

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1149]

DMB

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Certifier	J. M. W. S. M.

Guidance for Industry on Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing.” This guidance is intended to assist sponsors of new drug applications (NDA’s) for levothyroxine sodium tablets who wish to conduct in vivo pharmacokinetic and bioavailability studies and in vitro dissolution testing for their products.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mei-Ling Chen, Center for Drug Evaluation and Research (HFD-350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5688.

SUPPLEMENTARY INFORMATION:

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I. Background

FDA is announcing the availability of a guidance for industry entitled “Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing.” This guidance contains agency recommendations on how to design in vivo pharmacokinetics and bioavailability studies and perform in vitro dissolution testing for levothyroxine sodium tablets, which were identified as new drugs in a notice published in the **Federal Register** of August 14, 1997 (62 FR 43535).

FDA announced the availability of a draft version of this guidance in the **Federal Register** of June 10, 1999 (64 FR 31280). The June 1999 draft document gave interested persons 60 days to submit comments. FDA carefully considered the comments it received and has made appropriate revisions. A separate section on biowaiver has been added to clarify information that appeared elsewhere in the draft guidance. The guidance also specifies that plasma/serum profiles and pharmacokinetic measures should be presented without adjustment of baseline levels.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency’s current thinking on in vivo pharmacokinetic and bioavailability studies and in vitro dissolution testing for levothyroxine sodium tablets. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

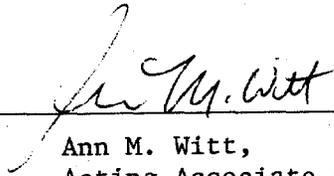
II. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

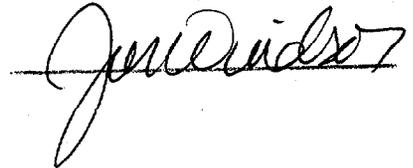
Persons with access to the Internet may obtain this guidance at <http://www.fda.gov/cder/guidance/index.htm>.

Dated: March 1, 2001
March 1, 2001.



Ann M. Witt,
Acting Associate Commissioner for Policy.

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COPY OF THE ORIGINAL



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