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MEMORANDUM

TO: Mark Whitten, Executive Director
Board of Pharmacy

FROM: Michele Bass, Paralegal Specialist 

RE: Rule 64B16-28.802

DATE: October 3, 2013

We are pleased to inform you that the above-referenced rule was filed for adoption on September 30, 2013, and will become effective October 20, 2013. Attached is a copy of the rule for your records.

Enclosure

cc: Jennifer Tschetter, General Counsel

RECEIVED
OCT 07 2013
Florida Board of Pharmacy

CERTIFICATION OF
BOARD OF PHARMACY ADMINISTRATIVE RULES
FILED WITH THE DEPARTMENT OF STATE

I hereby certify:

(1) That all statutory rulemaking requirements of Chapter 120, F.S., and all rulemaking requirements of the Department of State have been complied with; and

(2) There is no administrative determination under subsection 120.56(2), F.S., pending on any rule covered by this certification; and

(3) All rules covered by this certification are filed within the prescribed time limitations of paragraph 120.54(3)(e), F.S. They are filed not less than 28 days after the notice required by paragraph 120.54(3)(a), F.S., and;

(a) Are filed not more than 90 days after the notice; or

(b) Are filed not more than 90 days after the notice, but not more than 60 days after the administrative law judge files the final order with the clerk or until 60 days after the subsequent judicial review is complete; or

(c) Are filed more than 90 days after the notice, but not less than 21 days nor more than 45 days from the date of publication of the notice of change; or

(d) Are filed more than 90 days after the notice, but not less than 14 nor more than 45 days after the adjournment of the final public hearing on the rule; or

(e) Are filed more than 90 days after the notice, but within 21 days after the date of receipt of all material authorized to be submitted at the hearing; or

(f) Are filed more than 90 days after the notice, but within 21 days after the date the transcript was received by this agency; or

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DEPARTMENT OF STATE
TALLAHASSEE, FLORIDA

[] (g) Are filed not more than 90 days after the notice, not including the days the adoption of the rule was postponed following notification from the Joint Administrative Procedures Committee that an objection to the rule was being considered; or

[] (h) Are filed more than 90 days after the notice, but within 21 days after a good faith written proposal for a lower cost regulatory alternative to a proposed rule is submitted which substantially accomplishes the objectives of the law being implemented; or

[] (i) Are filed more than 90 days after the notice, but within 21 days after a regulatory alternative is offered by the small business regulatory advisory committee.

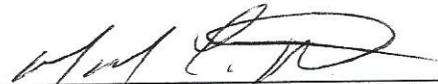
Attached are the original and two copies of each rule covered by this certification. The rules are hereby adopted by the undersigned agency by and upon their filing with the Department of State.

Rule No(s).

64B16-28.802

Under the provision of subparagraph 120.54(3)(e)6., F.S., the rules take effect 20 days from the date filed with the Department of State or a later date as set out below:

Effective: _____
(Month) (Day) (Year)



Signature, Person Authorized
To Certify Rules

Executive Director _____
Title

Number of Pages Certified _____

DEPARTMENT OF HEALTH

BOARD OF PHARMACY

ADDITIONAL STATEMENT TO THE SECRETARY OF STATE

RULE NO.:
64B16-28.802

RULE TITLE:
Special Sterile
Compounding Permits.

SUMMARY: The proposed rule amendment adds language to clarify the requirements of Special Sterile Compounding Permits.

SUMMARY OF THE HEARING ON THE RULE:

No timely request for a hearing was received and no hearing was held.

STATEMENT OF FACTS AND CIRCUMSTANCES JUSTIFYING RULE PROPOSAL:

The proposed rule amendments are necessary to add language to clarify the requirements of Special Sterile Compounding Permits.

64B16-28.802 Special Sterile Compounding Permits. (Substantial Rewrite)

With the exception of those pharmacies which hold an active stand alone Special Parenteral/Enteral or Special Parenteral / Enteral Extended Scope Compounding permit, 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. This permit is an additional permit required by a licensed pharmacy and shall not be considered a modifier. The compounding of sterile products must be in strict compliance with the standards set forth in Rules 64B16-27.700 and 64B16-27.797, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History—New 6-18-13. Amended_____.