Whistleblower Protection Laws up to and including removal. If OSC has initiated an investigation under 5 U.S.C. 1214, however, according to 5 U.S.C. 1214(f), agencies must seek approval from the Special Counsel to discipline employees for, among other activities, engaging in prohibited retaliation. Nothing in the No FEAR Act alters existing laws or permits an agency to take unfounded disciplinary action against a Federal employee or to violate the procedural rights of a Federal employee who has been accused of discrimination.

VI. Existing Rights Unchanged

Pursuant to section 205 of the No FEAR Act, neither the Act nor this notice creates, expands, or reduces any rights otherwise available to any employee, former employee, or applicant under the laws of the United States, including the provisions of law specified in 5 U.S.C. 2302(d).

Authority: Title II of the No FEAR Act, Public Law 107–174; 5 CFR Part 724.

Dated: November 17, 2006.

Leslie Norwalk,

Acting Administrator.

[FR Doc. 06–9361 Filed 11–17–06; 4:32 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0002]

Guidance for Industry and Food and Drug Administration Staff; Saline, Silicone Gel, and Alternative Breast Implants; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Saline, Silicone Gel, and Alternative Breast Implants.'' This version of the guidance document updates preclinical, clinical, and labeling recommendations described in ''Guidance for Saline, Silicone Gel, and Alternative Breast Implants,'' dated January 13, 2004. The update is based on the latest scientific and medical information on breast implants, and clarifies the type and amount of scientific data that should be submitted to allow FDA to evaluate whether these devices are safe and effective.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Saline, Silicone Gel, and Alternative Breast Implants'' 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 guidance.

Submit written comments concerning this guidance 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.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nada Hanafi, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 144.

SUPPLEMENTARY INFORMATION:

I. Background

On January 13, 2004, FDA issued a draft guidance document entitled, ''Saline, Silicone Gel, and Alternative Breast Implants'' to clarify the type and amount of scientific data that should be submitted to allow FDA to evaluate whether these devices are safe and effective. The comment period closed on April 12, 2004. FDA received over 50 comments. FDA is now issuing a finalized update to this guidance document that reflects the latest scientific and medical thinking pertaining to breast implants, and is based on the April 2005 General and Restorative Devices Panel meeting, FDA's review of two premarket approval applications for silicone gel-filled breast implants, and comments received on the 2004 draft guidance document. The primary changes to the guidance document since the 2004 draft version are to the Mechanical Data, Device Explant Analyses (formerly Modes and Causes of Rupture), and Core Study Clinical Data sections. FDA also combined the former two clinical sections. Some of the recommendations in this guidance document apply to all premarket approval applications for these devices, while others are specific to a type of breast implant (i.e., silicone gel-filled, saline-filled, or alternative). This guidance document supercedes ''Guidance for Saline, Silicone Gel, and Alternative Breast Implants,'' dated February 11, 2003.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Saline, Silicone Gel, and Alternative Breast Implants.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Saline, Silicone Gel, and Alternative Breast Implants,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1239 to identify the guidance you are requesting.

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. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the

regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910–0231). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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.

Dated: October 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–9325 Filed 11–17–06; 4:30 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0463]

Draft Guidance for Industry on Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment.'' Sinusitis is a common disease affecting an estimated 16 percent of the adult U.S. population annually. At present, other than antimicrobials, the treatment options for sinusitis are limited. This guidance is intended to assist the pharmaceutical industry in designing clinical development programs for nonantimicrobial drug products for the treatment of sinusitis.

DATES: Submit written or electronic comments on the draft guidance by January 22, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dr. Badrul A. Chowdhury, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3316, Silver Spring, MD 20993–0002, 301–796–2300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment.'' Sinusitis is a disease characterized by inflammation of one or more of the paranasal sinuses. It is one of the most commonly diagnosed diseases in the United States affecting an estimated 16 percent of the adult population annually. At present, other than antimicrobials, some of which have a label indication of acute bacterial sinusitis, the treatment options for sinusitis are limited. There is an interest within the pharmaceutical industry in the development of new drugs, including drugs other than antimicrobials, for the treatment of sinusitis.

This guidance focuses on the development of nonantibiotic drugs for the treatment of acute sinusitis as well as the development of drugs for other types of sinusitis. This guidance also focuses on the assessment of efficacy in phase 3 clinical studies of sinusitis. In addition, this guidance addresses chemistry, manufacturing, and controls issues and pharmacology and toxicology issues, because some of the products for sinusitis are developed for nasal delivery, and there are nuances to nasal route of delivery that should be considered for appropriate clinical study design.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on designing clinical development programs of nonantimicrobial drugs for the treatment of sinusitis. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: November 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–19689 Filed 11–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Children's Hospitals Graduate Medical Education Payment Program (CHGME PP)

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Children's Hospitals Graduate Medical Education Payment Program (CHGME PP) Conference Call.

SUMMARY: This document announces a scheduled CHGME PP conference call for Federal fiscal year (FY) 2007. The purpose of this conference call is to discuss new annual reporting requirements as required under Public Law (Pub. L.) 109–307 for children's hospitals participating in the CHGME PP.

DATES: The conference call will be held on Wednesday, December 6, 2006, from 2 p.m. to 4 p.m. EST.