consistent with the proposed activities; (5 points) and

4. The quality of the applicant's plan to focus the proposed program and activities on communities that are at high risk for HIV. (7 points)

E. Coordination With Other Programs (Total 10 Points)

1. The extent to which the applicant describes and documents intended coordination with other national, regional, State, and local governmental and nongovernmental organizations and HIV prevention providers, such as other national agencies or organizations, State and local health departments; (4 points)

2. The quality of the applicant's plan to ensure consistency with applicable State and local comprehensive HIV prevention community plans when conducting activities at the State and local levels; (4 points) and

3. The quality of the applicant's plan for communicating successful approaches and ''lessons learned'' to other organizations. (2 points)

F. Scientific, Theoretical, or Conceptual Foundation (Total 10 Points)

1. The extent to which the program, as described, has a clearly described and sound scientific, theoretical, or conceptual foundation; (5 points) and

2. The extent to which data, theory, or conceptual framework convincingly demonstrate that the proposed activities are likely to meet the stated needs. (5 points)

G. Evaluation and Technical Assistance (Total 15 Points)

1. The quality of the applicant's evaluation plan for monitoring the implementation of proposed activities and measuring the achievement of program goals and objectives; (10 points) and

2. The quality of the applicant's plan for obtaining needed technical assistance and staff training to support the proposed program. (5 points)

H. Budget (Not Scored)

Extent to which the budget is reasonable, itemized, clearly justified, and consistent with intended use of funds.

A fiscal Recipient Capability Audit may be required of some applicants before funds will be awarded.

H. Other Requirements

A. Reporting Requirements

Provide CDC with the original plus two copies of:

1. Semiannual progress reports which should document services provided and problems encountered, with careful attention to answering questions and documenting accomplishments and problems encountered in meeting program objectives. Progress reports should follow the OMB report format (OMB 0920–0249) as indicated in the application kit. In the third and final year of the project, CDC will ask recipients to report on their plans to sustain the program in the event CDC funding is not continued for another project period;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial report and performance report, no more than 90 days after the end of the project period.

Send all reports to: Julia Valentine, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE, Mailstop E–15, Atlanta, GA 30305–2209.

For descriptions of the following Other Requirements, see Attachment I:

AR98–4 HIV/AIDS Confidentiality Provisions
AR98–5 HIV Program Review Panel Requirements
AR98–7 Executive Order 12372 Review
AR98–8 Public Health System Reporting Requirements
AR98–9 Paperwork Reduction Act Requirements
AR98–10 Smoke-Free Workplace Requirements
AR98–11 Healthy People 2000
AR98–12 Lobbying Restrictions
AR98–14 Accounting System Requirements
AR98–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act, Section 301(a) [42 U.S.C. 241(a)], 317(k)(2) [42 U.S.C. 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance Number is 93.939.

J. Where to Obtain Additional Information

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Julia Valentine, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98043, Centers for Disease Control and Prevention, Room 300, 255 East Paces Ferry Road, NE., Mailstop E–15, Atlanta, GA 30305–2209, telephone (404) 842–6871; Email address JXV1@CDC.GOV.

For program technical assistance, contact Victor Barnes, M.D., Division of HIV/AIDS Prevention—Intervention Research and Support; National Center for HIV, STD, and TB Prevention; Centers for Disease Control and Prevention (CDC), Mail Stop E–58, Atlanta, GA 30333, telephone (404) 639–5200, E-mail address VCB3@CDC.GOV.

See also the CDC homepage on the Internet: http://www.cdc.gov.

Dated: May 28, 1998.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention.

[FR Doc. 98–14645 Filed 6–2–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0393]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by July 6, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA–80), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the

PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

MedWatch: FDA's Medical Product Reporting Program, Forms FDA 3500 and FDA 3500A (OMB Control Number 0910–0291—Reinstatement)

Under sections 505, 507, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 357, 360b, 360c, 360e, and 393) and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(2) of the act, a drug or device is misbranded if it fails to bear adequate warnings, and under section 502(j), a drug or device is misbranded if it is dangerous to health when used as directed in its labeling. To carry out its responsibilities under these statutory provisions, the agency needs to be informed whenever an adverse event or product problem occurs. Only if FDA is provided with such information will the agency be able to evaluate the risk, if any, associated with the product, and take whatever action necessary to reduce or eliminate the public's exposure to the risk through regulatory action ranging from labeling changes to the rare product withdrawal. To ensure the marketing of safe and effective products, certain adverse events must be reported. FDA has issued regulations requiring reporting of adverse events and product problems for human drugs, biologics, and devices in 21 CFR 310.305, 314.80, 600.80, 803.30, 803.50, 805.53, and 803.56. These regulations implement statutory adverse event reporting requirements in sections 505(k) and 512(l) of the act and section 2125 of the Public Health Service Act (42 U.S.C. 300aa-25).

To carry out these provisions for mandatory reporting of adverse events and product problems with human drugs, biologics, and devices, and to facilitate voluntary reporting for certain other products that FDA regulates, two very similar forms are used. These forms replaced other forms previously used by the agency, including Form FDA 1639. Form FDA 3500A is used for mandatory reporting. Form FDA 3500 is used for voluntary (i.e., not mandated by law or regulation) reporting of adverse events and product problems by health professionals.

Respondents to this collection of information are health professionals; hospitals and other health care providers (i.e., nursing homes, etc.); manufacturers of biologics, drugs, and medical devices; user facilities; distributors; and importers.

In a notice published in the **Federal Register** of December 18, 1996 (61 FR 66673), FDA invited comments on Forms FDA 3500 and FDA 3500A (hereinafter referred to as the December 18, 1996, notice).

FDA received two comments in response to the December 18, 1996, notice, one from industry and one from a trade association. Both comments generally supported the reinstatement of Form FDA 3500A and opposed any major changes to the structure of the form, since many manufacturers have made investments in systems that produce computer facsimiles of the form. However, both comments questioned the need for Form FDA 3417, the medical device ''Baseline Report,'' saying that virtually all of the information is or could be provided to FDA on either the 3500A form or through the medical device registration and listing process.

FDA agrees that there is a redundancy of certain data elements between the MedWatch Form FDA 3500A, the medical device baseline report, and the medical device registration and listing forms. The Center for Devices and Radiological Health (CDRH) plans to evaluate data collected under the current medical device reporting (MDR) program over the next 6 months. CDRH will then attempt to redesign the forms related to medical device reporting, including parts of Form FDA 3500A. The redesign will be presented in an interactive fashion to industry and OMB in late 1998. The redesigned forms will be made available for public comment in early 2001 and will be instituted in late 2001, assuming that OMB approval has been obtained.

Both comments disagreed with FDA's estimate of the hours per response for medical device reports submitted on Form FDA 3500A. One of the comments correctly stated that the estimate of one hour per response ''may be about right for the physical act of filling out the form itself,'' but felt it was ''a gross underestimate of the time necessary to 'respond'' due to the number of hours it takes to gather the information required by the form. The comment suggested that FDA's original estimate of 1 hour per response be changed to a range of 1 to 5 hours, depending on the complexity of the event. FDA agrees with the comment's statement that the agency's estimate accurately reflects the time necessary to fill out the form; however, the agency disagrees that the estimate for Form 3500A should be modified to cover the time necessary to gather the required information, as this burden has already been counted under the medical device reporting regulations. The burden placed on medical device user facilities, importers, distributors, and manufacturers to investigate a report and compile the necessary information to complete Form FDA 3500A was included in a separate burden estimate that was subjected to public comment (see 60 FR 63578 at 63597) and approved by OMB (OMB control number 0910–0059). Accordingly, to avoid duplication, FDA's estimate for Form 3500A has been intentionally limited to the time needed for the actual completing of the form.

This comment also stated that FDA's estimate did not account for the burden of filing a supplemental MedWatch report on Form FDA 3500A when more information is obtained after the filing of the original report. FDA disagrees with the comment's second criticism, however. Supplemental MedWatch reports are also filed on Form FDA 3500A. Although such supplemental reports are not listed separately in the burden chart, they are included as part of the estimated total number of Form FDA 3500A submissions for each agency component.

The other comment argued that FDA's estimate was too low because it did not include the burden of preparing and submitting medical device baseline reports on Form FDA 3417. FDA disagrees with this comment. The medical device baseline report is not part of the MedWatch collection of information (OMB control number 0910–0291) for which FDA is requesting reinstatement. Rather, the medical device baseline report is a separate collection of information that has already undergone public comment (see 60 FR 63578 at 63597) and received OMB approval (OMB control number 0910–0059). As noted above, however, FDA does plan to revise the medical device baseline report form and other medical device reporting forms to eliminate duplication, and the agency will seek public comment on the revisions.

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

Table 1.—Estimated Annual Reporting Burden[1]

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CBER:					
Form FDA 3500	804	1	804	0.5	402
Form FDA 3500A	63	158.5	9,988	1.0	9,988
CDER:					
Form FDA 3500	14,875	1	14,875	0.5	7,438
Form FDA 3500A	500	375	187,522	1.0	187,522
CDRH:					
Form FDA 3500	2,807	1	2,807	0.5	1,404
Form FDA 3500A	39,889	2.05	81,928	1.0	81,928
CFSAN:					
Form FDA 3500	646	1	646	0.5	323
Form FDA 3500A	0	0	0	1.0	0
Total Hours					289,005
Form FDA 3500					9,567
Form FDA 3500A					279,438

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

Note: CBER = Center for Biologics Evaluation and Research; CDER = Center for Drug Evaluation and Research; CDRH = Center for Devices and Radiological Health; CFSAN = Center for Food Safety and Applied Nutrition. Form FDA 3500 is for voluntary reporting; Form FDA 3500A is for mandatory reporting.

As more medical products are approved by FDA and marketed, FDA expects that more reports will be submitted. The figures in the table are based on the average number of reports received in FY 1996, adjusted for the anticipated annual increase in reports. The anticipated annual increase in reports is based on the average annual increase from 1993 to 1996. There are zeroes in the CFSAN row for Form FDA 3500A because mandatory reporting using Form FDA 3500A is not applicable to foods.

Dated: May 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14721 Filed 6–2–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on June 18, 1998, 8 a.m. to 5:30 p.m., and on June 19, 1998, 8 a.m. to 3 p.m.

Location: Doubletree Hotel, Plazas I and II, 1750 Rockville Pike, Rockville, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 18, 1998, the committee will: (1) Hear updates on hepatitis C recipient notification and partner deferral of xenotransplantation recipients; (2) discuss information provided on the Blood Action Plan, Immune Globulin Intravenous supply issues, and Plasma Inventory Hold; and (3) discuss and make recommendations on standard testing for human immunodeficiency virus (HIV) variants. On June 19, 1998, the committee will: (1) Discuss and make recommendations on the review of clinical trial design for Alpha-1-Proteinase Inhibitor; and (2) review and discuss the draft report on the intramural site visit of the Laboratories of Hemostasis and Cellular Hematology, Division of Hematology, and the Laboratories of Hepatitis and Molecular Virology, Division of Transfusion Transmitted Diseases.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 9, 1998. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. on June 18, 1998, and between 10:45 a.m. and 11:15 a.m. on June 19, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 9, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On June 18, 1998, from 3 p.m. to 3:30 p.m., and on June 19, 1998, from 10:15 a.m. to 10:45 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). These portions of the meeting will be closed to discuss increased sensitivity of manufacturers' tests for HIV variants and review of clinical trial design for Alpha-1-Proteinase Inhibitor. On June 19, 1998, from 2 p.m. to 3 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to discuss the draft report of the intramural site visit.