committee in order to promote and enhance public health protection in this forum.

Other comments by the food trade associations related to FDA and CFSAN resources needed to accomplish the proposed international priorities, the need for CFSAN to develop a more detailed list of specific activities within each of the broad priority areas in the draft International Affirmative Agenda, and a suggestion that CFSAN's ''first'' priority, both in its domestic and international activities, should be development, maintenance, and dissemination of its science base. Finally, several comments stressed that CFSAN should strive to involve the public fully in its international activities through appropriate notice and comment opportunities and other means.

III. Final CFSAN International Affirmative Agenda for 2000 to 2002

FDA appreciates the comments submitted by the eight organizations and recognizes that all of the comments have merit with regard to CFSAN's current and future international activities. The agency agrees, in principle, with most of the comments and believes that the priorities that CFSAN has articulated in its draft International Affirmative Agenda are compatible with all of the comments.

The international priorities as expressed in the International Affirmative Agenda represent a general framework for the center's international activities for 2000 to 2002. Many specific activities within the broader priority areas are to be planned and accomplished by the center on an annual basis over the next 3 years. Therefore, as these specific, annual international activities are identified and developed, CFSAN will solicit and consider additional public comments, in addition to those submitted on the draft International Affirmative Agenda.

Based on CFSAN's intent to consider comments on its specific international activities on an annual basis during development of its annual international program priorities, the center has elected to finalize CFSAN's International Affirmative Agenda without any changes from the original draft text.

Dated: December 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–32787 Filed 12–15–99; 8:59 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0483]

Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2.'' The guidance document addresses general and specific concerns for gene based detection techniques for human immunodeficiency virus (HIV). The document provides guidance on manufacturing and clinical trial design issues pertaining to the validation of tests based on nucleic acid detection either in the presence or absence of an amplification step.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2'' 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 guidance 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 guidance document.

Submit written comments on the 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 guidance document entitled ''Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2.'' The guidance document announced in this notice finalizes the draft guidance entitled ''Guidance for Industry in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Virus Type 1'' published in the **Federal Register** of July 10, 1998 (63 FR 37402). The guidance document clarifies the following issues as a result of public comments submitted on the draft guidance document: (1) The definition of limit of detection and limit of quantitation for a nucleic acid test and laboratory studies recommended for validation of these limits; (2) the analytical sensitivity study recommendations, including the FDA standard for sensitivity of the pool test in the case of nucleic acid testing, for testing pooled plasma; (3) the numbers of sites, specimens, and design of clinical specificity and sensitivity studies recommended for pooled plasma tests; and (4) the clinical studies to validate a claim for viral load tests used in patient management, i.e., prognosis and therapy.

The guidance document outlines some of the major regulatory and scientific issues concerning gene based tests for HIV–1 and HIV–2. These considerations also apply to tests for other transfusion transmitted viruses including hepatitis C virus, hepatitis B virus, and human T-cell Lymphotropic viruses types I and II.

The guidance document represents the agency's current thinking with regard to the manufacture and clinical evaluation of in vitro testing to detect specific nucleic acid sequences of HIV types 1 and 2. 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 requirements of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this guidance to be all-inclusive and cautions that not all information may be applicable to all situations. The guidance document is intended to

provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding the guidance document. Two copies of any comments are to be submitted, except 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 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 guidance document at http://www.fda.gov/cber/guidelines.htm.

Dated: December 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–32789 Filed 12–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1557]

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:* Survey Report Form Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1–493.2001; Form No.: HCFA–1557 (OMB# 0938–0544); *Use:* CLIA requires the Department of Health and Human Services (DHHS) to establish certification requirements for any laboratory that performs tests on human specimens, and to certify through the issuance of a certificate that those laboratories meet the requirements established by DHHS. The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA. In order for the State survey agency to report to HCFA its findings on facility compliance with the individual standards on which HCFA determines compliance, the surveyor completes the Survey Report Form. The Survey Worksheet provides space to document the surveyor's notes.; *Frequency:* Biennially; *Affected Public:* Business or other for profit, Not for profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 30,512; *Total Annual Responses:* 15,526; *Total Annual Hours:* 7,628.

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, DC 20503.

Dated: December 10, 1999.

John Parmigiani,

Manager, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–32808 Filed 12–17–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3024–NC]

RIN 0938–AH15

Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces the requests we have received from entities seeking review of the appropriateness of the Medicare payment amount for new technology intraocular lenses furnished by Ambulatory Surgical Centers (ASCs). Interested parties submitted these requests under the provisions of a final rule published June 16, 1999. This rule detailed the process for requesting a review of these lenses.

DATES: We will consider comments regarding the lenses listed in this notice if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 19, 2000.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services (HHS), Attention: HCFA–3024–NC, P.O. Box 8017, Baltimore, MD 21244–8017.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, 20201, or 7500 Security Boulevard, Baltimore, Maryland 21244.

Because of the staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–3024–NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's office at 200 Independence Avenue, SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Claude Mone, (410) 786–5666.

SUPPLEMENTARY INFORMATION: The following application requests have been submitted timely to the Health Care Financing Administration for review: