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has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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.

[FR Doc. 04–3414 Filed 2–17–04; 8:45 am]

BILLING CODE 4160–01–S

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

time it was decided to form a GHTF to facilitate harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices in order to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation in order to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF has formed four study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by all four Study Groups (1, 2, 3, and 4).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidance that could help lead to harmonization. As a result of their efforts, this group has developed SG1/N011R17, SG1/N015R22, SG1/N029R13, SG1/N041R6 and SG1/N044R4. SG1/N011R17 (proposed document) ''Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)'' applies to all products that fall within the definition of a medical device that appears within the GHTF document entitled ''Information Document Concerning the Definition of the Term 'Medical Device' '' (SG1/N029R13, proposed document), other than those used for the in vitro examination of specimens derived from the human body. This guidance document provides guidance on Summary Technical Documentation (abbreviated to STED) for demonstrating conformity to the ''Essential Principles of Safety and Performance of Medical Devices'' (SG1/N020, final document). It describes the format for a globally harmonized STED and provides general recommendations on the content of the formatted elements.

SG1/N015R22 (proposed document) ''Principles of Medical Devices Classification'' applies to all products that fall within the definition of a medical device that appears within the GHTF document ''Information Document Concerning the Definition of the Term 'Medical Device' '' (SG1/N029R13, proposed document), other than those used for the in vitro examination of specimens derived from the human body. The purpose of this document is to assist a manufacturer to allocate its medical device to an appropriate risk class using a set of harmonized rules.

SG1/N029R13 (proposed document) ''Information Document Concerning the Definition of the Term 'Medical Device' '' applies to all products that fall within the definition of a medical device, including those used for the in vitro examination of specimens derived from the human body. It provides a summary of the common ground found in the definition of the term ''medical device'' in different jurisdictions.

SG1/N041R6 (proposed document) ''Essential Principles of Safety and Performance of Medical Devices (Including In Vitro Diagnostic Devices)'' applies to all products that fall within the definition of a medical device that appears within the GHTF document ''Information Document Concerning the Definition of the Term 'Medical Device' '' (SG1/N029R13, proposed document), including those used for the in vitro examination of specimens derived from the human body. The purpose of this document is to describe generic product performance criteria, collectively referred to as ''essential principles'' that may be used to assess the safety of a particular medical device.

SG1/N044R4 (proposed document) ''Role of Standards in the Assessment of Medical Devices (Including In Vitro Diagnostic Devices)'' applies to all products that fall within the definition of a medical device that appears within the GHTF document ''Information Document Concerning the Definition of the Term ''Medical Device'' (SG1/N029R13, proposed document), including those used for the in vitro examination of specimens derived from the human body. Its purpose is to describe the role of technical standards during the design of a medical device, as well as the role of standards in demonstrating that a device conforms to ''Essential Principles of Safety and Performance of Medical Devices'' (SG1/N020, final document).

Study Group 2 was initially tasked with the responsibility of developing guidance documents that will be used for the exchange of adverse event reports. As a result of their efforts, this group has developed SG2/N31R8 and SG2/N32R5. SG2/N31R8 (final document) ''Medical Device Postmarket Vigilance and Surveillance: Proposal for Reporting of Use Errors With Medical Devices by their Manufacturer or Authorized Representative'' provides information to manufacturers and authorized representatives on factors to consider regarding the reporting of adverse events that are associated with use error. SG2/N32R5 (final document) ''Medical Device Postmarket Vigilance and Surveillance: Universal Data Set for Manufacturer Adverse Event Reports'' identifies and defines the various data elements that a manufacturer or authorized representative should include when filing a postmarket adverse event report to the national competent authority.

Study Group 3 was initially tasked with the responsibility of developing guidance documents on quality systems. As a result of their efforts, this group has developed SG3/N99–10 and SG3/N15R6. ''Quality Systems—Process Validation Guidance,'' originally finalized in 1999, is being republished as ''GHTF/SG3/N99–10:2003 (Edition 2)'' after revisions due to the changes in ISO 13485:2003, which is utilized in some regulatory systems. The process validation guidance has been revised in sections 0 through 3.4, figure 1 and annex B. The revisions can be generalized in two categories: (1) Editorial revision of terminology to be consistent with ISO 13485:2003 (i.e., ''quality system'' to ''quality management system'' and ''design controls'' to ''design and development controls''), and (2) changes to figure 1 and the corresponding text to reflect the new process validation requirements found in clause 7.5.2 of ISO 13485:2003. This process validation guidance is intended to assist manufacturers in understanding quality management system requirements concerning process validation and has general applicability to manufacturing (including servicing and installation) processes for medical devices. The guidance provides general suggestions on ways manufacturers may prepare for and carry out process validations. This guidance does not suggest particular methods of implementation, and therefore, should not be used to assess compliance with quality management system requirements. Rather the intent is to expand on quality management system requirements with practical explanations and examples of process validation principles. Manufacturers can and should seek out/select technology-specific guidance on applying process validation to their particular situation.

SG3/N15R6 ''Risk Management as an Integral Part of the Quality Management System'' is intended to assist medical

device manufacturers with the integration of risk management concepts into their quality management system by providing practical explanations and examples. It is based on general principles of a quality management system and general principles of a risk management system and not on any particular standard or regulatory requirement. This document has general applicability to quality management systems for organizations providing medical devices. This document will discuss risks related to product safety, rather than other business risks. The integration of risk management into the quality management system is applicable to all stages of the life cycle of a medical device. This guidance does not suggest particular methods of implementation and therefore should not be used to assess or audit compliance with regulatory requirements.

Study Group 4 was initially tasked with the responsibility of developing auditing guidelines. These guidelines are intended to provide guidance on regulatory auditing of quality systems of medical device manufacturers. As a result of their efforts, this group has developed SG4/N30R6 (proposed document) entitled ''Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers—Part 2: Regulatory Auditing Strategy.'' This document is intended to be used by regulatory auditing organizations and auditors as a guide for conducting medical device quality systems audits based on the process approach to quality management of ISO 13485:2003. Additional regulatory requirements and guidance will need to be considered, depending on the regulatory authorities who will receive and use the audit report. This guidance document applies to initial audits and to surveillance audits as they are defined in ''Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers—Part I: General Requirements (SG4/N28R2)''—including the supplements—developed by GHTF Study Group 4 as a guide for auditing organizations.

These documents represent recommendations from the GHTF Study Groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions.

II. Electronic Access

Persons interested in obtaining copies of these draft documents may also do so using the Internet. Updated on a regular basis, the CDRH home page includes device safety alerts (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video-oriented conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at *http://www.fda.gov/cdrh*. Information on the GHTF may be accessed at *http://www.ghtf.org*.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding any of these documents. 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 and with the full title of these documents. The draft documents and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 4, 2004.

Lillian J. Gill,

Acting Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–3412 Filed 2–17–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0050]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Dandruff Control Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following conditions as part of FDA's ongoing review of over-the-counter (OTC) drug products: Piroctone olamine, 0.05 percent to 0.5 percent and 0.1 percent to 1.0 percent, for use as a dandruff control single active ingredient in leave-on and rinse-off dosage forms, respectively. FDA has reviewed a time and extent application (TEA) for these conditions and determined that they are eligible for consideration in its OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether these conditions can be generally recognized as safe and effective (GRAS/E) for their proposed OTC use.

DATES: Submit data, information, and general comments by May 18, 2004.

ADDRESSES: Submit written comments, data, and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term ''condition'' means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14(a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEA that the agency reviewed (Ref. 1) and FDA's evaluation of the TEA (Ref. 2) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. Information deemed confidential under 18 U.S.C. 1905, 5