Methods (SACATM), ICCVAM unanimously endorsed the nomination with a high priority. ICCVAM and NICEATM began evaluation activities and also initiated development of proposed test method performance standards for the LLNA since these had not previously been developed (*http://iccvam.niehs.nih.gov/methods/immunotox/immunotox.htm*). NICEATM and ICCVAM compiled a comprehensive draft BRD on the rLLNA test method and a draft test method performance standards document for the LLNA and released them for public comment in January 2008 (73 FR 1360).

NICEATM and ICCVAM convened the Panel at a meeting on March 4–6, 2008, to review the draft BRDs and evaluate the validation status of the proposed test methods and applications. The Panel also reviewed the extent that the information contained in the draft BRDs supported draft ICCVAM test method recommendations for test method uses and limitations, updated standardized test method protocols, and proposed future studies. The Panel reviewed the draft ICCVAM LLNA test method performance standards for their adequacy for assessing the accuracy and reliability of test method protocols that are based on similar scientific principles and that measure the same biological effect as the traditional LLNA. The Panel considered public comments made at the meeting as well as public comments submitted in advance of the meeting, before concluding their deliberations. The Panel's report was made available in May 2008 (73 FR 29136) for public comment. The draft ICCVAM BRDs, draft ICCVAM test method recommendations, draft ICCVAM LLNA test method performance standards, the Panel's report, and all public comments were made available to the SACATM for comment on June 18–19, 2008 (73 FR 25754).

ICCVAM considered the Panel's report, all public comments, and SACATM comments in finalizing its recommendations for the rLLNA, the updated LLNA test method protocol, and LLNA test method performance standards. ICCVAM has forwarded its test method recommendations to U.S. Federal agencies for consideration, in accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3(e)(4)). Agency responses to the ICCVAM test method recommendations will be made available on the NICEATM–ICCVAM Web site as they are received.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found on their Web site (*http://www.iccvam.niehs.nih.gov).*

SACATM was established January 9, 2002, and is composed of scientists from the public and private sectors (67 FR 11358). SACATM provides advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding the statutorily-mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167.*

Dated: September 22, 2009.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. E9–23534 Filed 9–29–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Renewal of Charter for the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of Disease Prevention and Health Promotion.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the U.S. Department of Health and Human Services is hereby announcing that the charter for the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020 (Healthy People 2020 Advisory Committee; HPAC) has been renewed.

FOR FURTHER INFORMATION CONTACT: Emmeline Ochiai, Executive Secretary, Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020, Department of Health and Human Services, Office of Public Health and Science, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Room LL–100, Rockville, MD 20852; Telephone: (240) 453–8259; Fax (240) 453–8281. Additional information is available on the Internet at *http://www.healthypeople.gov*.

SUPPLEMENTARY INFORMATION: Every ten years, through the Healthy People initiative, the U.S. Department of Health and Human Services (HHS) leverages scientific insights and lessons from the past decade, along with the new knowledge of current data, trends, and innovations to develop the next iteration of the national health promotion and disease prevention objectives. Healthy People provides science-based, ten-year national objectives for promoting health and preventing disease. Since 1980, Healthy People has set and monitored national health objectives to meet a broad range of health needs, encourage collaborations across sectors, guide individuals toward making informed health decisions, and measure the impact of our prevention and health promotion activities. *Healthy People 2020* will reflect assessment of major risks to health and wellness, changing public health priorities, and emerging technologies related to our nation's health preparedness and prevention.

The Committee will continue to provide advice and consultation to the Secretary of Health and Human Services for developing and implementing the next iteration of the national health promotion and disease prevention goals and objectives and provide recommendations for initiatives to occur during the implementation phase of the goals and objectives. HHS will use the recommendations to form the development of the national health promotion and disease prevention objectives for 2020 and the process for implementing the objectives. The intent is to develop and launch objectives designed to improve the health status and reduce health risks for Americans by the year 2020. Renewal of the HPAC charter provides authorization for the Committee to operate until September 4,

2011. A copy of the Committee charter can be obtained by contacting the Committee's Executive Secretary. A copy of the Committee charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is *http://fido.gov/facadatabase*.

Dated: September 23, 2009.

Penelope Slade-Sawyer,

RADM, USPHS, Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion), Office of Disease Prevention and Health Promotion.

[FR Doc. E9–23539 Filed 9–29–09; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0434]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff: Humanitarian Device Exemption Regulation: Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by October 30, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and FDA Staff: Humanitarian Device Exemption Regulation: Questions and Answers; Availability. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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

Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and FDA Staff: Humanitarian Device Exemption Regulation: Questions and Answers—(OMB Control Number 0910–NEW)

Title III of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) amended chapter V of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351 *et seq*.) by inserting section 515A, Pediatric Uses of Devices (21 U.S.C. 360e–1).

This new provision requires that new applications under section 520(m) of the act (21 U.S.C. 360j(m)) include both a description of any pediatric subpopulation that suffer from: (1) A disease or condition that the device is intended to treat, diagnose, or cure and (2) the number of affected pediatric patients.

Title III of FDAAA also amended section 520(m) of the act as follows:

Section 520(m)(6)(A)(ii) of the act provides that the Secretary of Health and Human Services will assign an annual distribution number (ADN) for devices indicated for use in a pediatric population or in a pediatric subpopulation. The ADN shall be based on the following information in a humanitarian device exemption (HDE) application: (1) The number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure and of that number; (2) the number of individuals likely to use the device and (3) the number of devices reasonably necessary to to treat such individuals.

Section 520(m)(6)(A)(iii) of the act provides that an HDE holder immediately notify the agency if the number of devices distributed during any calendar year exceeds the ADN.

Section 520(m)(6)(C) of the act provides that an HDE holder may petition to modify the ADN if additional information on the number of individuals affected by the disease or condition arises.

In the **Federal Register** of August 5, 2008 (73 FR 45460), FDA published a 60-day notice requesting public comment on the information collection provisions. Seven comments were received in response to the 60-day notice. Of the seven comments received, six related to the guidance and the information collection requests. We received one comment that did not address the content of the guidance nor the information collection.

There were a number of comments received that clarified the reporting requirements for HDE holders and institutional review boards (IRBs). In response to these comments, FDA responded by referring to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 803.50 have been approved under OMB control number 0910–0437 and the collections of information in part 814 (21 CFR part 814) have been approved under OMB control number 0910–0332. FDA received comments that sought clarification regarding how an IRB distinguishes between the use of a humanitarian use device (HUD) and the study of an HUD in a clinical investigation. FDA responded by providing additional background information related to the collection of safety and effectiveness information related to clinical investigation for HDE approved indications and referring to previously approved collections of information found in FDA regulations. This collection of information is approved under OMB control number 0910–0078.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515A(a)(2)	5	1	5	100	500