

GEORGIA BOARD OF PHARMACY
Conference Call
2 Peachtree St., N.W., 6th Floor
Atlanta, GA 30303
January 28, 2015
3:00 p.m.

The following Board members were present:

Laird Miller
Mike Faulk
Vicki Arnold
Jim Bracewell
Chris Jones
Tony Moye
Bill Prather
Bob Warnock

Staff present:

Tanja Battle, Executive Director
Janet Wray, Senior Assistant Attorney General
Rick Allen, GDNA
Anil Foreman, Legal Officer
Brandi Howell, Business Operations Specialist

Open Session

Chairperson Miller established that a quorum was present and called the meeting to order at 3:03 p.m.

Bob Warnock made a motion to adopt emergency Rule 480-34-0.22-.07 Fluticasone. Bill Prather seconded and the Board voted unanimously in favor of the motion.

480-34-0.22-.07 Fluticasone

(1) This rule was adopted to protect the health, safety, and welfare of the public. Effective February 1, 2015, Official Code of Georgia Annotated (O.C.G.A.) §16-13-71, relating to the definition of a dangerous drug, is hereby amended by revising paragraph (402.7) of subsection (b) to read as follows: “(402.7) Fluticasone – See exceptions.”

(2) Effective February 1, 2015, O.C.G.A. §16-13-71 is further amended by adding a new paragraph to subsection (c) of Code Section § 16-13-71, relating to the definition of a dangerous drug, to read as follows: “(9.75) Fluticasone – when available in a device that delivers a metered spray of 0.05 mg and to be used for the temporary relief of symptoms due to hay fever or other upper respiratory allergies.”

The adoption of the aforementioned Emergency Rule by the Board is necessary to protect the health, safety and/or welfare of the citizens of the State of Georgia. This rule is based on the Board’s consideration of the eight criteria listed in O.C.G.A. §16-13-71; the Board’s receipt of the reliable information that the Food and Drug Administration has made the drug available over-the-counter for some uses; and the need to make the drug similarly situated for those uses in the State of Georgia.

A motion was made by Jim Bracewell, seconded by Chris Jones, and the Board voted that the formulation and adoption of this rule does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

In the same motion, the Board voted that it is not legal or feasible to meet the objectives of the relevant code sections 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 this rule will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

The hearing concluded at 3:09 p.m.

Petition for Rule Waiver – Rockwell Medical, Inc.

Bob Warnock made a motion to grant the rule waiver petition. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Chris Jones made a motion and Jim Bracewell seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2) and §43-1-2(k) to deliberate and to receive information on applications. Voting in favor of the motion were those present who included Vicki Arnold, Jim Bracewell, Mike Faulk, Chris Jones, Laird Miller, Tony Moye, Bill Prather, and Bob Warnock.

Executive Session

Correspondence/Request

- G.M.

No votes were taken in Executive Session. Chairperson Miller declared the meeting back in Open Session.

Open Session

Jim Bracewell made a motion for the Board to take the following action:

Correspondence/Request

- G.M. Request for fee waiver Denied request

Bill Prather seconded and the Board voted unanimously in favor of the motion.

Miscellaneous

The Board briefly discussed proposed legislation regarding biosimilars about which the Board did not take an official position.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, February 18, at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

The Board meeting adjourned at 3:30 p.m.

Minutes recorded by Brandi P. Howell, Business Operations Specialist
Minutes edited by Tanja D. Battle, Executive Director