warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the Web cast, will be available at the following Web site: *http://oba.od.nih.gov/SACGHS/sacghs_meetings.html.*

Dated: August 10, 2009.

Jennifer Spaeth,

Director, NIH Office of Federal Advisory Committee Policy.

[FR Doc. E9–19584 Filed 8–14–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Sterilization of Persons in Federally Assisted Family Planning Projects (July 17, 2009); Correction

AGENCY: Department of Health and Human Services.

ACTION: Notice: correction.

SUMMARY: The Department of Health and Human Services (HHS) published a document in the **Federal Register** of July 17, 2009, requesting OMB reauthorization of the form ''Sterilization of Persons in Federally Assisted Family Planning Projects.'' The document contained an incorrect citation to the HHS sterilization regulations; incorrectly identified the Office of Population Affairs (OPA), rather than the Public Health Service (PHS), as the agency within HHS that administers programs of health services which are supported by Federal financial assistance and which are required to obtain informed consent from persons undergoing sterilizations; incorrectly described the form that is required to be used to obtain informed consent; and incorrectly referred to the regulations to which the consent form is appended as OPA regulations rather than PHS regulations.

FOR FURTHER INFORMATION CONTACT: Sherette Funn-Coleman, 202–690–5683.

Corrections:

In the **Federal Register** of July 17, 2009, in FR Doc. OS–0937–0166, on page 34757, in the second column, correct the citation to the sterilization regulations to read:

Proposed Project: HHS 42 CFR part 50, subpart B; Sterilization of Persons in Federally Assisted Family Planning Projects—

In the third column, correct the ''Abstract'' related to the consent form to read as follows:

The consent form solicits information to assure voluntary and informed consent to persons undergoing sterilization in programs of health services which are supported by Federal financial assistance administered by the Public Health Service (PHS). The form provides additional procedural protections to individuals undergoing sterilization. In order to obtain informed consent, the regulation requires that programs use either the form that is appended to the PHS regulation or another consent form approved by the Secretary.

Dated: August 7, 2009.

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E9–19566 Filed 8–14–09; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0443]

Determination That DEMADEX (Torsemide) Injection, 20 Milligrams/2 Milliliter (10 Milligrams/Milliliter) and 50 Milligrams/5 Milliliter (10 Milligrams/Milliliter), Was 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 DEMADEX (torsemide) injection, 20 milligrams (mg)/2 milliliter (mL) (10 mg/mL) and 50 mg/5 mL (10 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for torsemide injection, 20 mg/2mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, 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). 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 before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

PharmaForce, Inc., submitted a citizen petition dated August 5, 2008 (Docket No. FDA–2008–P–0443), under 21 CFR 10.30 requesting that the agency determine whether DEMADEX (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), was withdrawn from sale for reasons of safety or effectiveness. DEMADEX (torsemide) injection is the subject of NDA 20–137, held by Roche Pharmaceuticals (Roche) and was initially approved on August 23, 1993. DEMADEX is indicated for the treatment of edema associated with congestive heart failure, renal disease, or hepatic disease. Roche notified FDA on June 16, 2008, that it was no longer marketing DEMADEX (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), and the drug product was moved to the ''Discontinued Drug Product List'' section of the Orange Book.

FDA has reviewed its records and, under § 314.161, has determined that DEMADEX (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10

mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that DEMADEX (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), was 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 DEMADEX (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), 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 DEMADEX (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), 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: August 7, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–19641 Filed 8–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0268]

Draft Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration.'' This guidance, when finalized, will provide industry with information on how to label beers that are subject to FDA's labeling laws and regulations. This draft guidance is being issued in light of the recent ruling by the Alcohol and Tobacco Tax and Trade Bureau (TTB) (formerly The Bureau of Alcohol, Tobacco, and Firearms (ATF)) clarifying that certain beers do not meet the definition of a ''malt beverage'' under the Federal Alcohol Administration Act (FAA Act). Because these beers are not subject to the labeling provisions of the FAA Act, they are subject to the labeling provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). FDA, in this draft guidance, also reminds manufacturers that the labeling of wine beverages containing less than 7 percent alcohol by volume, such as wine coolers, diluted wine beverages, dealcoholized or partially dealcoholized wine and ciders, is also subject to FDA labeling requirements. FDA is also announcing an opportunity for public comment on the proposed collection of certain information by the agency.

DATES: Submit written or electronic comments on the draft guidance at any time. Submit written or electronic comments on the proposed collection of information by October 16, 2009.

ADDRESSES: Submit written comments on this draft guidance, including comments regarding the proposed collection of information, to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance, including comments regarding the proposed collection of information, to *http://www.regulations.gov*. Submit written requests for single copies of the draft guidance to Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

With regard to the proposed collection of information: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the draft guidance entitled ''Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration.'' This guidance, when finalized, will provide industry with information on how to label beers that are subject to FDA's labeling laws and regulations. FDA, in this draft guidance, also reminds manufacturers that the labeling of wine beverages containing less than 7 percent alcohol by volume, such as wine coolers, diluted wine beverages, dealcoholized or partially dealcoholized wine and ciders, is also subject to FDA labeling requirements (Ref. 1).

As reflected in the 1987 Memorandum of Understanding between FDA and TTB's predecessor agency, the ATF (Ref. 2), TTB is responsible for the issuance and enforcement of regulations with respect to the labeling of distilled spirits, wines, and malt beverages under the FAA Act.

TTB recently clarified that certain beers, which are not made from both malted barley and hops but are instead made from substitutes for malted barley (such as sorghum, rice or wheat), or are made without hops do not meet the definition of a malt beverage under the FAA Act (see TTB Ruling 2008–3) (Ref. 3). TTB stated in its ruling that such products (other than sake, which is classified as a wine under the FAA Act) are not subject to the labeling, advertising, and other provisions of the TTB regulations issued under the FAA Act. Therefore, these beers are subject to the labeling requirements under FDA's laws and regulations. However, as explained in the TTB ruling, some TTB labeling requirements such as the Government Health Warning Statement under the Alcoholic Beverage Labeling Act and certain marking requirements under the Internal Revenue Code continue to apply to these products.

This draft guidance is intended to assist manufacturers in labeling beers that are subject to FDA's labeling laws and regulations. In general, FDA requires that food products under its labeling jurisdiction be truthfully and informatively labeled in accordance with the FD&C Act and the FPLA, and FDA's implementing regulations. These FDA labeling requirements are explained in the draft guidance document.