

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:

*AFIPProgram@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@lcn.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.*

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## 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