comments is available as described in Units I.B.1. and I.B.2.

IV. Policies Not Rules

The policy document discussed in this notice is intended to provide guidance to EPA personnel and decision-makers, and to the public. As a guidance document and not a rule, the policy in this guidance is not binding on either EPA or any outside parties. Although this guidance provides a starting point for EPA risk assessments, EPA will depart from its policy where the facts or circumstances warrant. In such cases, EPA will explain why a different course was taken. Similarly, outside parties remain free to assert that a policy is not appropriate for a specific pesticide or that the circumstances surrounding a specific risk assessment demonstrate that a policy should be abandoned.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests.


Susan H. Wayland,
Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 00–15917 Filed 6–22–00; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL HOUSING FINANCE BOARD

Sunshine Act Meeting: Announcing an Open Meeting of the Board

STATUS: The entire meeting will be open to the public.

MATTERS TO BE CONSIDERED DURING PORTIONS OPEN TO THE PUBLIC:
• Final Rule: Federal Home Loan Bank Acquired Member Assets, Core Mission Activities, Investments and Advances.
  • Final Rule: Amendments to Advances and Other Regulations to Implement Gramm-Leach-Bliley Act Collateral Provisions and Make Related Revisions.

CONTACT PERSON FOR MORE INFORMATION:
Elaine L. Baker, Secretary to the Board, (202) 408–2837.

William W. Ginsberg,
Managing Director.

[FR Doc. 00–16010 Filed 6–20–00; 4:59 pm]
BILLING CODE 6725–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
Research Integrity Office Findings; Lingxun Duan, M.D.

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that based on oversight by the Office of Research Integrity (ORI) and decision by the Assistant Secretary for Health, the U.S. Public Health Service has taken final action in the following case:
Lingxun Duan, M.D., Thomas Jefferson University: The U.S. Public Health Service (PHS) alleges that Dr. Duan, former Research Assistant Professor of Medicine, Division of Infectious Diseases, Department of Medicine, Jefferson Medical College, Thomas Jefferson University, engaged in scientific misconduct by reporting research that was inconsistent with original data or could not be supported because original data were not retained. The research in question was supported by a National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grant, R01 AI36532, entitled ‘‘Intracellular antibodies and HIV 1’’. Specifically, the research in question was reported in an NIAID, NIH, grant application; in an FDA-approved phase I gene therapy investigational new drug (IND) application entitled ‘‘Intracellular immunization against HIV—1 infection using an anti-rev single chain variable fragment (SFV)’’; and in two publications: (1) Duan, L., Bagasra, O., Laughlin, M.A., Oakes, J.W., & Pomerantz, R.J., ‘‘Potent inhibition of human immunodeficiency virus type 1 replication by an intracellular anti-Rev single chain antibody,’’ Proc. Natl. Acad. Sci. USA 91:5075–5079, 1994; and (2) Levy-Mintz, P., Duan, L., Zhang, H., Hu, B., Domnulsa, G., Zhu, M., Kulkosky, J., Bizub-Bender, D., Skalka, A.M., and Pomerantz, R.J., ‘‘Intracellular expression of single-chain variable fragments to inhibit early stages of the viral life cycle by targeting human immunodeficiency virus type 1 integrase,’’ J. Virol. 70:8821–8823, 1996.

Dr. Duan denies all allegations of scientific misconduct and contends that some of his original data is missing. Both Dr. Duan and PHS are desirous of concluding this matter without further expense of time and other resources. Thus, Dr. Duan has entered into a Voluntary Exclusion Agreement (Agreement) with PHS, in which Dr. Duan has voluntarily agreed:
(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 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, storage, or other 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