NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-7-.01 MANUFACTURER'S PERMIT, AND NOTICE OF PUBLIC HEARING

TO ALL INTERESTED PERSONS AND PARTIES:
Notice is hereby given that pursuant to the authority set forth below, the Georgia State Board of Pharmacy (hereinafter "Board") proposes amendments to the Georgia Board of Pharmacy Rules, Rule 480-7-.01 MANUFACTURER'S PERMIT (hereinafter "proposed amendments").

This notice, together with an exact copy of the proposed amendments and a synopsis of the proposed amendments, is being forwarded to all persons who have requested, in writing, that they be placed on an interested parties list. A copy of this notice, an exact copy of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments may be reviewed during normal business hours of 8:00 a.m. to 5:00 p.m. Monday through Friday, except official State holidays, at the Department of Community Health at 2 Peachtree Street NW, Atlanta, Georgia, 30303. These documents will also be available for review on the Georgia State Board of Pharmacy's web page at www.gbp.georgia.gov.

A public hearing is scheduled to begin at 11:00 AM on June 10, 2015 at a meeting of the Georgia State Board of Pharmacy at University of Georgia College of Pharmacy, 250 W. Green Street, Athens, Georgia 30602 to provide the public an opportunity to comment upon and provide input into the proposed amendments. At the public hearing, anyone may present data, make a statement, comment or offer a viewpoint or argument whether orally or in writing. Lengthy statements or statements of a considerable technical or economic nature, as well as previously recorded messages, must be submitted for the official record. Oral statements should be concise and will be limited to 5 minutes per person. Additional comments should be presented in writing. Written comments are welcome. To ensure their consideration, written comments must be received prior to June 3, 2015. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, Atlanta, Georgia 30303 FAX: 678-717-6694. You may email your comments to tbattle@dch.ga.gov.

The proposed amendments will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 11:05 AM on 6/10/2015 at the University of Georgia College of Pharmacy, 250 W. Green Street, Athens, Georgia 30602. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed amendments pursuant to authority contained in O.C.G.A. §§ 16-13-35, 16-13-45, 16-13-72, 26-4-20, 26-4-27 to 26-4-29, 26-4-60, 26-4-111, 26-4-113, 26-4-115, 26-4-120, 26-4-131, 43-1-19, 50-18-72.

At its meeting on April 15, 2015, the Board voted that the formulation and adoption of these rule amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22.

At its meeting on 4/15/2015, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A§ 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these amendments will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

For further information, contact the Board office at 404-651-8000.

This notice is given in compliance with O.C.G.A. §50-13-4.

This 7th day of May, 2015.

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: May 7, 2015

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-7-.01 MANUFACTURER'S PERMIT

Purpose of Rule: The purpose of this amendment is to require an application for reinstatement after a license has lapsed.

Main Feature: The main feature of this amendment is to provide that reinstatement is at the sole discretion of the Board.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-7-.01 MANUFACTURER'S PERMIT

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

480-7-.01 Manufacturer's Permit

(1) Applications for registration for a manufacturer's permit must be filed with the Office of the Georgia State Board of Pharmacy ("Board") with the required fee.
(2) Registration of a manufacturer will be considered on the basis of the application filed, fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a permit.
(3) Application fees shall NOT be refundable.
(4) Permits shall not be transferable. Permits become null and void upon the sale, or change of mode of operation of the business, or location of business.
(5) Licenses are renewed for two years and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st of the odd numbered year, the license shall lapse and shall not be ~~renewable except by application for a new license.~~ renewed, and an application for reinstatement shall be required. Reinstatement is at the sole discretion of the Board.
(6) Upon request by the Board or its designee, any manufacturer holding a permit issued by the Board that causes a dangerous drug or controlled substance product to be marketed or distributed in this state shall provide, at no cost to this state, a quantity of one gram or more of the pure compound of each such product to the Georgia Drugs and Narcotics Agency. Such quantities of pure compound will only be used for testing and analysis purposes.
(a) All quantities of a pure compound provided to the Georgia Drugs and Narcotics Agency will be accounted for using a perpetual inventory system, and a copy of each product inventory will be available for review by the manufacturer providing the compound upon written request to the Board.
(b) As the manufacturer is required by this subsection to submit the dangerous drug or controlled substance for analysis, the results of any chemical analysis shall be considered a trade secret within the meaning of Code Section 50-18-72(b)(1).

Authority: O.C.G.A. §§ 16-13-35, 16-13-45, 16-13-72, 26-4-20, 26-4-27 to 26-4-29, 26-4-60, 26-4-111, 26-4-113, 26-4-115, 26-4-120, 26-4-131, 43-1-19, 50-18-72.