Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–118, State & Territory	56	.5	30	840
ACF–118A, Tribal	240	.5	30	3,600

Estimated Total Annual Burden Hours: 4,440.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 16, 1996.

Douglas J. Godesky,

Reports Clearance Officer.

[FR Doc. 96–32940 Filed 12–26–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96N–0487]

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.

DATES: Submit written comments on the collection of information by January 27, 1997.

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: Geraldine M. Hogan, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1481.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Title: Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting human immunodeficiency virus (HIV) Infection.

Description: The final rule requires that blood establishments prepare and follow written procedures when the blood establishments have collected Whole Blood, blood components, Source Plasma and Source Leukocytes later determined to be at risk for transmitting HIV infections. This final rule requires that when a donor who previously donated blood is tested in accordance with 21 CFR 610.45 on a later donation, and tests repeatedly reactive for antibody to HIV, the blood establishment shall perform more specific testing using a licensed test, and notify consignees who received Whole Blood, blood components, Source Plasma or Source Leukocytes from prior collections so that appropriate action is taken. Blood establishments and consignees are required to quarantine previously collected Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors, and if appropriate, notify transfusion recipients. The agency is issuing this final rule to help ensure the continued safety of the blood supply, to help ensure that information is provided to users of blood and blood components, and to help ensure that transfusion recipients of blood and blood components at risk for transmitting HIV will be notified as appropriate.

Description of Respondents: Blood establishments (Business and Not-for-Profit).

The total estimated annual burden is 85,528 hours. FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING/DISCLOSURE BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.46(a)	3,015	60	180,900	.17	30,753
610.46(b)	3,015	60	180,900	.17	30,753
610.47(b)	200	16	3,200	.5	1,600
Total	.....	.....	.....	.....	63,106

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.100(b)(19)	3,015	1	3,015	2	6,300
606.160(b)(1)(vii)	150	160	24,000	12.8	1,920
606.160(b)(1)(viii)	3,015	60	180,900	4.8	14,472
Total	.....	.....	.....	.....	22,422

There are no capital costs or operating and maintenance costs associated with this collection.

Dated: December 20, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32882 Filed 12–26–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0400]

Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a points to consider (PTC) document entitled ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications.'' The PTC document is intended to provide manufacturers with preliminary guidance regarding the manufacture and preclinical evaluation of plasmid deoxyribonucleic acid (DNA) vaccines intended for clinical studies in preventive infectious disease indications and to assist manufacturers in the preparation of investigational new drug (IND) applications for use of these vaccines. This document is also intended to assist manufacturers with their product development plans for preventive vaccines for infectious diseases.

DATES: Written comments may be submitted at any time; however, to ensure comments are considered in any future revisions they should be submitted by February 25, 1997.

ADDRESSES: Submit written requests for single copies of ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications'' to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Persons with access to the INTERNET may obtain the document using the World Wide Web (WWW) or bounce-back e-mail. For WWW access, connect to CBER at ''http://www.fda.gov/cber/cberftp.html''. To receive the document by bounce-back e-mail, send a message to ''plasmid@a1.cber.fda.gov''. Submit written comments on the PTC document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this notice. A copy of the PTC document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a PTC document entitled ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications.'' Plasmid DNA vaccines are defined as purified preparations of plasmid DNA designed to contain a gene or genes for the intended vaccine antigen as well as genes incorporated into the construct to allow for production in a suitable host system. The use of purified preparations of plasmid DNA constitutes a new approach to vaccine development.

The following topics are addressed in the PTC document to assist manufacturers with their product development plans: (1) CBER's approach to regulation of plasmid DNA preventive vaccines; (2) product considerations for an IND submission; (3) considerations for plasmid DNA vaccine modifications; (4) preclinical immunogenicity and safety evaluation; (5) use of adjuvants and devices to deliver the vaccine; (6) pre-IND meetings; and (7) IND submissions.

This PTC document is intended to provide manufacturers with information regarding concerns that are associated with the new technology of plasmid DNA preventive vaccines and to provide early guidance to the regulated industry. The goal is to create a regulatory environment that will encourage innovation and at the same time ensure that products are both safe and effective.

As with other PTC documents, FDA does not intend this PTC document to be all-inclusive and cautions that not all information may be applicable to all situations. The PTC document is intended to provide information and does not set forth requirements. FDA anticipates that manufacturers and other interested parties may develop alternative methods and procedures, and discuss them with FDA. FDA recognizes that advances will continue in the area of plasmid DNA vaccines and intends to update and revise the document in order to improve its usefulness.

Although the PTC document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, it does represent CBER's current thinking regarding issues related to plasmid DNA vaccines.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding the PTC document. Two copies of any comments are to be submitted, 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. A copy of the PTC document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether