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

Institutes of Health (NIH) announces its intent to prepare an environmental impact statement (EIS) to evaluate a proposed new containment laboratory on the campus of Rocky Mountain Laboratories (RML) in Hamilton, Montana. This EIS is being prepared and considered in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969, and the President's Council on Environmental Quality Regulations (40 CFR parts 1500–1508).

DATES: A public scoping meeting will be held on October 21, 2002 beginning at 7 pm in Hamilton, Montana. Comments on the scope of the EIS for the proposed project should be received no later than November 4, 2002. To ensure that the full range of issues related to this proposed action and the scope of this EIS are addressed, comments are invited from all interested parties, including appropriate Federal, State, and local agencies, and private organizations and citizens. Comments and questions should be directed to the NIH at the address listed below.

ADDRESSES: The scoping meeting will be held at Hamilton High School, Commons Room. Comments should be addressed to: Valerie Nottingham, Chief, Pollution Control Section, EPB, ORS, National Institutes of Health, B13/2W64, 9000 Rockville Pike, Bethesda, Maryland 20892.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Chief, Pollution Control Section, EPB, ORS, National Institutes of Health, B13/2W64, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone: 301–496–7775.

SUPPLEMENTARY INFORMATION: Rocky Mountain Laboratories (RML) in Hamilton, MT is one of the oldest research components of the NIH, and plays a key role in the nation's biomedical research program. RML's mission is to study infectious microbes that cause diseases in humans and animals. The RML campus currently includes Biosafety Level 1, 2, and 3 laboratories and administrative and support areas. The lab employs approximately 230 people.

The Federal Government has approved 66.5 million dollars to fund a proposed expansion of the existing Rocky Mountain Laboratory for biodefense and emerging infectious diseases research. The proposed expansion includes a new suite of laboratories designed and constructed to the maximum biosafety level, Biosafety Level 4 (BSL–4).

NIH originally determined that an Environmental Assessment should be prepared to evaluate whether an EIS was needed for this project. A public scoping/open house meeting was held on July 15, 2002 at the Hamilton Community Center to solicit public comment and discussion of issues. Notification of the meeting was via local print and radio media. A web site for comments was also provided.

After review of public comment and information collected to date, NIH has determined that an EIS should be prepared to assess potential impacts of the proposed project.

The proposed action is to construct and operate a new laboratory building that includes BSL–4, BSL–3, and BSL–2 laboratories and administrative and support offices for all of the associated activities. In addition, upgrades to the RML facility infrastructure including heating and cooling facilities, electrical service, security, and emergency power generation will be made to support the laboratory.

Preliminary alternatives will be considered including the No Action Alternative under which the new facility would not be built.

Authority: 42 U.S.C. 4321–4347 (National Environmental Policy Act).

Dated: September 27, 2002.

Stephen A. Ficca,

Associate Director for Research Services, National Institutes of Health.

[FR Doc. 02–25233 Filed 10–3–02; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting: Scientific Workshop—Menopausal Hormone Therapy

Notice is hereby given that the Office of the Director, National Institutes of Health (NIH), Department of Health and Human Services, will convene a workshop on October 23, 2002, 8:30 am–5 pm; and October 24, 2002, 8:30 am–3:30 pm. The workshop will be held at the Natcher Conference Center, NIH, 45 Center Drive, Bethesda, Maryland 20892.

This meeting is open to the public. Advance registration and evidence of such upon arrival are required as seating is limited. Proceedings will be videocast to additional conference rooms within the Natcher Conference Center. The meeting will be webcast at *http://videocast.nih.gov/*. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The purpose of this NIH conference is to review the results from the arm of the Women's Health Initiative (WHI) clinical trial studying the use of combination estrogen and progestin in post-menopausal women. This portion of the clinical trial was halted recently. The workshop will place the results of this portion of the trial in the context of other completed and ongoing Federally funded research on menopausal combination hormone therapy (HT). It will help clinicians and patients understand the implications of current knowledge on decisions regarding short- and long-term use of HT. In addition, the most recent information from the U.S. Preventive Services Task Force on hormone therapy and its use for chronic disease prevention will be presented, as will recommendations on specific clinical uses of HT from professional organizations. The conference will provide information about alternatives for HT for treatment of specific conditions such as osteoporosis, heart disease, and vasomotor symptoms that include mood and sleep disorders. Other ongoing studies will be reviewed.

Time will be provided for public statements to be presented during the second day of the workshop, October 24. Any registered participant may submit a statement of no more than five double-spaced typewritten pages. All statements submitted will be made available as handouts during the conference. Due to time constraints, oral statements will be accommodated on a first-come first-served basis, and will be limited to three minutes each. Registration forms and requests to present oral statements should be sent to Ms. Robin Counts, Courtesy Associates Inc., 2025 M Street, NW, Suite 800, Washington, DC, 20036. To register for this conference, please use the online registration form at *http://www4.od.nih.gov/orwh/* or contact the Courtesy Associates HT Conference Line at 202–973–8673 (*HT@courtesyassoc.com*) by October 14, 2002.

Dated: September 26, 2002.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 02–25231 Filed 10–3–02; 8:45 am]

BILLING CODE 4140–01–P