## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 00P–1548]**

### Determination That Cyclosporine Capsules USP, 50 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that cyclosporine capsules USP (Neoral Soft Gelatin Capsules), 50 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for cyclosporine capsules USP, 50 mg.

**FOR FURTHER INFORMATION CONTACT:** Paul C. Varki, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Cyclosporine capsules USP, 50 mg, are the subject of NDA 50–715. On July 14, 1995, Sandoz, Inc. (now Novartis), obtained approval to market the 25-, 50-, and 100-mg capsules. Novartis has never marketed the 50-mg capsules.

On September 29, 2000, Lachman Consultant Services, Inc., submitted a citizen petition (Docket No. 00P–1548/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether cyclosporine capsules USP, 50 mg, were withdrawn from sale for reasons of safety or effectiveness. FDA has determined that, for purposes of § 314.161(a) and (c), never marketing an approved drug product is equivalent to withdrawing the drug from sale.

FDA has reviewed its records and, under § 314.161, has determined that Novartis' decision not to market cyclosporine capsules USP, 50 mg, was not due to concerns about safety or effectiveness of the product. Accordingly, the agency will maintain cyclosporine capsules USP, 50 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to cyclosporine capsules USP, 50 mg, may be approved by the agency.

Dated: July 6, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01–17496 Filed 7–12–01; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### National Mammography Quality Assurance Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: National Mammography Quality Assurance Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on August 22, 2001, from 9 a.m. to 6 p.m.

*Location*: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact*: Charles Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: The committee will review facility inspection findings and current compliance followup actions, the Mammography Quality Standards Act (the MQSA) compliance guidance, facility satisfaction survey, mammography access issues and the future direction of the MQSA program. The committee will also receive updates on the status of accreditation and certification of full field digital mammography, States as certification agencies under the MQSA, and the inspection demonstration project. The MQSA compliance guidance documents, which are in a question and answer format, are available to the public on the Internet at http://www.fda.gov/cdrh/mammography. This guidance is being updated continually in response to questions that FDA receives from the public. Additional information regarding guidance updates may be obtained by calling the Information Line.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 27, 2001. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on August 22, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 27, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the

approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 6, 2001.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 01–17537 Filed 7–12–01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0314]**

### Guidance for Industry on Levothyroxine Sodium Products—Enforcement of August 14, 2001, Compliance Date and Submission of New Applications; 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 Products—Enforcement of August 14, 2001, Compliance Date and Submission of New Applications.'' This guidance discusses how FDA plans to exercise its enforcement discretion after August 14, 2001, with regard to levothyroxine sodium products that are marketed without approved applications. This guidance also answers certain frequently asked questions concerning the submission of applications for levothyroxine sodium products. It replaces the previously issued guidance entitled ''Levothyroxine Sodium, Questions and Answers'' (February 2001).

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

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), 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. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** David T. Read, 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 Products—Enforcement of August 14, 2001 Compliance Date and Submission of New Applications.'' This guidance discusses how FDA plans to exercise its enforcement discretion after August 14, 2001, with regard to levothyroxine sodium products that are marketed without approved applications. This guidance also answers certain frequently asked questions concerning the submission of applications for levothyroxine sodium products and replaces the previously issued guidance entitled ''Levothyroxine Sodium, Questions and Answers'' (February 2001) (see 66 FR 13935, March 8, 2001).

In the **Federal Register** of August 14, 1997 (62 FR 43535), FDA announced that orally administered levothyroxine sodium drug products are new drugs. The notice stated that by August 14, 2000, manufacturers who wish to continue to market these products must obtain approved applications as required by section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and 21 CFR part 314. The notice stated that after August 14, 2000, any orally administered drug product containing levothyroxine sodium that is introduced or delivered for introduction into interstate commerce without an approved application will be subject to regulatory action, unless found by FDA to be not subject to the new drug requirements of the act under a citizen petition submitted for that product. FDA issued a second **Federal Register** notice on April 26, 2000 (65 FR 24488), extending the deadline for obtaining approved applications until August 14, 2001.

The agency permitted orally administered levothyroxine sodium products to remain on the market during this period of time without approved new drug applications to give manufacturers time to conduct the required studies, prepare applications, and have them approved. FDA stated in the 1997 **Federal Register** notice that levothyroxine sodium products are used to treat hypothyroidism, and no alternative drug is relied on by the medical community as an adequate substitute.

As of June 2001, two orally administered levothyroxine sodium products have been approved by FDA. These approved products have been evaluated by FDA and found to be safe and effective for their intended uses. FDA has not evaluated the safety and effectiveness of unapproved marketed products, but it has determined that no currently marketed unapproved orally-administered levothyroxine sodium product is generally recognized as safe and effective (see 62 FR 43535 at 43538, August 14, 1997).

Notwithstanding the fact that there are now two approved applications for orally administered levothyroxine sodium, FDA has determined that it will take time for the millions of patients taking unapproved products to switch to approved products, and for manufacturers of approved products to scale up their production and to introduce this increased production into the distribution chain. To provide time for manufacturers of approved products to scale up their production and for patients and health care providers to make a reasonable transition from unapproved to approved products, FDA has decided to continue to exercise its enforcement discretion by establishing a gradual phase-out of unapproved products. The phase-out plan and a number of frequently asked questions are addressed in this guidance.

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 is being implemented immediately without prior public comment because there are public health reasons for the immediate implementation of the guidance document. The guidance pertains to the agency's exercise of enforcement discretion and it is being issued to facilitate planning by patients, health care providers, manufacturers, and distributors who need information about the agency's plans to transition patients from unapproved to approved levothyroxine sodium products after August 14, 2001. The guidance represents the agency's current thinking on this topic. 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 or electronic comments