agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Andre Raw, Center for Drug Evaluation and Research (HFD–620), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5758.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides: (1) A framework for making regulatory decisions on drug substance sameness in terms of polymorphic form, and (2) decision trees which provide a recommended course to monitor and control polymorphs in the drug substance and/or drug product when the drug substance exists in relevant polymorphic forms.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on pharmaceutical solid polymorphism. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 11, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–27736 Filed 12–17–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Framingham Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of the Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March June 30, 2004, page 39486, and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Framingham Study. *Type of Information Collection Request:* Reinstatement of a currently approved collection (OMB No. 0925–0216). *Need and Use of Information Collection:* This study will conduct examinations and morbidity and mortality follow-up in original, offspring, and third-generation participants to study the determinants of cardiovascular disease. *Frequency of Response:* The participants will be contacted annually. *Affected Public:* Individuals or households, businesses or other for profit, small businesses or organizations. *Type of Respondents:* Adult men and women; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number or Respondents:* 5,649; *Estimated Number of Responses Per Respondent:* 2.29; *Average Burden Hours Per Response:* 0.6; and *Estimated Total Annual Burden Hours Requested:* 6,886. There are no capital, operating or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Participants	3,513	2.86	0.606	6,085
Physician, hospital, nursing home staff	1,068	1.0	0.67	716
Participant's next of kin	1,068	1.0	.08	85
Total	6,649	2.29	.....	6,886

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Paul Sorlie, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892–7934, or call non-toll-free number (301) 435–0707 or E-mail your request, including your address to: *SorlieP@nhlbi.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: December 7, 2004.

Peter Savage,

Director, DECA, NHLBI.

[FR Doc. 04–27724 Filed 12–17–04; 8:45 am]

BILLING CODE 4167–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Human Monoclonal Antibodies Against Hendra and Nipah Viruses

Dimiter S. Dimitrov et al. (NCI). U.S. Provisional Application filed 1 Nov 2004 (DHHS Reference No. E–004–2005/0–US–01); Related to the Phage Display Library described in DHHS Reference No. E–005–2005/0.

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Available for licensing are neutralizing human monoclonal antibodies against the envelope proteins (Envs) of Hendra virus (HeV) and Nipah virus (NiV) for uses in immunotherapy, vaccine development and as diagnostic or research reagents. Monoclonal antibody variable region fragments (Fabs and scFvs) have been isolated from screening a human phage display library against the Envs. The phage display library (DHHS Ref. No. E–005–2005) is useful for screening other viral or cancer antigens and can be licensed from DHHS under a biological materials license.

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

Human Antibody Phage Display Library

Dimiter S. Dimitrov et al. (NCI). DHHS Reference No. E–005–2005/0—Research Tool; Related to the Monoclonal Antibodies Against Hendra and Nipah Viruses described in U.S. Provisional Application filed 1 Nov 2004 (DHHS Reference No. E–004–2005/0–US–01).

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Available for licensing as a biological material for either internal use or commercial distribution is a human F_{ab} immunoglobulin/antibody fragment phage display library. The library contains 10^{10} F_{abs} derived from the peripheral blood of ten (10) healthy human donors. The high quality of the library was demonstrated in the successful selection of high affinity antibodies specific for Hendra and Nipah viruses; however, the library is useful for selecting a variety of antigen specific immunoglobulin/antibody F_{ab} fragments especially for cancer or viruses.

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

Vaccines Against Crimean-Congo Hemorrhagic Fever

Dimiter Dimitrov and Xiadong Xiao (NCI). U.S. Provisional Patent Application filed 3 Nov 2004 (DHHS Reference Nos. E–299–2004/0–US–01 and E–299–2004/1–US–01).

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Crimean-Congo hemorrhagic fever (CCHF) is a tick-borne public health concern in many regions of the world including Africa, the Middle East, Europe, and Western Asia. The disease is etiologically linked to Crimean-Congo hemorrhagic fever virus (CCHFV) from the *Nairovirus* genus of the *Bunyaviridae* family of viruses and is transmitted primarily through the bite of *Ixodid* ticks. Available for licensing and commercial development are antigens, immunogens, and nucleic acid constructs for the development of vaccines against CCHFV. The antigens and immunogens are peptides corresponding to the soluble ectodomains of CCHFV G1 (Gc) and G2 (Gn) glycoproteins. Also provided are coupled proteins that include soluble peptide fragments derived from the G1 (Gc) or G2 (Gn) ectodomains or portions thereof; peptidomimetics; vaccines; immunogenic compounds methods for vaccination and inhibitors of CCHFV cell entry. Expression vectors and DNA vaccines encoding these peptides are also within the scope of the invention as well as antibodies, aptamers and kits containing antibodies or aptamers that bind to these peptides. CCHFV has been implicated as a pathogen of biodefense significance.

Intracellular Contrast Agents for Magnetic Resonance Imaging

Mrinal K. Dewanjee (NIHCC). U.S. Provisional Patent Application filed 8 Oct 2004 (DHHS Reference No. E–291–2004/0–US–01).

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Available for licensing and commercial development are contrast agents for magnetic resonance imaging (MRI). These agents are composed of charge neutral and lipid-soluble complexes of paramagnetic cations bound by chelators. Unlike conventional extra-cellular contrast agents, these agents of the present