

#### VI. When Do I Submit a Fee For an Application I Submitted On or After September 1, 2003, and Before April 1, 2004?

You must pay a fee for any animal drug application or supplemental animal drug application subject to a fee that you submitted on or after September 1, 2003 (21 U.S.C. 379j-12(a)(1)(A)). FDA will issue invoices to all applicants who submitted animal drug applications and supplemental animal drug applications on or after September 1, 2003, and through March 31, 2004. FDA will issue those invoices during April 2004, and payment will be due within 30 days of issuance date. FDA will include detailed payment instructions with the invoices. Please include the invoice numbers on all payments submitted in response to these invoices.

#### VII. When Do I Submit the Fee for Applications Submitted On or After April 1, 2004?

If you submit an animal drug application or supplemental animal drug application subject to fees on or after April 1, 2004, you must pay the fee for the application at or before the time the application is submitted. If you have not paid all ADUFA user fees owed, FDA will consider the application incomplete and will not accept it for review (21 U.S.C. 379j-12(e)).

#### VIII. Product, Establishment, and Sponsor Fees to be Established Soon

A separate document will be published in the **Federal Register** providing the rates and payment procedures for establishment, product, and sponsor fees. After that document has been published in the **Federal Register**, invoices will be issued for the FY 2004 establishment, product, and sponsor fees.

Dated: February 10, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0047]

#### Determination That Chlorthalidone Tablets and Seven Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the eight drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) for the drug products, and it will allow FDA to continue to approve ANDAs for the products.

**FOR FURTHER INFORMATION CONTACT:** Mary Catchings, 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. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 (the 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).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or, (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that referred to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

The holders of the applications listed in table 1 of this document have informed FDA that the drug products have been withdrawn from sale. (As requested by the applicants, FDA withdrew approval of NDA 17-503 for COMBIPRES and ANDA 60-462 for GARAMYCIN in the **Federal Register** of August 18, 2003 (68 FR 49481)).

TABLE 1

Application No.	Drug	Applicant
12-283	HYGROTON (chlorthalidone) Tablets, 25 and 50 milligrams (mg).	Aventis Pharmaceuticals, 300 Somerset Corporate Blvd., Bridgewater, NJ 08807-2854.
17-503	COMBIPRES (clonidine hydrochloride (HCl); chlorthalidone) Tablets, 0.1 mg/15 mg, 0.2 mg/15 mg and 0.3 mg/15 mg.	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877-0368.

TABLE 1—Continued

Application No.	Drug	Applicant
17-884	CHRONULAC (lactulose) Oral Solution, 10 grams/15 milliliter (mL).	Aventis Pharmaceuticals, Inc.
18-581	SODIUM NITROPRUSSIDE Injection, 50 mg/vial.	Elkins-Sinn, Inc., Two Esterbrook Lane, Cherry Hill, NJ 08003-4099.
20-058	THIOPLEX (thiotepa) Injection, 15 mg/vial.	Immunex Corp., 51 University St., Seattle, WA 98101-2936.
50-621	SUPRAX (cefixime) Tablets, 200 and 400 mg.	Lederle Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
50-622	SUPRAX (cefixime) Powder for Oral Suspension, 100 mg/5 mL.	Do.
60-462	GARAMYCIN (gentamycin sulfate) Topical Cream, 0.1 percent.	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. Approved ANDAs that refer to the NDAs and ANDA listed in this document are unaffected by the withdrawal of the products subject to those NDAs and ANDA. Additional ANDAs for the products may also be approved by the agency.

Dated: February 9, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0001]

#### Global Harmonization Task Force, Study Groups 1, 2, 3, and 4; New Proposed and Final Documents; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of several proposed and

final documents that have been prepared by Study Groups 1, 2, 3, and 4 of the Global Harmonization Task Force (GHTF). These documents are intended to provide information only and represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on these documents.

**DATES:** Submit written or electronic comments on any of the documents by May 18, 2004. After the close of the comment period, written or electronic comments may be submitted at any time to the contact persons listed in this document.

**ADDRESSES:** Submit written comments on the documents to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the docket number found in brackets in the heading of this document. If you do not have access to the Internet, submit written requests for single copies on a 3.5" diskette of the document to the Division of Small Manufacturers, International and Consumer 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 requests, or fax

your request to 301-443-8818. See the **ELECTRONIC ACCESS** section for information on electronic access to these documents.

#### FOR FURTHER INFORMATION CONTACT:

*For Study Group 1:* Ginette Michaud, GHTF, Study Group 1, Office of In Vitro Diagnostic Devices (HFZ-440), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293, ext 157;

*For Study Group 2:* Deborah Yoder, GHTF, Study Group 2, Office of Surveillance and Biometrics (HFZ-520), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-2985;

*For Study Group 3:* Kimberly Trautman, GHTF, Study Group 3, Office of Compliance (HFZ-341), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD. 20850, 301-594-4659, ext. 126;

*For Study Group 4:* M. Christine Nelson, GHTF, Study Group 4, Office of Health Industry Programs (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-6597, ext. 128.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. At this