



Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., MPH
State Surgeon General

August 11, 2009

Dear Prescription Department Manager:

CORRECTION TO NOTICE OF APRIL 15, 2008.

Re: LEVOTHYROXINE SODIUM

Due to recent First DCA opinion, in Abbott v. Mylan, (Fla 1st DCA Case No.: 1D08-0602, June 22, 2009), the drug levothyroxine sodium is included on the Florida Negative Drug Formulary Rule 64B16-27.500, *Florida Administrative Code*, pursuant to Section 465.025(6)(b), *Florida Statutes*.

Effective immediately, substitution by a dispensing pharmacist on a new prescription written for any brand name equivalent of levothyroxine sodium is strictly prohibited.

If you have any questions or comments concerning this notice, please visit the Florida Board of Pharmacy web site at www.doh.state.fl.us/mqa/pharmacy, or you may contact the Board by telephone at (850) 245-4292 or by e-mail at MQA_Pharmacy@doh.state.fl.us.

Sincerely,

A handwritten signature in cursive script that reads "Rebecca R. Poston".

Rebecca R. Poston, BPharm
Executive Director
Board of Pharmacy



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64B16-27.500 Negative Drug Formulary.

The negative drug formulary is composed of medicinal drugs which have been specifically determined by the Board of Pharmacy and the Board of Medicine to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, could produce adverse clinical effects, or could otherwise pose a threat to the health and safety of patients receiving such prescription medications. Except where certain dosage forms are included on the negative drug formulary as a class, all medicinal drugs are listed by their official United States Pharmacopoeia Non-Proprietary (generic) name. The generic name of a drug shall be applicable to and include all brand-name equivalents of such drug for which a prescriber may write a prescription. Substitution by a dispensing pharmacist on a prescription written for any brand name equivalent of a generic named drug product listed on the negative formulary or for a drug within the class of certain dosage forms as listed, is strictly prohibited. In cases where the prescription is written for a drug listed on the negative drug formulary but a brand name equivalent is not specified by the prescriber, the drug dispensed must be one obtained from a manufacturer or distributor holding an approved new drug application or abbreviated new drug application issued by the Food and Drug Administration, United States Department of Health and Welfare permitting that manufacturer or distributor to market those medicinal drugs or when the former is non-applicable, those manufacturers or distributors supplying such medicinal drugs must show compliance with other applicable Federal Food and Drug Administration marketing requirements. The following are included on the negative drug formulary:

- (1) Digitoxin.
- (2) Conjugated Estrogen.
- (3) Dicumarol.
- (4) Chlorpromazine (Solid Oral Dosage Forms).
- (5) Theophylline (Controlled Release).
- (6) Levothyroxine Sodium.
- (7) Pancrelipase (Oral Dosage Forms).

Specific Authority 465.005, 465.025(6) FS., Ch. 2001-146, Laws of Florida. Law Implemented 465.025(6) FS., Ch. 2001-146, Laws of Florida. History—New 12-14-76, Amended 3-17-77, 7-2-79, 4-9-81, 9-14-82, 9-26-84, Formerly 21S-5.01, Amended 3-30-89, 7-1-90, Formerly 21S-5.001, Amended 12-25-90, 10-1-92, Formerly 21S-27.500, Amended 2-21-94, Formerly 61F10-27.500, 59X-27.500, Amended 12-4-01.