

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*

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[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 or Advisory 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](mailto:zab6@cdc.gov).

Toll Free 1-800-CDC-INFO, e-mail [ocas@cdc.gov](mailto: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.