Division of Federal Systems (KFB11)

Division of State and Tribal Systems (KFB12)

Division of Management Services (KFB2)

Division of Consumer Services (KFB3)

Division of Planning, Research, and Evaluation (KFB4)

Division of Policy (KFB5)

Division of Special Staffs (KFB6)

Division of State, Tribal and Local Assistance (KFB7)

Description of Division/Office Changes

In addition, we are making a technical correction by removing the last word of the first paragraph on page 8119, ''Tries'' and replacing it with ''Tribes.''

Also, on page 8119 we are removing in its entirety paragraph KFB6. Division of State, Tribal, and Local Assistance and replacing it with the following:

KFB6. Division of State, Tribal and Local Assistance, in concert with regional offices, provides information and assistance on CSE operations. It provides national direction and leadership for training and technical assistance activities and regional operations to increase CSE program effectiveness both at Federal and State/tribal levels; develops guides and resource materials and serves as a clearinghouse for specialized program techniques for use by ACF regional offices and States and tribes. The Division, through its Technical Assistance Branch, ensures the transfer of best practices among States/tribes and local CSE agencies and coordinates technical assistance nationally. The Division operates a national CSE training center which includes the operation of the National Electronic Resource System; provides logistical support for both training events and meetings; and monitors contracts with organizations affiliated with child support enforcement programs in the areas of training and technical assistance. The Division, through the Special Initiatives Branch, provides outreach and liaison services to a variety of special interest populations.

Dated: March 2, 2001.

Diann Dawson,

Acting Principal Deputy Assistant Secretary, Administration for Children and Families.

[FR Doc. 01–5758 Filed 3–7–01; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2636]

Guidance for Industry on Levothyroxine Sodium; Questions and Answers; 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: Questions and Answers.'' The guidance is intended to answer questions concerning applications for orally administered levothyroxine sodium drug 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: Christine F. Rogers, Center for Drug Evaluation and Research (HFD 7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 594 2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Levothyroxine Sodium: Questions and Answers.'' In the **Federal Register** of August 18, 1999 (64 FR 44935), FDA announced the availability of a draft version of this guidance. The August 18, 1999, document gave interested persons 60 days to submit comments. FDA has revised the guidance in response to comments. Among the revisions being made is that FDA has extended the deadline for levothyroxine sodium drug products to have approved applications from August 14, 2000, to August 14, 2001. This extension was announced in the **Federal Register** on April 26, 2000 (65 FR 24488).

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 issues concerning applications, including applications under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)), for levothyroxine sodium. 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 the document at http://www.fda.gov/cder/guidance/index.htm.

Dated: March 1, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–5609 Filed 3–7–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1149]

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:

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.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–5610 Filed 3–7–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0331]

Medical Devices; Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revision to the guidance document entitled ''Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997.'' The revised guidance supersedes the October 30, 1998, guidance. FDA has amended the October 30, 1998, guidance to include criteria for the review of additional moderate risk (class II) devices by accredited persons under the Federal Food, Drug, and Cosmetic Act (the act). The revised guidance will assist those who are interested in participating in the expanded program, which is now in effect.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance entitled ''Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597.

SUPPLEMENTARY INFORMATION:

I. Background

On August 1, 1996, FDA began a voluntary Third Party Review Pilot Program for selected medical device premarket notifications (''510(k)'s''). The purpose of the pilot program was to: (1) Provide manufacturers of eligible devices an alternative 510(k) review process that could yield more rapid marketing clearance decisions; and (2) enable FDA to target its scientific review resources at higher risk devices, while maintaining confidence in the review by third parties of low-to-moderate risk devices. Under the program, all class I devices that were not exempt from 510(k) at that time and 30 class II devices were eligible for third party review.

The Food and Drug Administration Modernization Act of 1997 (FDAMA) was signed into law by former President Clinton on November 21, 1997. Section 210 of FDAMA essentially codified and expanded the Third Party Review Pilot Program by establishing section 523 of the act (21 U.S.C. 360m). Section 523 of the act directs FDA to accredit third