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Draft Guidance for Industry on Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment.''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DATES: Submit written or electronic comments on the draft guidance by January 22, 2007.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.