SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP No. 2256) has been filed by Betty J. Pendleton, 768 Arbor Court, Mobile, Alabama 36609, US agent for Biomin GmbH, Industriestrasse 21, Herzogenburg, Austria 3130. The petition proposes to amend the food additive regulations in part 573, Food Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to provide for the safe use of *Eubacterium* bacterial species in feed for detoxifying trichothecene mycotoxins in the digestive tracts of swine and poultry.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **ADDRESSES**) for public review and comment.

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. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: October 18, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–21298 Filed 10–29–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0395]

Draft Guidance for Industry on Acute Bacterial Sinusitis: Developing Drugs for Treatment; Availability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 ''Acute Bacterial Sinusitis: Developing Drugs for Treatment.'' The purpose of this guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drug products for the treatment of acute bacterial sinusitis (ABS). The agency's thinking in this area has evolved in recent years, and this draft guidance, when finalized, will inform sponsors of our current thinking in this area. In addition, it will fulfill a statutory requirement to publish such a guidance enacted in the Food and Drug Administration Amendments Act of 2007 (FDAAA).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 28, 2008.

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* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Steve Gitterman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6134, Silver Spring, MD 20993–0002, 301–796–1600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Acute Bacterial Sinusitis: Developing Drugs for Treatment.'' The purpose of this guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drug products for the treatment of ABS. This guidance revises the draft guidance regarding ABS published in 1998. Section 911 of the FDAAA (Public Law 110–85) adds section 511 to the Federal Food, Drug, and Cosmetic Act that directs the Secretary for Health and Human Services to ''issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat acute bacterial sinusitis.'' This guidance will fulfill this statutory requirement.

The design of clinical trials for ABS was the subject of an Anti-Infective Drug Products Advisory Committee meeting on October 28, 2003. In addition, other advisory committee meetings have focused on the development of specific drug products for this indication. As a result of these public discussions, as well as review of pending applications at FDA, the agency's thinking in this area has evolved in recent years, and this guidance informs sponsors of the changes in our recommendations. Specifically, this guidance recommends that ABS clinical trials be designed as superiority rather than noninferiority trials, and discusses some possible study designs that might be employed in an ABS trial designed to show superiority. This guidance also recommends that microbiological information be obtained in at least one of the controlled studies. This guidance discusses patient-reported outcome instruments for assessing clinical response, and the use of time to resolution as a possible approach to assessing the primary endpoint. As required by FDAAA, this guidance also addresses the use of animal models and surrogate markers in the development of drugs for the treatment of ABS.

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 developing drugs for the treatment of acute bacterial 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information referred to in the guidance entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581.

III. 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.

IV. 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: October 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21332 Filed 10–29–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974: New System of Records

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notification of new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Health Resources and Services Administration (HRSA) is publishing a notice of a proposal to add a new system of records. The Campus Based Branch (CBB) of the Division of Health Careers Diversity and Development in the Bureau of Health Professions is currently utilizing a document management system (DMS) that dynamically manages its flow of documents produced and received. the DMS is an intra-office system in which documents contained within the system are only shared among CBB staff. The DMS contains names and other personally identifiable information of borrowers.

DATES: HRSA invites interested parties to submit comments on the proposed New System of Records on or before December 10, 2007. HRSA has sent a report of a New System of Records to Congress and to the Office of Management and Budget (OMB) on October 18, 2007. The New System of Records will be effective 40 days from the date submitted to OMB unless HRSA comments which would result in a contrary determination.

ADDRESSES: Please address comments to Donn Taylor, Health Resources and Services Administration, Privacy Act Coordinator, 5600 Fishers Lane, Room 14A–20, Rockville, Maryland 20857; Telephone (301) 443–0204. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday. this is not a toll-free number.

FOR FURTHER INFORMATION CONTACT: Henry Lopez, Director, division of Health Careers diversity and Development, Bureau of Health Professions, 5600 Fisher Lane, Room 8-42, Rockville, Maryland 20857; Telephone 301–443–1173. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Health Resources and Services Administration proposes to establish a New System of Records: ''Campus Based Branch Programs Document Management System, HHS/HRSA/BHPr.'' The CBB programs which use the DMS are authorized by the following sections of the Public Health Service Act: Section 721 of the Public Health Service Act (42 U.S.C. 292q) the Health Professions Student Loan Program; Section 724 of the Public Health Service Act (42 U.S.C. 292s) the Primary Care Loan Program; Section 724 of the Public Health Service Act (42 U.S.C. 292t) the Loans for Disadvantaged Students Program; Section 835 of the Public Health Service Act (42 U.S. C. 297a) the Nursing Student Loan Program; and Section 737 of the Public Health Service Act (42 U.S.C. 293a) the Scholarships for Disadvantaged Students Program. In accordance with their applicable regulations, the funds appropriated or distributed from these CBB programs are monitored by the CBB. The DMS is an automated system that enables CBB to fulfill its duty in monitoring these programs. The DMS contains annual operating and performance data from educational institutions participating in CBB programs, as well as personally identifiable information of borrowers.

Dated: October 12, 2007.

Elizabeth M. Duke,

Administrator.

Report of a New System of Records 09–15–0069

SYSTEM NAME:

Campus Based Branch (CBB) Program Document Management System (DMS), HHS/HRSA/BHPr.

SECURITY CLASSIFICATION:

None

SYSTEM LOCATION:

The Division of Health Careers Diversity and Development (DHCDD) of the Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS). Records are located at 5600 Fishers Lane, Room 8–42, Rockville, MD 20857.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Student and faculty borrowers who participate/participated in CBB loan and scholarship programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

The systems include materials such as:

1. Names, addresses, phone numbers, medical records, financial information, and social security numbers of borrowers.

2. Annual Operating Reports that contain financial information from institutions, including aggregate amounts of loans disbursed, collected and retired.

3. Performance reports on the aggregate number of borrowers, their classification in race/ethnicity categories, and whether they are practicing in primary care.

4. Contact information of financial aid officers that include name, title, school address and direct phone number.

5. Correspondence from the financial aid officers regarding issues with specific borrowers. The majority of these correspondence only indicate the borrower's name and/or amount borrowed.