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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))).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.

On August 20, 2007, AAIPharma submitted a citizen petition (Docket No. 2007P–0326/CP1) to FDA under 21 CFR 10.30. The petition requests that the agency determine whether SANOREX (mazindol) Tablets, 1 and 2 mg (NDA 17–247), manufactured by Novartis Pharmaceuticals Corp. (Novartis), were withdrawn from sale for reasons of safety or effectiveness. SANOREX is approved for the management of exogenous obesity as a short term adjunct in a regimen of weight reduction based on caloric restriction in certain patients. SANOREX Tablets were approved on June 14, 1973. SANOREX Tablets were discontinued in 1999, and the drug product was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book.

FDA has reviewed its records and, under § 314.161, has determined that SANOREX Tablets, 1 and 2 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that SANOREX Tablets, 1 and 2 mg, were withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list SANOREX Tablets 1 and 2 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 SANOREX (mazindol) Tablets, 1 and 2 mg, may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: July 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–15998 Filed 7–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0356]

Global Harmonization Task Force, Study Groups 1 and 3; 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 final and proposed documents that have been prepared by Study Groups 1 and 3 of the Global Harmonization Task Force (GHTF), respectively. These documents 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 FDA's current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. In particular, FDA seeks comments on the advantages and disadvantages of the approaches in the GHTF documents, particularly where they are not consistent with current practices for the manufacturer of products distributed within the United States.

DATES: Submit written or electronic comments on these documents by October 14, 2008. After October 14, 2008, written comments or electronic comments may be submitted at any time to the contact persons listed in this document.

ADDRESSES: Submit written requests for single copies of these documents 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 one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the documents.

Submit written comments concerning these 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.reguations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *For information regarding Study Group 1*: Ginette Y. Michaud, Chairperson, GHTF, Study Group 1, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700.

For information regarding Study Group 3: Kimberly Trautman, GHTF, Study Group 3, Office of Compliance, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0296.

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. This meeting led to the development of the organization now known as the GHTF to facilitate harmonization. Subsequent meetings have been held in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using their own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global

level of regulatory systems of medical devices 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 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 formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice relates to documents that have been developed by two of the Study Groups (1 and 3).

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 guidelines that could help lead to harmonization. As a result of its efforts, this group has developed final document GHTF/SG1/N011:2008. GHTF/SG1/N011:2008 ''Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)'' is intended to provide information on the content of the STED to be assembled and submitted to a Regulatory Authority (RA) or Conformity Assessment Body (CAB) for premarket review, and for use postmarket to assess continuing conformity to GHTF Study Group 1's document, GHTF/SG1/N41R9:2005, ''Essential Principles of Safety and Performance.''

Study Group 3 was initially tasked with the responsibility of developing documents on Quality Systems. As a result of their efforts, this group has developed proposed document SG3(PD)N17R7. The proposed document SG3(PD)N17R7 entitled, ''Quality Management System—Medical Devices—Guidance on the Control of Products and Services Obtained From Suppliers'' provides information for medical device manufacturers on control of products and services obtained from suppliers.

II. Significance of Documents

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. In particular, FDA seeks comments on the advantages and disadvantages of the approaches in the GHTF documents, particular where they are not consistent with current practices for the manufacturer of products distributed in the United States.

III. Electronic Access

Persons interested in obtaining a copy of these documents may do so by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. Information on the GHTF may be accessed at *http://www.ghtf.org*. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding these documents. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: July 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–16000 Filed 7–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–D–0157] (formerly Docket No. 2005D–0286)

Guidance for Industry: Current Good Manufacturing Practice for Phase 1 Investigational Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: CGMP for Phase 1 Investigational Drugs'' dated July 2008. The guidance provides assistance in applying relevant current good manufacturing practice (CGMP) requirements of the Federal Food, Drug, and Cosmetic Act (the act) to the manufacture of most investigational new drugs, including biological drugs, used in phase 1 clinical trials. FDA is issuing this guidance concurrently with a final rule published elsewhere in this issue of the **Federal Register** specifying that compliance with FDA's CGMP regulations is not required for most investigational drugs that are manufactured for use in phase 1 clinical trials. Therefore, FDA is recommending the approaches outlined in this guidance for complying with the statutory CGMP requirements in the act. The guidance announced in this notice finalizes the draft guidance entitled ''INDs—Approaches to Complying with CGMP During Phase 1'' dated January 2006.

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

ADDRESSES: Submit written requests for single copies of the 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, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.