

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#### Draft Guidance for Industry on Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment; Availability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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment."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**DATES:** Submit written or electronic comments on the draft guidance by January 22, 2007.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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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

**FOR FURTHER INFORMATION CONTACT:**

Ayah E. Johnson, Ph.D., telephone: (301) 443-1058; Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, 5600 Fishers Lane, Room 9A-05, Rockville, Maryland 20857; or by e-mail at: [ajohnson@hrsa.gov](mailto:ajohnson@hrsa.gov).

**SUPPLEMENTARY INFORMATION:**

The CHGME PP, as authorized by section 340E of the Public Health Service Act (the Act) (42 U.S.C. 256e), provides funds to children's hospitals to address disparity in the level of Federal funding for children's hospitals that result from Medicare funding for graduate medical education. Pub. L. 109-307 amended the CHGME statute to extend the program through FY 2011.

The statute authorizes \$330 million for both direct and indirect medical education payments for each of the FY 2007 through FY 2011. Congress appropriated \$300 million in FY 2006 for the CHGME PP. These funds have supported over 4,000 residents receiving training in children's teaching hospitals in 31 states.

The agenda for the conference call will include but not be limited to: (1) Welcome and opening comments and (2) news releases/updates. Time will also be available for a question and answer period.

Interested parties must register, in advance, but not later than 5 days prior to the scheduled conference call. Conference call registration forms and information about the Program can be found on the CHGME PP Web site. The Web site address is: <http://bhpr.hrsa.gov/childrenshospitalgme>.

Dated: November 15, 2006.

**Elizabeth M. Duke,**  
*Administrator.*

[FR Doc. E6-19688 Filed 11-21-06; 8:45 am]

**BILLING CODE 4165-15-P**

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**DEPARTMENT OF HOMELAND SECURITY**
**Citizenship and Immigration Services**
**RIN 1615-ZA44**
**[DHS Docket No. USCIS-2006-0066]**
**Changes to the Regional, District and Field Office Organizational Structure Within U.S. Citizenship and Immigration Services**

**AGENCY:** U.S. Citizenship and Immigration Services, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** This notice informs the public of changes to U.S. Citizenship and Immigration Services' (USCIS') regional, district and field office organizational structure due to a recent realignment of the command and control responsibilities within USCIS' Domestic Operations Directorate, Field Operations Division. This action is necessary to balance the workload and personnel among USCIS field offices and improve customer service. USCIS does not plan to close any of its existing offices as a result of this realignment.

**DATES:** This notice is effective November 22, 2006.

**FOR FURTHER INFORMATION CONTACT:**

David Gulick, Chief of Staff, Domestic Operations Directorate, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue, NW., 3rd Floor, Washington, DC 20529, telephone (202) 272-2700.

**SUPPLEMENTARY INFORMATION:****I. Background.**

Upon its establishment in 2003, USCIS inherited legacy Immigration and Naturalization Service's (legacy INS's) domestic field office structure consisting of 3 regions and 33 districts. USCIS' workload and workforce distribution, however, varies greatly from that of legacy INS. Consequently, the continuation of the legacy INS field office structure resulted in an unbalanced USCIS field office chain of command structure with one region having a larger workforce than the other two regions combined, and the largest districts having workforces up to 50 times larger than other districts.

In addition, within the pre-existing chain of command, in those districts with multiple field offices, the district director served as the office manager for one of the field offices while also managing the other field offices within the district. This dual role has been an obstacle to overall management of a district.

Moreover, under the pre-existing organizational structure, each regional office, district office, field office or sub-office had an assigned geographic area of responsibility. A field office manager could not exercise any power or authority over a matter that involved a customer whose place of residence or employment was located outside of his or her geographical area of responsibility, absent an express delegation of such authority by the appropriate USCIS official. In the adjudications context, rigid jurisdictional boundaries based on geography have led to situations where the USCIS office that is physically

located closer to a customer's residence or place of employment does not have geographical jurisdiction to provide the customer with the requested service.

In view of the aforementioned considerations, USCIS has made a determination to realign the domestic operations field office command and control structure. This realignment is effective November 22, 2006.

**II. Realignment**

Under this realignment, the following are the changes to the command and control structure within USCIS Domestic Operations Directorate, Field Operations Division.

*Field Offices, Districts, and Regions*

The keystones of USCIS' in-person services are its local offices. USCIS field offices exist based on the geographic distribution of workload requiring in-person services. No USCIS field office will be closed as a result of this realignment, nor will this realignment change the locations of any of the existing USCIS local offices. For clarity, USCIS will refer to each of these offices as a "field office," managed by a "field office director," rather than "district office," managed by a "district director." Field offices will continue to be responsible for the administration and enforcement of the Immigration and Nationality Act and all other laws relating to immigration and naturalization.

Where USCIS determines that an interview is necessary, it will schedule the applicant's interview at the appropriate field office. While most information and customer services are provided through the USCIS Web-site and toll-free customer service telephone number, individuals who believe they need in-person service can also use their zip code to make an appointment on-line at the appropriate office. Individuals without internet access can contact any USCIS office in-person for assistance in making an appointment. Using zip codes, rather than the current geographic jurisdictional alignment, to determine service areas will allow USCIS to shift interviews and other in-person services to the most convenient field office.

While the realignment does not change the locations of USCIS field offices, it does change the command structure for managing these field offices. USCIS will maintain a district management structure to lead a network of field offices. Each field office will be managed by a field office director who reports to a District Director. In the previous structure, the district director was both the field office director as well