DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: 45 CFR 1303 Appeal Procedures for Head Start Grantees and Current or Prospective Delegate Agencies.

OMB No.: 0980–0242.

Description: Section 646 of the Head Start Act requires the Secretary to prescribe a timeline for conducting administrative hearings when adverse actions are taken or proposed against Head Start or Early Head Start grantees or delegate agencies. The Office of Head Start is proposing to renew without changes this rule which implements these requirements and which prescribe when a grantee must submit information and what that information should include to support a contention that adverse action should not be taken.

Respondents: Head Start and Early Head Start grantees and delegate agencies against which the Head Start Bureau has taken or proposes to take adverse actions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Appeal	20	1	26	520

Estimated Total Annual Burden Hours: 520

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.*

Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–27583 Filed 11–13–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0911]

Privacy Act of 1974; Report of a New System of Records; Food and Drug Administration User Fee System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974 and the Food and Drug Administration's (FDA) regulations for the protection of privacy, FDA is publishing notice of a Privacy Act system of records entitled, ''FDA User Fee System, HHS/FDA,'' System Number 09–10–0021. FDA utilizes the User Fee System (UFS) to collect fees pursuant to Federal law and FDA's implementing regulations. The records kept in this system relate to fees assessed under the Freedom of Information Act (FOIA), the Prescription Drug User Fee Act, the Medical Device User Fee and Modernization Act, the Animal Drug User Fee Act, the Animal Generic Drug User Fee Act, the Mammography Quality Standards Act, the Family Smoking Prevention and Tobacco Control Act, the Food Safety Modernization Act, the Biosimilar User Fee Act, the Generic Drug User Fee Act, and other fees assessed by FDA under its Federal Food, Drug and Cosmetic Act authority such as color additive certification fees and export certificate fees. For purposes of this notice, these fees are collectively referred to as user fees.

DATES: *Effective Date:* The new system of records will be effective on November 14, 2012, with the exception of the routine uses. The routine uses will become effective on December 31, 2012. Submit either electronic or written comments by December 31, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–0911, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2012–N–0911 for this notice. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lisa Berry, Office of Financial Management,