

Levothyroxine and FDA bioequivalence ratings

TO THE EDITOR:

A Clinical Inquiry published in the November issue of the journal ("How should thyroid replacement be initiated?," *J Fam Pract* 2004; 53:925) discussed initiation of thyroid hormone replacement therapy. The authors and commentator do not specifically state that levothyroxine sodium preparations "usually are administered orally on an empty stomach, preferably one-half to one hour before breakfast or the first food of the day."¹

Additionally, there is information about the Food and Drug Administration's (FDA) bioequivalence ratings that became available after the authors had submitted. The October 2004 Supplement to the FDA "Orange Book" now lists generic equivalents to each brand-name levothyroxine product.²

FDA provides the following explanation and chart of therapeutic equivalence evaluations for levothyroxine sodium drug products:

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

"Levo-T (Alara) and Levothyroxine Sodium (Mylan) tablets have been determined to be therapeutically equivalent to corresponding strengths of Synthroid (Abbott) tablets.

"Levo-T (Alara), Unithroid (Jerome Stevens) and Levothyroxine Sodium (Mylan) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King/Jones Pharma) tablets."

Novothyrox (Genpharm), Thyro-Tabs (Lloyd), and Levolet (Vintage) are listed as requiring further investigation to establish therapeutic equivalence to other levothyroxine products.

Except for these latter 3, if one believes that

TABLE

FDA-rated equivalences for the 3 brand name products

Trade Name	Manufacturer
Unithroid equivalents	Jerome Stevens
Levothyroxine sodium	Mylan
Levoxyl	King/Jones
Synthroid equivalents	Abbott
Levothyroxine sodium	Mylan
Levo-T	Alara
Levoxyl equivalents	King/Jones
Levo-T	Alara
Unithroid	Jerome Stevens
Levothyroxine sodium	Mylan
No equivalents established	
Novothyrox	Genpharm
Thyro-Tabs	Lloyd
Levolet	Vintage

Adapted from:
www.fda.gov/cder/orange/supplement/cspreface.htm#1.

equivalents of equivalents are equivalent, as illustrated in the **Table**, all the major levothyroxine preparations appear equivalent.

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REFERENCES

1. AHFS Drug Information. Levothyroxine Sodium. (68:36.04 Thyroid Agents.) *AHFS Drug Information* (2004). Via Stat!Ref online. Available at: <http://online.statref.com/>. Accessed on November 23, 2004.
2. Food and Drug Administration, Center for Drug Evaluation and Research. *Approved Drug Products with Therapeutic Equivalence Evaluations*. 24th ed. Cumulative Supplement 10. Prepared By Office of Pharmaceutical Science, Office of Generic Drugs, Center for Drug Evaluation and Research, FDA. October 2004. Available at: www.fda.gov/cder/orange/supplement/cspreface.htm#1.4. Accessed on November 23, 2004.