SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 2002 (67 FR 39728), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0330. The approval expires on July 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25194 Filed 10–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 01D–0202

Medical Devices: The Least Burdensome Provisions of the FDA Modernization Act of 1997; Concept and Principles; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the final guidance entitled ''The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles.'' This final guidance discusses the agency's interpretation of the least burdensome provisions of the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles'' to the Division of Small Manufacturers, International and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850 301–594–1190; or Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, Bldg. 29B, rm. 5G07, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

A central purpose of the Food and Drug Administration Modernization Act of 1997 (FDAMA) was to ensure the timely availability of safe and effective new products that would benefit the American public. While Congress wanted to reduce unnecessary burdens associated with the premarket clearance and approval processes, Congress did not lower the statutory thresholds for substantial equivalence or reasonable assurance of safety and effectiveness. To help achieve this goal, Congress added section 513(i)(1)(D) and (a)(3)(D)(ii) to the act (21 U.S.C. 360c(i))(l)(D) and (a)(3)(D)(ii). Specifically, section 513(i)(1)(D) states:

> Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

Section 513(a)(3)(D)(ii) states that:

> Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as a result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

These two paragraphs of section 513 of the law contain what are commonly referred to as the ''least burdensome provisions'' of the act. CDRH worked with its stakeholders to develop an interpretation of the least burdensome provisions that would accurately capture Congress' intent and that could be implemented consistently by the agency and industry. As presented in this final guidance, the agency considers the least burdensome concept to be one that could affect almost all premarket regulatory activities, including presubmission meetings with industry, premarket submissions, and the development of guidance documents and regulations.

The level 1 draft was made available in the **Federal Register** of May 3, 2001 (66 FR 22241), and the 90-day comment period for the draft ended on August 1, 2001. While almost all of the comments strongly supported the guidance and encouraged full implementation of it as soon as possible, several comments included recommendations for the agency. Specifically, it was recommended that FDA develop a training program for its staff on the least burdensome approach as well as ways to assess both the agency's success in implementing the principles and industry's satisfaction with FDA's incorporation of them into its daily activities. The agency agrees with these comments, and its responses to them are discussed in the ''Foreword'' of the guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the least burdensome provisions of the act. 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 applicable statute and regulations.

III. Electronic Access

In order to receive ''The Least Burdensome Provisions of the FDA Modernization Act of 1997; Concept and Principles'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1332) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at *http://www.fda.gov/cdrh*.

IV. Comments

Interested persons may, at any time, submit written comments regarding this guidance to Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit two copies of any comments, 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. In many cases, comments may be submitted electronically at *http://www.fda.gov/opacom/backgrounders/voice.html*. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25195 Filed 10–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NIH Intramural Research, Training Award, Program Application

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 Office of the Director, 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: NIH Intramural Research Training Award, Program Application.

Type of Information Collection Request: Revision/OMB No. 0925–0299; 3/31/2003.

Need and Use of Information Collection: The proposed information collection activity is for the purpose of collecting data related to the availability of Training Fellowships under the NIH Intramural Research Training Award Program. This information must be submitted in order to received due consideration for an award and will be used to determine the eligibility and quality of potential awardees.

Frequency of Response: On occasion.

Affected Public: Individuals seeking Intramural Training award opportunities.

Type of Respondents: Postdoctoral, pre-doctoral, post-baccalaureate, technical, and student IRTA applicants. There are no capital costs, operating costs, and/or maintenance cost to report.

Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Postdoctoral IRTA	1,375	1.00	1.00	1375
Predoctoral	306	1.00	1.00	306
Postbaccalaureate	793	1.00	1.00	793
Technical IRTA	83	1.00	1.00	83
Student IRTA	3,800	1.00	1.00	3,800
References for all IRTA categories	15,188	1.00	0.33	5,012
Total	21,545	1.00	0.5276862	11,369

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 is necessary for the proper performance of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and the clarity of information to be collected; and (4) Ways to minimize the burden of the 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 CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Edie Bishop, Personnel Management Specialist, Office of Human Resource Management, OD, NIH, Building 31, Room B3C07, 31 Center Drive MSC 2203, Behtesda, MD, 20892–2203, or call non-toll-free number (301) 496–1443, or e-mail your request, including your address to: *Bishope@od.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within60 days of the date of this publication.

Dated: September 26, 2002.

Frederick C. Walker,

Acting Director of Human Resources.

[FR Doc. 02–25230 Filed 10–3–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Environmental Impact Statement: Ravalli County, MT

AGENCY: National Institutes of Health (NIH), DHHS.

ACTION: Notice of intent.

SUMMARY: Department of Health and Human Services (DHHS) National