under which the provisions governing mandatory estate recovery will be waived. That provision requires the State to use criteria established by the Secretary for determining whether estate recovery constitutes an undue hardship: 1. In resolving this issue, the hearing will consider whether publication in the State Medicaid Manual meets the requirements for adopting standards governing a homestead of modest value for purposes of qualifying for the undue hardship exception Section 1917(b)(3); 2. The hearing will also consider if properly adopted, whether the Secretary appropriately applied these standards in disapproving the amendment.

West Virginia initially submitted SPA 01–05 on March 13, 2001. Section 1917 (b)(3) of the Act requires the State agency to establish procedures and standards to waive estate recoveries when such recoveries would cause an undue hardship as determined on the basis of criteria established by the Secretary. The State Medicaid Manual (SMM) defines one basis for an undue hardship as ''a homestead of modest value.''

The SPA proposes to exempt homestead property based on a statewide arithmetic mean appraised value of a home that is to be updated yearly by the West Virginia Department of Tax and Revenue.

The Centers for Medicare & Medicaid Services (CMS) has informed West Virginia that it has provided standards for determining the maximum amount which can be excluded from estate recovery as a ''homestead of modest value.'' Section 3810.C1 provides that states may not set the threshold for the market value of a homestead of modest value so high as to negate the intent of the estate recovery program. It specifically notes that ''a homestead of 'modest value' can be defined as 50 percent or *less* of the average price of homes in the county where the homestead is located, as of the date of the beneficiary's death.'' Under West Virginia's amendment, in many counties, the $50,735 homestead of modest value exemption is greater than 100 percent of the average appraised value of homes in the county. In others it is twice that amount. Accordingly, CMS found the amendment did not comport with the standards for defining a homestead of modest value, which a state may exempt as part of its undue hardship exemption.

The CMS has noted that West Virginia's statewide homestead exemption was not included in the amendment as part of its ''undue hardship'' waiver of the mandatory estate recovery. The State included this exemption in the State plan as a separate item. Any homestead exempted must be excluded either on the basis of ''undue hardship'' or that it is not cost-effective for the State to recover.

I am scheduling a hearing on your request for reconsideration to be held on April 25, 2002, at 10 a.m.; Room 339; The Public Ledger Building; 150 South Independence Mall West; Philadelphia, Pennsylvania 19106–3499.

If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR, part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786–2055.

Sincerely,
Thomas A. Scully.

(Sect. 1116 of the Social Security Act (42 U.S.C. 1316); 42 CFR 430.18)

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: March 7, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–6349 Filed 3–15–02; 8:45 am]

BILLING CODE 4160–18–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0002]

Draft Guidance for Industry on Developing Drugs To Treat Inhalational Anthrax (Post-Exposure); 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 ''Inhalational Anthrax (Post-Exposure)—Developing Antimicrobial Drugs.'' This guidance focuses on the development of antimicrobial drugs for administration to persons who have inhaled aerosolized *Bacillus anthracis*, but who do not yet have the established disease. The treatment goal would be to prevent development of the infection in such persons.

DATES: Submit written or electronic comments on the draft guidance by May 17, 2002. 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 Dockets Management Branch (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: Renata Albrecht, Center for Drug Evaluation and Research (HFD–590), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2336.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Inhalational Anthrax (Post-Exposure)—Developing Antimicrobial Drugs.'' This guidance focuses on the development of antimicrobial drugs for administration to persons who have inhaled aerosolized *B. anthracis*, but who do not yet have the established disease. The treatment goal would be to prevent development of the infection in such persons.

In the fall of 2001, *B. anthracis*, the bacterium that causes anthrax, was used as a bioterrorism agent and sent through the U.S. mail, resulting in cases of cutaneous and inhalational anthrax in New York, New Jersey, the District of Columbia, Florida, and Connecticut. Ciprofloxacin hydrochloride tablets, ciprofloxacin intravenous (IV) solution, ciprofloxacin IV in 5 percent dextrose, ciprofloxacin IV in 0.9 percent saline, and ciprofloxacin oral suspension, which the agency had approved in August 2000 for use in the management of patients who have been exposed to aerosolized spores of *B. anthracis*, were used to treat the potentially infected persons.

Because of the bioterrorism incident, the agency is encouraging the development of additional antimicrobial agents to be used in the event of inhalational exposure to *B. anthracis*. This guidance provides recommendations on how to develop such agents. The guidance is intended to assist applicants who wish to plan, design, conduct, and appropriately monitor the studies, including clinical studies, for drugs to treat persons exposed to *B. anthracis*. Applications submitted to the agency based on studies conducted as recommended in this guidance should yield the information necessary for the agency to determine whether the antimicrobial under study is safe and effective for use

in persons exposed to aerosolized *B. anthracis* who do not yet have established disease.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on this topic. 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 Dockets Management Branch (address above) written or electronic comments on the draft guidance by May 17, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch 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: January 14, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–6319 Filed 3–15–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1033]

Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions.'' The document provides guidance for industry on procedures for submitting protocol information to the Clinical Trials Data Bank established by section 113 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). Section 113 of the Modernization Act creates a public resource for information on studies of drugs for serious or life-threatening diseases and conditions conducted under FDA's investigational new drug (IND) regulations.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBER–FAX. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments tohttp://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronicaccess to the guidance document.

FOR FURTHER INFORMATION CONTACT: Theresa Toigo, Office of Special Health Issues, Office of the Commissioner (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4460.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions.'' The agency has finalized the guidance after considering comments received on two draft guidance documents. In the **Federal Register** of March 29, 2000 (65 FR 16620), FDA published the notice of availability of a draft guidance entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank.'' The March 29, 2000, draft guidance provided recommendations for industry on the submission of protocol information to the clinical trials data bank. It included information on the types of clinical trials for which submissions are required under section 113 of the Modernization Act (42 U.S.C. 282) and on the content of those submissions.

Notice of the availability of the second draft guidance entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan,'' was published on July 9, 2001 (66 FR 35798). It addressed procedural issues, including how to submit required and voluntary protocol information to the Clinical Trials Data Bank through a Web-based Protocol Registration System (PRS) available at http://prsinfo.clinicaltrials.gov/.

This guidance, which is a combination of the informational and procedural draft guidances, was finalized after consideration of comments received on both draft guidances. The comments received addressed the following topics: (1) Scope of data requirements, (2) international trial sites, (3) voluntary information, (4) compliance, (5) timeframes, (6) procedural issues (e.g. contact names and intermediaries), and (7) burden estimate. Revisions made in the guidance are intended to clarify issues raised in the comments and to make the document clearer.

We note that Senate 1789, ''Best Pharmaceuticals for Children Act'' (Public Law 107–109), which was signed by the President on January 4, 2002, provides for a description of whether, and through what procedure, the manufacturer or sponsor of an IND will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the investigational drug, particularly in children. The agency intends to issue a revised guidance in the future to address this provision.

Along with the first draft guidance, FDA published a notice in the **Federal Register** of March 29, 2000, announcing a proposed collection of information. On November 9, 2000 (65 FR 67385), FDA published a notice stating that the proposed collection of information was submitted to the Office of Management and Budget (OMB) for review. The report considered comments received on the proposed collection of information. On March 23, 2001 (66 FR 16251), FDA announced OMB's approval of the agency's information collection activities for the program (OMB Control No. 0910–0459). This approval expires March 31, 2004. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.