Aerospace Building, Washington, DC 20447–0002.

VII. Agency Contacts

Program Office Contact: James Gatz, Office of Community Services, 370 L'Enfant Promenade, SW., Suite 500 West, Aerospace Building, Washington, DC 20447–0002, Email: *AFIProgram@acf.hhs.gov,* Telephone: (202) 401–4626.

Grants Management Office Contact: Barbara Ziegler Johnson, Office of Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Aerospace Building, Washington, DC 20447–0002. Email: *ocs@lcgnet.gov.* Telephone: 1–800–281–9519.

VIII. Other Information

Additional information about this program, including Application Package and tips on developing a high quality project, is posted on the Internet at: *http://www.acf.hhs.gov/assetbuilding/.*

Dated: May 20, 2004.

Clarence H. Carter,

Director, Office of Community Services.

[FR Doc. 04–12129 Filed 5–27–04; 8:45 am]

BILLING CODE 4184–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Delegation of Authority

Notice is hereby given that I have delegated to the Commissioner, Administration on Children, Youth and Families (ACYF), the following Authority:

1. Authority to carry out the provisions of the Family Violence Prevention and Services Act, 42 U.S.C. 10401 *et seq.*, and as amended, now and hereafter.

2. Authority to coordinate all programs involving family violence prevention and services within the Department of Health and Human Services; to seek to coordinate all other Federal programs involving family violence prevention and services; to provide for research; and to provide for training and technical assistance.

3. Authority to approve applications for Family Violence Prevention and Services grants authorized under the Family Violence Prevention and Services Act, 42 U.S.C. 10401 *et seq.*, and as amended, now and hereafter.

This delegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities. In addition, responsibilities under this Act are to be carried out in accordance with the requirements of section 307 of the Family Violence Prevention and Services Act, 42 U.S.C. 10406. (The Secretary has delegated to the Office for Civil Rights enforcement Authority under section 307.) Further, this delegation is null and void with respect to a Commissioner who, prior to appointment, has not had expertise in the field of family violence prevention and services.

I have affirmed and ratified any actions by the Commissioner, Administration on Children, Youth and Families or any other ACYF official which, in effect, involved the exercise of these authorities prior to the effective date of this delegation.

This delegation supersedes any previous delegation of authority pertaining to Family Violence Prevention and Services programs which could have been exercised by the Assistant Secretary for Children and Families or any designee thereof.

This delegation was effective on February 17, 2004.

Dated: May 18, 2004.

Wade F. Horn,

Assistant Secretary for Children and Families.

[FR Doc. 04–12090 Filed 5–27–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0537]

Guidance for Industry and FDA Staff; User Fees and Refunds for Premarket Notification Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''User Fees and Refunds for Premarket Notification Submissions (510(k)s).'' This guidance describes the user fees and refunds associated with the 510(k) program. The guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''User Fees and Refunds for Premarket Notification Submissions (510(k)s)'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on the 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.* See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For device issues: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190 ext. 143.

For biologics issues: Leonard Wilson, Center for Biologics Evaluation and Review (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107–250, amends the Federal Food, Drug, and Cosmetic Act (the act) to allow FDA to collect user fees for certain premarket reviews. The new law also permits refunds under certain circumstances. The guidance outlines the user fees due with 510(k) submissions and the circumstances in which FDA plans to provide refunds.

This guidance document is immediately in effect because the agency is already collecting user fees under the new law and wants to provide guidance to its stakeholders. On February 4, 2003, FDA published a notice in the **Federal Register** (68 FR 5643) to establish a public docket (02N–0534), so that we could share information on the implementation of MDUFMA and to provide interested persons an opportunity to share their views. On December 3, 2003, the agency held an open public meeting to update its stakeholders on its progress in implementing the new law, discuss some of MDUFMA's more challenging

provisions, and obtain input from interested parties. Since establishing the docket over a year ago, the agency has received quite a few comments from its stakeholders on a number of MDUFMA provisions, including the application and refund of user fees. During the drafting of this guidance, the agency specifically solicited comments to the docket in recognition of the interest in this issue. The agency has considered all comments received to date and believes that the approach presented below is a fair application of its refund policy. FDA will accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on user fees and refunds for 510(k)s. 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 and regulations.

III. Electronic Access

To receive ''User Fees and Refunds for Premarket Notification Submissions (510(k)s)'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1511) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB No. 0910–0120).

V. 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 to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12103 Filed 5–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: June 14, 2004, 10 a.m.–5 p.m., EDT.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The full ACCV will meet on Monday, June 14, from 10 a.m. to 5 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1–888–790–6041 on June 14 and providing the following information:

Leader's Name: Joyce Somsak.

Password: ACCV.

Agenda: The agenda items for June 14 will include, but are not limited to: a presentation on the Institute of Medicine's Immunization Safety Review Committee Report, ''Vaccines and Autism''; an overview of the Centers for Disease Control and Prevention's and the National Institutes of Health's research on thimerosal; an overview of the Vaccine Adverse Event Reporting System (VAERS) reports for influenza vaccine; a presentation on adding the influenza vaccine to the Vaccine Injury Table; and updates from the Division of Vaccine Injury Compensation, the Department of Justice, and the National Vaccine Program Office. Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Special Programs Bureau, Health Resources and Services Administration, Room 16C–17, 5600 Fishers Lane, Rockville, MD 20857 or by e-mail at *clee@hrsa.gov*. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of his/her assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as time permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Special Programs Bureau, Health Resources and Services Administration, Room 16C–17, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: (301) 443–2124 or e-mail: *clee@hrsa.gov.*

Dated: May 21, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–12082 Filed 5–27–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Special Diabetes Program for Indians Competitive Grant Program; New Request for Application of Funds

CFDA Number: 93.442.

Key Dates:

Letter of Intent Deadline: June 1, 2004.

Application Deadline: July 15, 2004.

Overview

The Indian Health Service (IHS) announces a new initiative under the Special Diabetes Program for Indians