The respondents for Type A medicated articles are pharmaceutical firms that manufacture human and veterinary drugs, veterinary drugs, and commercial feed mills.

FDA estimate the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
226.42	200	120	24,000	0.75	18,000
226.58	200	120	24,000	1.75	42,000
226.80	200	120	24,000	0.75	18,000
226.102	200	120	24,000	1.75	42,000
226.110	200	120	24,000	0.25	6,000
226.115	200	120	24,000	1.00	24,000
Total burden hours					150,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of Type A medicated articles being manufactured, etc.) are derived from agency records and experience.

Dated: December 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–151 Filed 1–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0520]

Abbott Laboratories, Premarket Approval of IMx® Tacrolimus II Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Abbott Laboratories, Abbott Park, IL, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the IMx® Tacrolimus II Assay. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 26, 1997, of the approval of the application.

DATES: Petitions for administrative review by February 5, 1998.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Steven I. Gutman, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, –2098 Gaither Rd., Rockville, MD 20850, 301–594–1243.

SUPPLEMENTARY INFORMATION: On February 18, 1997, Abbott Laboratories, Abbott Park, IL 60064–3537, submitted to CDRH an application for premarket approval of the IMx® Tacrolimus II Assay. The device is an in vitro reagent system for the quantitative determination of tacrolimus and some metabolites in human whole blood as an aid in the management of liver allograft patients receiving tacrolimus therapy.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Clinical Chemistry and Toxicology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On August 26, 1997, CDRH approved the application by a letter to the applicant from the Deputy Director, Clinical and Review Policy, the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before February 5, 1998, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the

Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: December 1, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 98–153 Filed 1–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Appointment of Performance Review Board (PRB) Members

The Health Care Financing Administration (HCFA) announces the names of new and current members of the Performance Review Board as required by 5 U.S.C. 4314(c)(4). HCFA's PRB consists of: Mary May Smith, Chairperson; David S. Cade; Richard S. Foster; Barbara S. Cooper; A. Peter Bouxsein; Linda A. Ruiz; and Charles R. Booth.

For further information, contact the Director, Human Resources Management Group, Office of Internal Customer Support, Teresa A. Smith, 7500 Security Boulevard, Room C2–09–27, Baltimore, Maryland 21244–1850, telephone number 410–786–5489.

Dated: December 17, 1997.

Teresa A. Smith,

Director, Human Resources Management Group.

[FR Doc. 98–211 Filed 1–5–98; 8:45 am]

BILLING CODE 4120–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 1998 Funding Opportunities

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of funding availability.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services and Center for Substance Abuse Prevention announce the availability of FY 1998 funds for grants and/or cooperative agreements for the following activities. These activities are discussed in more detail under Section 4 of this notice. This notice is not a complete description of the activities; potential applicants must obtain a copy of the Guidance for Applicants (GFA) before preparing an application.

Activity	Application deadline	Estimated funds available (million)	Estimated number of awards	Project period (years)
State Incentive Program	03/06/98	$42.0	12–18	3
HIV/AIDS Education	04/03/98	2.0	7–9	3
Child Mental Health Initiative	04/03/98	8–12	8–12	5

Note: SAMHSA plans to publish additional notices of available funding opportunities for FY 1998 in subsequent issues of the **Federal Register**.

The actual amount available for awards and their allocation may vary, depending on unanticipated program requirements and the volume and quality of applications. Awards are usually made for grant periods from one to three years in duration. FY 1998 funds for activities discussed in this announcement were appropriated by the Congress under Public Law 105–78. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement applications were published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The SAMHSA Centers' substance abuse and mental health services activities address issues related to Healthy People 2000 objectives of Mental Health and Mental Disorders; Alcohol and Other Drugs; Clinical Preventive Services; HIV Infection; and Surveillance and Data Systems. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0) or Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (Telephone: 202–512–1800).

General Instructions: Applicants must use application form PHS 5161–1 (Rev. 5/96; OMB No. 0937–0189). The application kit contains the GFA (complete programmatic guidance and instructions for preparing and submitting applications), the PHS 5161–1 which includes Standard Form 424 (Face Page), and other documentation and forms. Application kits may be obtained from the organization specified for each activity covered by this notice (see Section 4).

When requesting an application kit, the applicant must specify the particular activity for which detailed information is desired. This is to ensure receipt of all necessary forms and information, including any specific program review and award criteria.

The PHS 5161–1 application form and the full text of each of the activities (i.e., the GFA) described in Section 4 are available electronically via SAMHSA's World Wide Web Home Page (address: http://www.samhsa.gov). The GFAs are also available on SAMHSA's Bulletin Board (800–424–2294 or 301–443–0040).

Application Submission: Unless otherwise stated in the GFA, applications must be submitted to: SAMHSA Programs, Center for Scientific Review, National Institutes of Health, Suite 1040, 6701 Rockledge Drive MSC–7710, Bethesda, Maryland 20892–7710*

(* Applicants who wish to use express mail or courier service should change the zip code to 20817)

Application Deadlines: The deadlines for receipt of applications are listed in the table above. Please note that the deadlines may differ for the individual activities.

Competing applications must be received by the indicated receipt dates to be accepted for review. An application received after the deadline may be acceptable if it carries a legible proof-of-mailing date assigned by the carrier and that date is not later than one week prior to the deadline date.