STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

MYLAN PHARMACEUTICALS, INC.,	)	
	)	
Petitioner,	)	
	)	
vs.	)	Case No. 07-3704RX
	)	
DEPARTMENT OF HEALTH, BOARD OF PHARMACY AND BOARD OF MEDICINE,	)	
	)	
Respondents,	)	
	)	
and	)	
	)	
ABBOTT LABORATORIES,	)	
	)	
Intervenor.	)	
	)	

SUMMARY FINAL ORDER

Pursuant to notice, an oral argument was held in this case on December 11, 2007, in Tallahassee, Florida, before Susan B. Harrell, a designated Administrative Law Judge of the Division of Administrative Hearings.

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STATEMENT OF THE ISSUE

The issue in this case is whether Florida Administrative Code Rule 64B16-27.500(6) regarding the negative drug formulary is an invalid exercise of delegated legislative authority within the meaning of Subsection 120.52(8), Florida Statutes (2007).[1]

PRELIMINARY STATEMENT

On August 17, 2007, Petitioner, Mylan Pharmaceuticals, Inc. (Mylan), filed a Petition Seeking an Administrative Determination of the Invalidity of an Existing Rule, challenging the validity of Florida Administrative Code Rule 64B16-27.500(6) relating to the inclusion of Levothyroxine Sodium on the

negative drug formulary. On August 24, 2007, Intervenor, Abbott Laboratories (Abbott), filed a Petition to Intervene, which was granted by Order dated August 29, 2007. The final hearing was originally scheduled for September 17, 2007. The parties stated that they intended to file motions for final summary judgment, and the final hearing was continued and rescheduled for December 10 and 11, 2007. On November 5, 2007, Mylan and Abbott filed motions for summary final judgment. On November 9, 2007, Respondent, Board of Medicine, filed a Notice of Joining with Intervenor in its Motion for Final Summary Judgment. On November 19, 2007, the final hearing was continued and rescheduled for January 3 and 4, 2008. On November 27, 2007, Mylan and Abbott filed responses to each other's motions for final summary judgment, and the Board of Medicine joined in Abbott's response.

On December 11, 2007, the parties presented oral argument on the motions for final summary judgment. The final hearing scheduled to commence on January 3, 2008, was cancelled pending a ruling on the motions for final summary judgment.

FINDINGS OF FACT

1. Levothyroxine Sodium is a drug used to treat Hypothyroidism and Pituitary TSH Suppression.

2. Mylan develops, manufactures, and sells generic pharmaceuticals and is licensed as a non-resident prescription

drug manufacturer and an out-of-state prescription drug wholesaler in Florida pursuant to Section 499.01, Florida Statutes. Mylan has received approval from the United States Food and Drug Administration (FDA) to market 12 strengths of generic Levothyroxine Sodium tablets, which the FDA has determined to be bioequivalent and therefore therapeutically equivalent to corresponding strengths of four reference listed drugs[2]: Unithorid® tablets, Synthroid® tablets, Levoxyl® tablets, and Levothroid® tablets.

3. Abbott is the manufacturer of Synthroid®, a Levothyroxine Sodium product marketed in Florida and other places.

4. The Board of Pharmacy "has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of [Chapter 465] conferring duties upon it." § 465.005, Fla. Stat. Subsection 465.025(6), Florida Statutes, provides:

> The Board of Pharmacy and the Board of Medicine shall establish by rule a formulary or generic drug type and brand name drug products which are determined by the boards to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication.

5. Subsection 465.025(1)(a), Florida Statutes, defines "brand name" as "the registered trademark name given to a drug

product by its manufacturer, labeler, or distributor."

"Generically equivalent drug product" is defined in Subsection 465.025(1)(b), Florida Statutes, as "a drug product with the same active ingredient, finished dosage form, and strength."

6. Subsection 465.025(2), Florida Statutes, provides:

> (2) A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product that is:
>
> (a) Distributed by a business entity doing business, and subject to suit and service of legal process, in the United States; and
>
> (b) Listed in the formulary of generic and brand name products as provided in subsection (5) for the brand name drug prescribed unless the prescriber writes the words "MEDICALLY NECESSARY," in her or his own handwriting, on the face of a written prescription; unless, in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary; or unless, in the case of a prescription that is electronically generated and transmitted, the prescriber makes an overt act when transmitting the prescription to indicate that the brand name drug prescribed is medically necessary. When done in conjunction with the electronic transmission of the prescription, the prescriber's overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.

7. Subsection 465.025(5), Florida Statutes, provides:

> Each community pharmacy shall establish a formulary of generic and brand name drug products which, if selected as the drug

> product of choice, would not pose a threat to the health and safety of patients receiving prescription medication. In compiling the list of generic and brand name drug products for inclusion in the formulary, the pharmacist shall rely on drug product research, testing, information, and formularies compiled by other pharmacies, by states, by the United States Department of Health, Education, and Welfare, by the United States Department of Health and Human Services, or by any other source which the pharmacist deems reliable. Each community pharmacy shall make such formulary available to the public, the Board of Pharmacy, or any physician requesting same. The formulary shall be revised following each addition, deletion, or modification of said formulary.

8. If a brand name drug or a generic drug type drug product is listed on the negative drug formulary established by the Board of Pharmacy and Board of Medicine, a pharmacist is prohibited from substituting a generically equivalent drug product for a prescribed brand name drug product. § 465.025(6)(b), Fla. Stat. The Board of Pharmacy has adopted a negative drug formulary which is contained in Florida Administrative Code Rule 64B16-27.500, and Levothyroxine Sodium is listed on the negative drug formulary. Thus, Mylan's generic products currently cannot be substituted where a prescription is written for a brand name Levothyroxine Sodium product.

9. Mylan has challenged Florida Administrative Code Rule 64B16-27.500(6), which provides:

> 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 drug 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 name brand 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 not 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:

* * *

(6) Levothyroxine Sodium.

10. Subsection 465.0251(1), Florida Statutes, provides:

> The Board of Pharmacy and the Board of Medicine shall remove any generic named drug product from the formulary established by s. 465.025(6), if every commercially marketed equivalent of that drug is "A" rated as therapeutically equivalent to a reference listed drug or is a reference listed drug as referred to in "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) published by the United States Food and Drug Administration.

11. The Orange Book identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. It also includes therapeutic equivalence evaluations for approved multisource prescription drug products. The Orange Book is updated annually and is supplemented with monthly cumulative updates. Additionally, the FDA has a website containing an electronic version of the Orange Book, which is also updated. The Orange Book used in 2007 is the 27th Edition. The Orange Book in effect at the date of the enactment of Section 465.0251, Florida Statutes,[3] was the 21st Edition.

12. Generally, approval by the FDA is required before a prescription drug product may be marketed, distributed, or sold in the United States. See 21 U.S.C. § 355(a). When a product contains a new active ingredient or otherwise differs significantly from previously approved products, the sponsor must provide the FDA with data demonstrating the product's

safety and effectiveness for the intended use. See, e.g., 21 U.S.C. § 355(b). When a product is a copy of a previously approved product—-what is commonly called a "generic" version of the original drug—-proof of safety and effectiveness is not required. Instead, the FDA requires a showing that, with regard to certain characteristics, the proposed generic product is essentially the same as the approved product it purports to copy, which is called the "reference listed drug." See 21 U.S.C. § 355(j). The FDA's previous finding that the reference listed drug is safe and effective is then imputed to the generic product.

13. In general, the generic product must contain the same active ingredient in the same strength, and it must be in the same dosage form (e.g., tablet, capsule, solution) as the reference listed drug. See 21 U.S.C. § 355(j). Products that share these characteristics are considered "pharmaceutical equivalents" by the FDA. Orange Book, 27th Ed., at v-vi (Jan. 2007). Subsection 465.025(1)(b), Florida Statutes, uses the term "generically equivalent drug products" to describe such products. "Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling." Orange Book, 27th Ed. at vi.

14. The FDA classifies as therapeutically equivalent those products that meet the following criteria:

> (1) they are approved as safe and effective;
>
> (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the same active drug ingredient in the same dosage form and same route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; (5) they are manufactured in compliance with Current Good Practice Manufacturing Practice regulations.

Id. These criteria are essentially the same criteria that existed in 2001 as shown in the final staff analysis of HB69, which was passed and became Chapter 2001-146, Laws of Florida, now codified as Section 465.0251, Florida Statutes.

15. Drug products that have been relied on as reference listed drugs are so identified in the Orange Book, and products that are therapeutically equivalent to each other are identified by a shared therapeutic equivalence evaluation code (TE code). These are primarily, but not exclusively, reference listed drugs and the generic drugs approved on the grounds of pharmaceutical equivalence and bioequivalence to those reference listed drugs.

16. Generally, the FDA uses a two-letter TE code, with a code of "AB" given to solid oral dosage form products that have demonstrated therapeutic equivalence. Orange Book, 27th Ed. at xii-xiii. For the vast majority of most multi-source drugs, there is one product that is the reference listed drug and one or more generic versions of that product, and all the products share a TE code of AB. However, there are situations in which there is more than one reference listed drug. These situations are discussed in the Orange Book, 27th Ed. at xiv.

> In certain instance, a number is added to the end of the AB code to make a three character code (i.e., AB1, AB2, AB3, etc.). Three-character codes are assigned only in situations when more than one reference listed drug of the same strength has been designated under the same heading. Two or more reference listed drugs are generally selected only when there are at least two potential reference drug products which are not bioequivalent to each other. If a study is submitted that demonstrates bioequivalence to a specific listed drug product, the generic product will be given the same three-character code as the reference listed drug it was compared against. . . . Drugs coded as AB under a heading are considered therapeutically equivalent only to other drugs coded as AB under that heading. Drugs coded with a three-character code under a heading are considered therapeutically equivalent only to other drugs coded with the same three-character code under that heading.

The FDA first officially described the three-character code rating system in the 16th edition of the Orange Book in 1996.

17. Levothyroxine Sodium tablets are a drug product for which there are multiple reference listed drugs. Currently the Orange Book identifies seven Levothyroxine Sodium products approved for sale in the United States: Synthroid®, Levo-T®, Levoxyl®, Levothroid®, Unithroid®, a generic-named product manufactured by Genpharm, and a generic manufactured by Mylan. The current Orange Book also contains the following levothyroxine sodium products in a section identifying "Discontinued" products that, although approved for distribution in the United States, are not being marketed: Novothyrox, Levolet, and Tirosint. The following drug products are currently identified in the Orange Book as reference listed drugs: Synthroid®, Levo-T®, Levoxyl®, Levothroid®, and Unithroid®.

18. In the case of Levothyroxine Sodium products, not all the reference listed drugs are considered therapeutically equivalent to one another. The Orange Book discusses this situation and explains the therapeutic evaluations for Levothyroxine Sodium products as follows:

> Because there are multiple reference listed drugs of levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character TE codes may be potentially confusing and inadequate for these drug

products. Accordingly, FDA provides the following explanation and chart of therapeutic equivalence evaluations for levothyroxine sodium products.

Levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets.

Levo-T (Alara NDA 021342), Levothyroxine Sodium (Mylan ANDA 76187), Unithroid (Jerome Stevens NDA 021210) and Levothyroxine Sodium (Genpharm ANDA 76752) tablets have been determined to be therapeutically equivalent to corresponding strengths of Synthroid (Abbott NDA 021402) tablets.

Levo-T (Alara NDA 021342), Unithroid (Jerome Stevens NDA 021210), Levothyroxine Sodium (Mylan ANDA 076187) and Levothyroxine Sodium (Genpharm ANDA 76752) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King/Jones Pharma NDA 021301) tablets.

Levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levothroid (Lloyd NDA 021116) tablets.

Novothyrox (Genpharm NDA 021292) requires further investigation and review to establish therapeutic equivalence to corresponding strengths of any other Levothyroxine Sodium drug products and is rated BX.

Levolet (Vintage NDA 021137) requires further investigation and review to establish therapeutic equivalence to corresponding strengths of any other Levothyroxine Sodium drug products and is rated BX.

The chart outlines TE codes for all 0.025mg products with other products being similar. Therapeutic equivalence has been established between products that have the same AB+number TE code. More than one TE code may apply to some products. One common TE code indicates therapeutic equivalence between products.

Trade Name	Applicant	Potency	TE CODE	Appl No	Product No
UNITHROID	STEVENS J	0.025mg	AB1	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025mg	AB1	76187	001
LEVOXYL	JONES PHARMA	0.025mg	AB1	21301	001
SYNTHROID	ABBOTT	0.025mg	AB1	21402	001
SYNTHROID	ABBOTT	0.025mg	AB2	21402	001
LEVOTHYROXINE SODIUM	MYLAN	0.025mg	AB2	76187	001
LEVO-T	ALARA PHARM	0.025mg	AB2	21342	001
UNITHROID	STEVENS J	0.025mg	AB2	21210	001
LEVOTHYROXINE SODIUM	GENPHARM	0.025mg	AB2	76752	001
LEVOXYL	JONES PHARMA	0.025mg	AB3	21301	001
LEVO-T	ALARA PHARM	0.025mg	AB3	21342	001
UNITHROID	STEVENS J	0.025mg	AB3	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025mg	AB3	76187	001
LEVOTHYROXINE SODIUM	GENPHARM	0.025mg	AB3	76752	001
LEVOTHROID	LLOYD	0.025mg	AB4	21116	001
LEVOTHYROXINE SODIUM	MYLAN	0.025mg	AB4	76187	001
NOVOTHYROX	GENPHARM	0.025mg	BX	21292	001
LEVOLET	VINTAGE PHARMS	0.025mg	BX	21137	001

Orange Book, 27th Ed. at xix-xx.

19. In the Orange Book, 21st Ed. (Cumulative Supplement 6, June 2001), only two Levothyroxine Sodium tablet products were listed, Levoxyl® and Unithroid®, and both were rated as BX, meaning that the data that had been reviewed by FDA was insufficient to determine therapeutic equivalence. There were also 12 additional Levothryroxine Sodium products that were

being commercially marketed in the United States and were not listed in the Orange Book.

CONCLUSIONS OF LAW

20. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of this proceeding. §§ 120.56(1) and (3), Fla. Stat.

21. Subsection 120.56(1)(a), Florida Statutes, provides that "any person substantially affected by a rule . . . may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority." Subsection 120.52(8), Florida Statutes, defines "invalid exercise of delegated legislative authority" as follows:

> "Invalid exercise of delegated legislative authority" means action which goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:
>
> (a) The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in this chapter;
>
> (b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1.;
>
> (c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;

> (d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;
>
> (e) The rule is arbitrary or capricious. A rule is arbitrary if not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational; or
>
> (f) The rule imposes regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.
>
> A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers or duties conferred by the same statute.

22. As the petitioner, Mylan has the "burden of proving by a preponderance of the evidence that the existing rule is an invalid exercise of delegated legislative authority as to the objections raised." § 120.56(3)(a), Fla. Stat.

23. Mylan argues that the inclusion of Levothyroxine Sodium in the negative drug formulary of Florida Administrative Code Rule 64B16-27.500 contravenes Subsection 465.0251(1), Florida Statutes, which requires that a drug be removed from the negative drug formulary "if every commercially marketed equivalent of that drug product is 'A' rated as therapeutically equivalent to a reference listed drug or is a reference listed drug as referred to in" the Orange Book.

24. For Levothyroxine Sodium, the 27th edition of the Orange Book lists five reference listed drug products and two generic drugs which are commercially marketed. They are all "A" rated. One of the generic drug products is therapeutically equivalent to some but not all the reference listed drug products, and one of the generic drug products is therapeutically equivalent to all the reference listed drug products. Thus, the commercially marketed generic drug products for Levothyroxine Sodium are therapeutically equivalent to at least one of the reference listed drug products. Not all the reference listed products are therapeutically equivalent to all the other reference listed products.

25. Abbott and the Board of Medicine argue that Subsection 425.0251(1), Florida Statutes, requires that all commercially marketed generic drug products for Levothyroxine Sodium and apparently all commercially marketed reference listed drug

products for Levothyroxine Sodium be therapeutically equivalent to one another.

26. Subsection 425.0251(1), Florida Statutes, is clear and unambiguous. As the Florida Supreme Court stated in A. R. Douglass, Inc. v. McRainey, 102 Fla. 1141, 1144, 137 So. 157, 159 (Fla. 1931):

> The intention and meaning of the Legislature must primarily be determined from the language of the statute itself and not from conjectures aliunde. When the language of the statute is clear and unambiguous and conveys a clear and definite meaning, there is no occasion for resorting to the rules of statutory interpretation and construction; the statute must be given its plain and obvious meaning.

27. The plain and obvious meaning of Subsection 465.0251(1), Florida Statutes, is that a generic named drug product is to be removed from the negative drug formulary if the generic equivalent is "A" rated as therapeutically equivalent to a reference listed drug as referred to in the Orange Book. The statute does not state that all generic drug products must be "A" rated as therapeutically equivalent to all the reference listed drugs in the Orange Book listed for a specific generic named drug product. It just requires that every commercially marketed generic drug be "A" rated as therapeutically equivalent to a reference listed drug in the Orange Book. "A" is singular, meaning one.

28. At the time that Section 465.0251, Florida Statutes, was enacted, the FDA had been listing more than one referenced drug product in certain situations and had been utilizing the three-character TE codes. Obviously since the Legislature referenced the Orange Book in the statute, the Legislature was aware that the Orange Book used multiple reference listed drug products at times and had adopted a three-character rating code for those situations. The Legislature is presumed to know that "a" means one. In Ward v. State, 936 So. 2d 1143, 1146 (Fla. 3rd DCA 2006), the court stated:

> We presume the legislature understands the meaning of the language it uses and the implications of its placement in a statute. See, e.g., Rinker Materials Corp. v. City of N. Miami, 286 So. 2d 552, 553 (Fla. 1972)("In statutory construction, statutes must be given their plain and obvious meaning and it must be assumed that the legislative body knew the plain and ordinary meanings of the words."); State ex rel. Bie v. Swope, 159 Fla. 18, 24 So. 2d 748, 751 (1947) ("[t]he legislator is presumed to know the meaning of words and the rules of grammar . . .").

If the Legislature had intended to mean that all generic drugs must be therapeutically equivalent to all reference listed drugs for a specific drug, it could have worded the statute to say so. It did not.

29. Abbott and the Board of Medicine argue that if Levothyroxine Sodium is removed from the negative drug formulary

that patients will be endangered because pharmacists will substitute a generic drug which is not therapeutically equivalent to the brand name drug prescribed and therefore is harmful to the patient. The Legislature has addressed this issue in Subsection 465.025(5), Florida Statutes, by requiring "[e]ach community pharmacy [to] establish a formulary of generic and brand name drug products, which if selected as the drug product of choice, would not pose a threat to the health and safety of patients receiving prescribed medication." The Legislature has left it to the professional judgment of licensed pharmacists to determine what substitutions would not pose a threat to the health and safety of the patients. The Legislature has required the pharmacy in compiling the formulary to "rely on drug product research, testing, information, and formularies compiled by other pharmacies, by states, by the United States Department of Health, Education, and Welfare, and by the United States Department of Health and Human Services, or by any other source which the pharmacist deems reliable." The Orange Book is a publication of the United States Department of Health and Human Services and has listed the therapeutic equivalents for the drug products listed under the hearing of Levothyroxine Sodium. Although, a pharmacy is not required by law to follow the Orange Book, it is to consider the Orange Book in developing the formulary.

30. Abbott and the Board of Medicine have also argued that by deleting Levothyroxine Sodium from the negative drug formulary that a pharmacist could substitute a reference listed drug product that is not therapeutically equivalent to another reference listed drug product. Again, the Legislature left the decision of what drugs could safely be substituted to the pharmacists by requiring the pharmacies to develop the formulary set forth in Subsection 465.025(5), Florida Statutes.

31. It should be noted that Subsection 465.0251(1), Florida Statutes, does not require that all reference listed drug products be therapeutically equivalent to one another. The statute provides that if every commercially marketed equivalent of a generic named drug product is a reference listed drug as referred to in the Orange Book that the drug product should be removed from the negative drug formulary. Thus, in the case where there are multiple reference listed drugs for one drug product listed in the Orange Book and they are the only commercially marketed products for that particular drug, the drug should not be listed on the negative drug formulary.

32. Abbott and the Board of Medicine argue that the current version of the Orange Book should not be used to determine whether a drug should be removed from the negative drug formulary, contending that the 21st Edition of the Orange Book in effect at the time of the enactment of Section 465.0251,

Florida Statutes, is to be utilized. They cite Florida Industrial Commission v. State, 21 So. 2d 599 (Fla. 1945), for the general rule that the Legislature may adopt rules and laws of federal bodies and other states that are in existence and in effect at the time the Legislature adopts the rules and laws. See also Freimuth v. State, 272 So. 2d 473 (Fla. 1972). In Freimuth, the court held that a Florida statute defining "hallucinogenic drug" by reference to federal law did not include those drugs listed in the federal law after the enactment of the Florida statute. Id. at 476.

33. Mylan contends that the 27th edition of the Orange Book should be used, citing Eastern Air Lines v. Department of Revenue, 455 So. 2d 311 (Fla. 1984). In Eastern Air Lines, Eastern Air Lines sought a declaratory judgment that a fuel tax calculated by reference to the Federal Consumer Price Index (CPI) then in effect was unconstitutional. Eastern Air Lines contended that the use of the varying price component of the CPI issued by the United States Department of Labor in determining the amount of the fuel tax was an improper delegation of legislative authority because the CPI which was being used was not in existence at the time the statute requiring its use was enacted.

34. The Court in Eastern Air Lines held that the statute's reference to the CPI and basing tax adjustments on a changing

numerical figure did not amount to an unconstitutional delegation of legislative power. Id. at 316. The Court stated:

> Here, the legislature is merely setting forth the manner in which the department is to determine the appropriate total motor fuel and special fuel retail price. The department is directed with precision how to make such a determination. We think the language of Welch[4] and Freimuth should be interpreted to apply to statutes which incorporate federal statutes or administrative rules which substantively change the law, and not to a statute which incorporates a federal index to provide aid in making ministerial decisions.

35. In Section 465.0251, Florida Statutes, the Legislature has set out specific standards, which when met require the removal of a drug product from the negative drug formulary. It is akin to the use of the CPI in Eastern Air Lines. The standards which the FDA used in 2001 to determine whether a drug product is therapeutically equivalent are essentially the same standards used in 2007. The final staff analysis of HB 169 listed those criteria, and they are listed in the current version of the Orange Book. Naturally, as new drugs are sought to be approved, the list of reference listed, "A" rated, and therapeutically equivalent drug products will vary, like the CPI will vary. When drug products meet the criteria listed in Section 465.0251, Florida Statutes, the removal becomes a ministerial duty.

36. Mylan has demonstrated that Levothyroxine Sodium does meet the criteria listed in Subsection 465.0251(1), Florida Statutes, and should be removed from the negative drug formulary contained in Florida Administrative Code Rule 64B16-27.500. Because Florida Administrative Code Rule 64B16-27.500(6) lists Levothyroxine Sodium on the negative drug formulary, the Rule contravenes Subsection 456.0251(1), Florida Statutes, and is an invalid exercise of legislative delegated authority.

ORDER

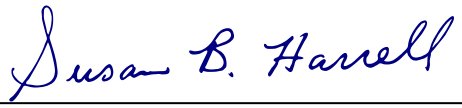
Based on the foregoing Findings of Fact and Conclusions of Law, it is ORDERED

1. Mylan's Motion for Summary Final Order is GRANTED.

2. Abbott's Motion for Summary Final Order is DENIED.

3. Florida Administrative Code Rule 64B16-27.500(6) is an invalid exercise of legislative delegated authority.

DONE AND ORDERED this 28th day of January, 2008, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
Division of Administrative Hearings
this 28th day of January, 2008.

ENDNOTES

[1/] Unless otherwise indicated, references to the Florida Statutes are to the 2007 version.

[2/] The FDA defines a reference listed drug (RLD) as "an approved drug product to which new generic versions are compared to show that they are bioequivalent."

[3/] Section 465.0251, Florida Statutes, became law effective June 1, 2001.

[4/] State v. Welch, 279 So. 2d 11 (Fla. 1973).

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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a Notice of Appeal with the agency clerk of the Division of Administrative Hearings and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the appellate district where the party resides. The Notice of Appeal must be filed within 30 days of rendition of the order to be reviewed.