FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Privacy Act of 1974; System of Records

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Notice of altered record system.

SUMMARY: The Executive Director of the Federal Retirement Thrift Investment Board (Board) is adopting as final the Board's proposed alteration to the Government-wide system of records, FRTIB–1, Thrift Savings Plan Records. This alteration adds new categories of records for spouses, former spouses, and beneficiaries of Thrift Savings Plan (TSP) participants.

DATES: Effective January 3, 2000.

FOR FURTHER INFORMATION CONTACT: Thomas L. Gray, (202) 942–1662. FAX (202) 942–1676.

SUPPLEMENTARY INFORMATION: The Board was established by the Federal Employees' Retirement System Act of 1986 (FERSA), Pub. L. 99–335, 100 Stat. 514, which has been codified, as amended, largely at 5 U.S.C. 8351 and 8401–8479 (1994), to administer the TSP. The TSP is a tax-deferred retirement savings plan for Federal employees which is similar to cash or deferred arrangements established under section 401(k) of the Internal Revenue Code.

On May 7, 1990, initial notice of the Board's systems of records, including FRTIB–1, was published in the **Federal Register** (55 FR 18949). A minor amendment to FRTIB–1 was published in the May 20, 1994, **Federal Register** (59 FR 26469), to delete routine use provisions allowing disclosure to the Department of Veterans Affairs, the Federal Housing Administration, and private financial institutions, because disclosure to those entities could be made at the written request of the participant. The provision allowing disclosure to beneficiaries of deceased participants was also deleted as unnecessary. Subsequently, on September 15, 1999, the Board published a proposed alteration to FRTIB–1 in the **Federal Register** (64 FR 50092) to add new categories of records to cover spouses, former spouses, and beneficiaries of participants, to state routine uses which may be made of records on these individuals, and to clarify that the term ''participant'' includes a former participant.

This alteration is necessary because the Board is updating its computerized data base for the TSP record keeping system. FRTIB–1 currently lists TSP participants as the only category of individuals covered by this system of records. Under the new TSP record keeping system, spouses, former spouses, and beneficiaries of participants will be added to this system of records.

In addition to publishing a notice of proposed alteration, the Board filed an altered record system report with the Chairman of the Committee on Government Reform of the U.S. House of Representatives, the Chairman of the Committee on Governmental Affairs of the U.S. Senate, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, on September 13, 1999. The Board received no comments on the proposed alteration; therefore, it is adopting the proposed alteration without change.

Roger W. Mehle,

Executive Director, Federal Retirement Thrift Investment Board.

Accordingly, the proposed notice of alteration to record system published on September 15, 1999, in the **Federal Register** (64 FR 50092), adding new categories of records and stating the uses to be made of those records maintained for spouses, former spouses, and beneficiaries of TSP participants, is adopted as final without change.

[FR Doc. 99–30924 Filed 12–2–99; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Filing of Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 1998.

ADDRESSES: Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301–827–6860.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5496.

SUPPLEMENTARY INFORMATION: Under section 13 of the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR 14.60(c), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 1997, through September 30, 1998:

Center for Biologics Evaluation and Research:

Allergenic Products Advisory Committee,

Biological Response Modifiers Advisory Committee,

Blood Products Advisory Committee,

Vaccines and Related Biological Products Advisory Committee.

Center for Drug Evaluation and Research:

Anti-Infective Drugs Advisory Committee,

Antiviral Drugs Advisory Committee,

Cardiovascular and Renal Drugs Advisory Committee,

Dermatologic and Ophthalmic Drugs Advisory Committee,

Drug Abuse Advisory Committee,

Endocrinologic and Metabolic Drugs Advisory Committee.

Center for Devices and Radiological Health:

Medical Devices Advisory Committee.

National Center for Toxicological Research:

Science Advisory Board to the National Center for Toxicological Research.

Annual reports are available for public inspection at: (1) The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., rm. 133, Washington, DC; and (2) the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 26, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–31315 Filed 12–2–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0514]

Guidance for Industry on ANDA's: Impurities in Drug Substances; 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 ''ANDA's: Impurities in Drug Substances.'' This guidance provides recommendations for including information in abbreviated new drug applications (ANDA's) and supporting drug master files on the content and qualification of impurities in drug substances produced by chemical syntheses for both monograph and nonmonograph drug substances.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist the 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.

FOR FURTHER INFORMATION CONTACT: Robert W. Trimmer, Center for Drug Evaluation and Research (HFD–625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5848.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' This guidance provides information on (1) Qualifying impurities found in a drug substance used in an ANDA by a comparison with impurities found in the related *U.S. Pharmacopeia* (USP) monograph, scientific literature, or innovator material; (2) qualifying impurities found at higher levels in a drug substance used for an ANDA than found in the related USP monograph, scientific literature, or innovator material; (3) qualifying impurities in a drug substance used for an ANDA that are not found in the related USP monograph, scientific literature, or innovator material; and (4) threshold levels below which qualification is *not* needed.

In the **Federal Register** of July 24, 1998 (63 FR 39880), FDA announced the availability of a draft version of this guidance. The July 1998 document gave interested persons an opportunity to submit comments through September 22, 1998. On October 19, 1998 (63 FR 55876), in response to requests from the public, the agency reopened the comment period until November 23, 1998. All comments received during the comment period have been carefully reviewed and the guidance was revised, where appropriate.

This level 1 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 the content and qualification of impurities in drug substances produced by chemical syntheses that are used in generic drug products. 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.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). 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 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.

Dated: November 23, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31316 Filed 12–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0038]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Conditions of Participation for Rural Health Clinics, 42 CFR 491.9 Subpart A; *Form No.:* HCFA-R–38;

Use: This information is needed to determine if rural health clinics meet the requirements for approval for Medicare participation.

Frequency: Other (Initial application for Medicare);

Affected Public: Individuals or households; business or other for profit; not for profit institutions; farms; Federal Government; and State, Local or Tribal Government;

Number of Respondents: 3,538;

Total Annual Hours: 9,456.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 22, 1999.

John Parmigiani,

Manager, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–31325 Filed 12–2–99; 8:45 am]

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