

**NOTICE OF INTENT TO ADOPT PROPOSED RULE IN THE GEORGIA STATE BOARD
OF PHARMACY RULES,
RULE 480-34-.11 LEVOCETIRIZINE DIHYDROCHLORIDE., 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 a new Rule to the Georgia Board of Pharmacy Rules, Rule 480-34-.11 LEVOCETIRIZINE DIHYDROCHLORIDE (hereinafter "proposed rule").

This notice, together with an exact copy of the proposed rule and a synopsis of the proposed rule, 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, and a synopsis of the rule 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 11:30 AM on July 12, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th Floor, Atlanta, Georgia 30303 to provide the public an opportunity to comment upon and provide input into the proposed rule. 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 July 5, 2017. 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 rule will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 11:35 AM on 7/12/2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th Floor, Atlanta, Georgia 30303. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed rule pursuant to authority contained in O.C.G.A. §§ 16-13-71, 26-4-27.

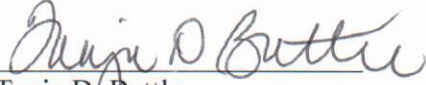
At its meeting on April 12, 2017, the Board voted that the formulation and adoption of this rule do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22.

At its meeting on 4/12/2017, 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 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.

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 8th day of May, 2017.


Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: May 8, 2017.

**SYNOPSIS OF PROPOSED RULE OF THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-34-.11 LEVOCETIRIZINE DIHYDROCHLORIDE.**

Purpose of Rule: The purpose of this rule is to partially remove levocetirizine dihydrochloride from the list of dangerous drugs.

Main Features: The main feature of this rule is to permit over-the-counter sales of levocetirizine dihydrochloride in 5 mg tablets or an oral solution of 2.5 mg per 5 mL (.05 mg per mL).

**PROPOSED RULE OF THE GEORGIA STATE BOARD OF PHARMACY RULES
480-34-.11 LEVOCETIRIZINE DIHYDROCHLORIDE.**

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

480-34-.11 Levocetirizine Dihydrochloride.

(1) This rule was adopted to protect the health, safety, and welfare of the public. Levocetirizine dihydrochloride in 5 mg tablets or an oral solution of 2.5 mg per 5 mL (.05 mg per mL), as identified in Official Code of Georgia Annotated (O.C.G.A.) §16-13-71(b)(516.75), is hereby removed from the list of dangerous drugs of the Georgia Dangerous Drugs Act.

(2) This rule is based on the following findings of the Board:

(a) that levocetirizine dihydrochloride does not have a high potential for abuse;

(b) that the Board has considered the scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; the potential of the drug to produce psychic or physiological dependence liability; and

(c) that the drug, when in 5 mg tablets or an oral solution of 2.5 mg per 5 mL (.05 mg per mL), has been approved for non-prescription status by the Federal Food and Drug Administration.

Authority: O.C.G.A. §§16-13-71, 26-4-27