DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5347]

Draft ''Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts.'' The draft guidance document is intended to provide recommendations to all registered blood and plasma establishments, and establishments engaged in manufacturing plasma derivatives. The draft guidance document provides recommendations regarding donor deferral and the disposition of blood products.

DATES: Submit written comments at any time, however, comments should be submitted by February 28, 2000, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts'' 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 the 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts.'' The draft guidance document provides FDA's recommendations to all registered blood and plasma establishments and establishments engaged in manufacturing plasma derivatives regarding donor deferral. It also provides recommendations on the disposition of blood products manufactured from a donor who is retrospectively discovered to have received a xenotransplantation product or to have been in close contact with a recipient of a xenotransplantation product.

Concerns have arisen in the last few years about the potential infectious disease and public health risks associated with xenotransplantation. Zoonoses are infectious diseases of animals that can be transmitted to humans through exposure to, or consumption of animals. Because transplantation necessitates disruption of the recipient's usual protective physical and immunologic barriers, xenotransplantation may facilitate transmission of known or as yet unrecognized infectious agents to humans.

The ''Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation'' published in the **Federal Register** of September 23, 1996 (61 FR 49920). The draft guideline, which includes outlines of health surveillance programs and principles for screening candidate source animals for infectious agents of concern, indicated that patient consent forms should state clearly that xenotransplantation product recipients should never, subsequent to receiving the transplant, donate Whole Blood, blood components, Source Plasma, Source Leukocytes, tissues, breast milk, ova, sperm, or any other body parts for use in humans.

In an open public meeting on December 17, 1997 (62 FR 62776, November 25, 1997), the Xenotransplantation Subcommittee of the Biological Response Modifiers Advisory Committee recommended that close contacts of xenotransplantation product recipients, as well as the recipients themselves, should not donate blood or tissue because these individuals are theoretically at risk of acquiring zoonoses, and of transmitting them through blood and tissue donations. At FDA's Blood Products Advisory Committee open public meeting held on March 19, 1998 (63 FR 8461, February 19, 1998), donor deferral issues related to xenotransplantation were also discussed.

The draft guidance document represents the agency's current thinking with regard to possible risk of transmission of zoonoses by xenotransplantation product recipients and their contacts, through blood and blood products. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

The draft guidance document is being distributed for comment, however, the recommendations may be implemented immediately without prior approval by FDA. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by February 28, 2000, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: December 22, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–33940 Filed 12–29–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0232]

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

AGENCY: Health Care Financing Administration; HHS,

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Program Integrity Program Organizational Conflict of Interest Disclosure Certificate and Supporting Regulations in 42 CFR 421.310 and 421.312;

Form No.: HCFA–R–0232 (OMB# 0938–0723); *Use:* This information is used to assess whether contractors who perform, or who seek to perform, Medicare Integrity Program functions, such as medical review, fraud review or cost audits, have organizational conflicts of interest and whether any conflicts have been resolved. The entities providing the information will be organizations that have been awarded, or seek award of, a Medicare Integrity Program contract; *Frequency:* On occasion; *Affected Public:* Businesses or other for profit; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 2,400.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 6, 1999.

John Parmigiani,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–33987 Filed 12–29–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health and Human Services

National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request The Multi-Ethnic Study of Atherosclerosis

Summary

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: The Multi-Ethnic Study of Atherosclerosis.

Type of Information Request: New.

Need and Use of Information Collection: MESA is a cohort study evaluating people aged 45–84 years and measures of subclinical disease cardiovascular disease (disease detected before it has produced signs and symptoms) that predict progression to clinically overt disease in a diverse population. The purpose is to develop population-based methods for identifying asymptomatic people at high risk of clinical events. The results of this study will allow application for future screening for identification of people at increased risk for cardiovascular disease and intervention studies for treatment of those at increased risk. This study will include a substantial proportion of previously understudied minority groups.

Need and use of Information Collection; Frequency of Response; Affected Public and Type of Respondents: The annual reporting burden is as follows:

Estimated number of Respondents: 16,514;

Estimated Responses/Respondent: 3.88;

Average Burden Hours/Response: 4.55; and

Estimated Total Annual Burden Hours Requested: 25,070.

There are no costs for respondents. Estimated annualized cost for information collection for information collection for a 10-year period (in thousands) is $6870. The estimated annualized start-up costs are $756, and the estimated annualized operating and maintenance costs are $6114.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information will have practical utility; (2) The accuracy of the agency's estimate of burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information

To request more information on the proposed project or to obtain a copy of data collection plans and instruments, contact Dr. Robin Boineau, Epidemiology and Biometry Program, Division of Epidemiology and Clinical Applications, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, MSC # 7934, Bethesda, MD, 20892–7934, or call non-toll-free number (301) 435–0707, or E-mail your request, including your address to: boineau@nih.gov.