor for public comments.

Michael Jackson (Florida Pharmacy Association) approached the committee to discuss injectable vitamins and its relation to acupuncturists.

Mr. Kennedy responded that the Division of Medical Quality Assurance is already aware of the issue.

Motion: by Dr. Fallon, seconded by Mrs. Glass, to adjourn the meeting at 4:07p.m. Motion carried.