(1) To exclude himself from any contracting of subcontracting with any agency of the United States government and from eligibility for, or involvement in, nonprocurement transactions (*e.g.,* grants and cooperative agreements) of the United States Government as defined in 45 CFR part 76 for a period of two (2) years, beginning on June 7, 2000;

(2) That for a period of one (1) year after the conclusion of the voluntary exclusion period, any institution that submits an application for PHS support for a research project on which his participation is proposed or that uses him in any capacity on PHS supported research, or that submits a report of PHS funded research in which Dr. Duan is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of Dr. Duan's research contribution, and the institution must also submit a copy of the supervisory plan to ORI;

(3) To exclude himself from serving in any advisory capacity to PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of two (2) years, beginning on June 7, 2000;

(4) That he will not oppose the submission to journals of a statement summarizing the current state of the science with respect to the scientific matters at issue relating to grant R01 AI36552, which has been jointly agreed to by Thomas Jefferson University and the United States of America.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852 (301) 443–5330.

Chris B. Pascal, J.D.,

Acting Director, Office of Research Integrity.

[FR Doc. 00–15900 Filed 6–22–00; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1328]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension; Latex Condoms; User Labeling; Expiration Dating

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the**Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for an expiration date on latex condom labeling based on physical and mechanical testing performed after exposing the product to varying conditions that age latex.

DATES: Submit written comments on the collection of information by August 22, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520) Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the**Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the 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 the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Latex Condoms; User Labeling; Expiration Dating—21 CFR 801.435 (OMB Control No. 0910–0352)—Extension

Sections 502(a), 519, 701, and 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(a), 360(i), 371, and 374) establish the statutory authority to collect information under this regulation. Section 519 of the act describes recordkeeping, section 502(a) misbranding, section 704 authority for inspections, and section 701 general administrative procedures and regulations and hearings.

To protect the public health and minimize the risk of device failure, latex condoms are required to be labeled with an expiration date, which must be supported by data from quality control tests demonstrating physical and mechanical integrity of three random lots of the same product that were stored under accelerated and real time conditions (§ 801.435 (21 CFR 801.435)).

The recording of shelf life testing by condom manufacturers is used to support the expiration dating on the labeling of latex condoms. Information concerning latex shelf life is necessary to allow lay users to use these products safely by avoiding use of products that may have degraded. Degradation of latex film products like latex condoms occurs when latex is exposed to various types of environmental conditions normally experienced in product use, shipment, or storage situations. The effectiveness of latex condoms as a barrier to the transmission of infectious agents is dependent upon the integrity of the latex material. The information and records generated by condom manufacturers under this regulation will be used to establish an expiration date that will inform consumers when the product should no longer be used.

Section 510(h) of the act (21 U.S.C. 360(h)) requires that condom manufacturers as device manufacturers be inspected at least once in a 2-year period. During that inspection, FDA inspectors will review the test records

used to support the expiration date in order to ensure that the expiration date is accurate.

The respondents to this collection of information are domestic and foreign condom manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.435	45	1	45	96	4,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of domestic establishments was estimated by reviewing the FDA data base of registered medical device manufacturers to arrive at 5 domestic and 40 foreign condom manufacturers. Based upon conversations with condom manufacturers, FDA field personnel, and comments received from the public during this collections initial approval, FDA determined the number hours to complete labeling and testing of condoms to be 96 hours per respondent.

Dated: June 15, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–15865 Filed 6–22–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Children's Hospitals Graduate Medical Education (CHGME) Program Conference

On June 19, 2000, the Health Resources and Services Administration (HRSA) published a notice in the **Federal Register** announcing the Children's Hospitals Graduate Medical Education (CHGME) Program (65 FR 37985). Interested parties are invited to attend a briefing conference on July 7, 2000, from 1 p.m. to 3 p.m. EDT in conference room D in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Parties may also participate in the conference by telephone. To do so, dial: 800–545–4387 or 700–991–1738 (for Federal Government employees), then enter the access code ID# 28353. Telephone participants should call by 12:45 p.m.

The conference is to provide information on the topics contained in the CHGME notice: proposed eligibility criteria, funding factors and methodology, and performance measures. It will include a question and answer period.

For additional information call or write to: F. Lawrence Clare, telephone: (301) 443–7334; Division of Medicine and Dentistry, Bureau of Health Professions, Room 9–A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; *lclare@hrsa.gov.*

Dated: June 19, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00–15901 Filed 6–22–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Development of Innovative Idiotype Tumor Vaccines

Multiple opportunities are available for collaboration with the National Cancer Institute (NCI), Division of Clinical Sciences, for the pre-clinical and clinical development of protein and/or DNA-based idiotypic vaccines using novel formulations, adjuvants or delivery systems and directed against low-grade and intermediate B-cell lymphomas, mantle cell lymphomas or chronic lymphocytic leukemias (CLL). It is anticipated that because of the magnitude and diversity of these projects the collaboration(s) will take the form of multiple Cooperative Research and Development Agreements (CRADAs). The collaboration(s) may involve any aspect of the therapeutic development of these tumor vaccines from basic scientific inquiry to late stage clinical trials.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunities for Cooperative Research and Development Agreements.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) is seeking pharmaceutical or biotechnology companies which can effectively collaborate on the scientific and commercial development of idiotypic tumor vaccines for treatment of low-grade and intermediate B-cell lymphomas, mantle cell lymphoma or chronic lymphocytic leukemia (CLL). The goal of the collaboration(s) will be the development of novel vaccine strategies to elicit an immune response directed against autologous idiotypic surface immunoglobulin derived from these tumors. Any CRADA for further development of this technology that focuses on preclinical or clinical studies of idiotypic vaccines for treatment of the indicated diseases will be considered. The CRADA would have an expected duration of three (3) to five (5) years. The goals of the CRADA will include the rapid publication of research results and timely commercialization of products, diagnostics, and treatments that result from the research. The CRADA Collaborators will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADA.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Thomas M. Stackhouse, Technology Development & Commercialization Branch, National Cancer Institute—Frederick Cancer Research and Development Center, Fairview Center, 1003 West Seventh Street, Room 502, Frederick, MD 20852, Telephone: (301) 846–5222; Facsimile: (301) 846–6820. Scientific Inquiries may be directed to Dr. Larry Kwak, M.D., Ph.D., Senior Investigator, Division of Clinical Sciences, National Cancer Institute, Bldg. 567, Room 205, Frederick, MD 21702–1201, Telephone: (301) 846–1607; Facsimile: (301) 846–6107.

EFFECTIVE DATE: Organizations must submit a proposal summary preferably two pages or less, to NCI within 90 days from date of this publication. Guidelines