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