

recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 20, 2000, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Ave., Gaithersburg, MD.

Contact Person: Sandra L. Titus or Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, or e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will consider new drug application (NDA) 21-229 proposing over-the-counter (OTC) use of Prilosec® (omeprazole), Astra-Zeneca with distribution by Procter and Gamble. This is proposed to: (1) Relieve heartburn, acid indigestion and sour stomach, and (2) prevent heartburn, acid indigestion, and sour stomach brought on by consuming food and beverages, or associated with events such as stress, hectic lifestyle, lying down, or exercise.

The background material that the committees will review will be available 1 business day before the meeting on the Internet at: <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. Click on the year 2000 and then locate the Nonprescription Drugs Advisory Committee meeting for October 20, 2000.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 9, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. on October 20, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 9, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 21, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-22144 Filed 8-29-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1424]

Draft Guidance for Industry on Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation; Availability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 "Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation." This draft guidance is intended to provide recommendations to applicants on submitting analytical procedures, validation data, and samples to support the identity, strength, quality, purity, and potency of drug substances and drug products. The recommendations apply to drug substances and drug products covered in new drug applications (NDA's), abbreviated new drug applications (ANDA's), biologics license applications (BLA's), product license applications (PLA's), and supplements to these applications.

DATES: Submit written comments on the draft guidance by November 28, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, 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, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1488, FAX 888-CBERFAX or 301-827-3844. Send one self-addressed adhesive label to assist the 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. To expedite FDA review of your comments to the docket on this draft guidance, CDER requests that, if possible, you also send an electronic copy of these comments by e-mail to cunninghamp@cder.fda.gov.

FOR FURTHER INFORMATION CONTACT:

Radhika Rajagopalan, Center for Drug Evaluation and Research (HFD-645), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5849, or

Alfred Del Grosso, Center for Biologics Evaluation and Research (HFM-250), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-435-4988.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation." This draft guidance is intended to assist applicants in assembling information, submitting samples, and presenting data to support analytical methodologies. The recommendations apply to drug substances and drug products covered in NDA's, ANDA's, BLA's, PLA's, and supplements to these applications. The principles also apply to drug substances and drug products covered in Type II drug master files.

The principles of methods validation described in this guidance apply to all types of analytical procedures; however, the specific recommendations in this guidance may not be applicable to certain analytical procedures unique to products such as biological, biotechnological, botanical, or radiopharmaceutical drugs.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on analytical procedures and methods validation. 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, regulations, or both.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance by November 28, 2000. 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

Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>.

Dated: August 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-22143 Filed 8-29-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4456—N-11]

Privacy Act of 1974—Proposed Amendment to a System of Records

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notification of the re-designation of an existing system of records and proposed amendments to the system of records.

SUMMARY: Pursuant to the provision of the Privacy Act of 1974, as amended (5 U.S.C. 552a), the Department of Housing and Urban Development is re-designating HUD/PIH-1, "Tenant Eligibility Verification Files," previously published on February 9, 1999 (64 FR 6371); to the new designation HUD/REAC-1, "Tenant Eligibility Verification Files." The system of records notice below supersedes the system of records notice published on, February 9, 1999 (64 FR 6371). HUD/REAC-1 contains the same provisions as HUD/PIH-1 except for the following substantive changes: (1) The re-designation of the system of records to HUD/REAC-1 recognizes the transfer of responsibilities for the computer matching program from the Office of Public and Indian Housing to the Real Estate Assessment Center (REAC); and (2) HUD/REAC-1 expands the type of files to include: (a) Automated records used by housing agencies, owners and agents when providing HUD with information on actions taken to resolve income differences noted by computer matching, and (b) encrypted read-only files REAC employees may use while at housing agency, owner or agent sites containing SSA and IRS information subject to the disclosure provisions of

26 U.S.C. 6103. Aggregated statistics on the initial computer matching results and actions taken to resolve income differences may be made available to internal HUD Program Offices and HUD-contracted Contract Administrators.

HUD/REAC-1 contains computer matching and other tenant eligibility verification records necessary to support the identification of tenants who have been or may be obtaining inappropriate (excessive or insufficient) rental assistance. The system of records also supports disclosure of information, other than Federal tax return information, concerning those tenants to entities that administer HUD rental assistance programs and to law enforcement agencies for possible administrative or legal actions, as appropriate. Entities that administer HUD rental assistance programs are: housing agencies, Indian Tribes and Tribally Designated Housing Entities participating in the Section 8 Program, owners of subsidized multifamily projects, and management agents (hereinafter referred to collectively as "POAs"); under certain limited circumstances, such as when HUD declares a Public Housing Authority in breach of an annual contributions contract, HUD itself may act as a POA. Additionally, HUD/REAC-1 provides information needed to evaluate actions taken to resolve income discrepancies affecting rental assistance.

DATES: *Effective Date:* This proposal shall become effective without further notice on September 29, 2000 unless comments are received during or before this period which would result in a contrary determination.

Comments Due By: September 29, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410-0500. Communications should refer to the above docket number and title. An original and four copies of comments should be submitted. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Jeanette Smith, Departmental Privacy Act Officer, Telephone Number (202) 708-2374, concerning Privacy Act matters. Regarding records maintained in Washington, DC; Chicago, Illinois; and Seattle, Washington contact the

following, respectively: David L. Decker, Project Manager, Tenant Assessment Sub-System, REAC, Telephone Number (202) 708-4932, extension 3214; William Siska, Director, Chicago Technical Assistance Center, Telephone Number (312) 353-6236, extension 2084; and Gordon Brandhagen, Director, Seattle Technical Assistance Center, Telephone Number (206) 220-5312. (These are not toll free numbers.)

SUPPLEMENTARY INFORMATION: HUD published a notice on September 14, 1999 (64 FR 49817) of its plan for large-scale implementation of its existing computer matching program concerning tenant data in assisted housing programs. During the second and third quarter of Fiscal Year 2000 HUD began sending letters containing SSA and IRS return information to tenants, and notices of potential income discrepancies to housing agencies, owners and agents based on its large-scale matching initiative.

A report of the Department's intention to establish the system has been submitted to the Office of Management and Budget (OMB), the Senate Committee on Governmental Affairs, and the House Committee on Government Operations pursuant to paragraph 4c of Appendix I to OMB Circular No. A-130, "Federal Agency Responsibilities for Maintaining Records About Individuals," July 25, 1994; 59 FR 37914.

Authority: 5 U.S.C. 552a; 88 Stat. 1896; 42 U.S.C. 3535(d).

Dated: August 22, 2000.

Gloria R. Parker,

Chief Information Officer.

HUD/REAC-1

SYSTEM NAME:

Tenant Eligibility Verification Files.

SYSTEM LOCATIONS:

The files will be maintained at the following locations: (1) U. S. Department of Housing and Urban Development, Real Estate Assessment Center, 1280 Maryland Avenue, SW, Suite 800, Washington, DC 20024-2635; (2) Chicago Technical Assistance Center, U.S. Department of Housing & Urban Development, Ralph H. Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, Illinois 60604; (3) Seattle Technical Assistance Center, U.S. Department of Housing & Urban Development, Seattle Federal Building, 909 First Avenue, Seattle, Washington 98104. Controls will be established at 1280 Maryland Avenue, SW, for any encrypted files containing SSA and IRS return information (subject to the