websites for ordinary business purposes, including advertising their goods or services and to facilitate communication with the public. Accordingly, any costs franchisors would incur specifically as a result of electronic disclosure under part 436 appear to be minimal.

As set forth in the 2005 Notices, staff estimates that the non-labor burden incurred by franchisors under part 436 will differ based on the length of the disclosure document and the number of disclosure documents produced. Staff estimates that 2,000 franchisors (80% of total franchisors covered by the Rule) will print and mail 100 disclosure documents at $35 each. Thus, these franchisors will each incur $3,500 in printing and mailing costs. Staff estimates that the remaining 20% of covered franchisors (500) will transmit 50% of their 100 disclosure documents electronically, at $5 per electronic disclosure. Thus, these franchisors will each incur $2,000 in distribution costs (($250 for electronic disclosure [$5 for electronic disclosure x 50 disclosure documents]) + ($1,750 for printing and mailing [$35 for printing and mailing x 50 disclosure documents])).

Accordingly, the cumulative annual non-labor costs for part 436 of the amended Rule is approximately $8,000,000 (($3,500 printing and mailing costs x 2,000 franchisors = $7,000,000) + ($250 electronic distribution costs + $1,750 printing and mailing costs) x 500 franchisors = $1,000,000)).

William Blumenthal

General Counsel

[FR Doc. E8–16092 Filed 7–15–08: 8:45 am]

[BILLING CODE 6750–01–S]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

National Institute for Occupational Safety and Health (NIOSH) Advisory Board on Radiation and Worker Health (ABRWH orAdvisory Board)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention announces the following committee meeting:

Name: Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health.

Audio Conference Call Time And Date: 11 a.m.–4 p.m., EDT, Tuesday, August 5, 2008.

Place: Audio Conference Call via FTS Conferencing. The USA toll free dial in number is 1–866–659–0537 with a pass code of 9933701.

Status: Open to the public, but without a public comment period.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, most recently, August 3, 2007, and will expire on August 3, 2009.

Purpose: This Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Discussed: The agenda for the conference call includes: Special Exposure Cohort (SEC) Petition Status Updates; Updates from the Subcommittee on Dose Reconstruction and Work Groups; Update on selection of the Board's contractor; Future Plans; and Status of transcripts and minutes.

The agenda is subject to change as priorities dictate.

Because there is not a public comment period, written comments may be submitted. Any written comments received will be included in the official record of the meeting and should be submitted to the contact person below well in advance of the meeting.

Contact Person for More Information: Zaida Burgos, Committee Management Specialist, NIOSH, CDC, 1600 Clifton Road, Atlanta, Georgia 30033, Telephone (404) 498–2548 e-mail: *zab6@cdc.gov.*

Toll Free 1–800–CDC-INFO, e-mail *ocas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 8, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–16065 Filed 7–14–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–P–0326]

Determination That SANOREX (Mazindol) Tablets 1 and 2 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) is announcing its determination that SANOREX (mazindol) Tablets, 1 and 2 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 mazindol tablets if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6306 Silver Spring, MD 20993–0002, 301–796–3601.

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 applicants 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. ANDA applicants 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 (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