DATES: Submit written or electronic comments on the draft guidance by May 10, 2004. General comments on 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lewis Schrager, Center for Drug Evaluation and Research (HFD–970), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7265, or Debra Birnkrant, CDER (HFD–530) 301–827–2330.

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210; or

Steve Gutman, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Vaccinia Virus—Developing Drugs to Mitigate the Complications from Smallpox Vaccination.'' This draft guidance provides recommendations on the development of drugs to be used to treat complications that may occur from smallpox vaccination with vaccinia virus. The study of vaccinia complications poses challenges in drug development, such as sparse human data. Therefore, this draft guidance focuses on the design and characterization of animal models and of clinical trials and on the use of combinations of animal and human data. In addition, this draft guidance addresses data collection encompassing both preterrorism event controlled vaccination and postterrorism event emergent vaccination. It also addresses the collection of long-term and special population safety data.

This level 1 draft guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115). The guidance represents the agency's current thinking on developing drugs to mitigate the complications associated with vaccinia virus used for smallpox vaccination. 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 or 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 mailed 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 this document at either *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5241 Filed 3–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The National Diabetes Education Program Comprehensive Evaluation Plan

Summary: Under provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 9, 2003, pages 53176–53177, 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 Institute 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 National Diabetes Educations Program Comprehensive Evaluation Plan. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The National Diabetes Education Program (NDEP) is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private organizations. The long-term goals of the NDEP are to improve the treatment and health outcomes of people with diabetes, to promote early diagnosis, and, ultimately, to prevent the onset of diabetes. The NDEP objectives are: (1) To increase awareness of the seriousness of diabetes, its risk factors, and strategies for preventing diabetes and its complications among people at risk for diabetes; (2) to improve understanding about diabetes and its control and to promote better self-management behaviors among people with diabetes; (3) to improve health care providers' understanding of diabetes and its control and to promote an integrated approach to care; (4) to promote health care policies that improve the quality of and access to diabetes care.

Multiple strategies have been devised to address the NDEP objectives. These have been described in the NDEP Strategic Plan and include: (1) Creating partnerships with other organizations concerned about diabetes; (2) developing and implementing awareness and education activities with special emphasis on reaching the racial and ethnic populations disproportionately affected by diabetes; (3) identifying, developing, and disseminating educational tools and resources for the program's diverse audiences; (4) promoting policies and activities to improve the quality of and access to diabetes care.

The NDEP evaluation will document the extent to which the NDEP program has been implemented, and how successful it has been in meeting program objectives. The evaluation relies heavily on data gathered from existing national surveys such as National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey

(NHIS), the Behavioral Risk Factor Surveillance System (BRFSS), among others for this information. This generic clearance request is for the collection of additional primary data from NDEP target audiences on some key process and impact measures that are necessary to effectively evaluate the program. Approval is requested for up to 4 surveys of audiences targeted by the National Diabetes Education Program including people at risk for diabetes, people with diabetes and their families, health care providers, payers and purchasers of health care and health care system policy makers.

Frequency of Response: On occasion. *Affected Public:* Individuals or households; businesses or other for-profit organizations; not-for-profit institutions; Federal government; and State, local or tribal government. *Type of Respondents:* Adults. The annual reporting burden is as follows:

Estimated Number of Respondents: 2200, *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .25; and *Estimated Total Annual Burden Hours Requested:* 200. The annualized cost to respondents is estimated at $5,437.50. There are not Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Total hour burden
Patients and their family members	1000	1	.25	250
People at risk for diabetes	600	1	.25	150
Physicians or other health care providers	600	1	.25	150
Heath care systems	200	1	.25	50
Totals	2,200	.....	.....	600

COST TO RESPONDENTS

Type of respondents	Number of respondents	Frequency of response	Hourly wage rate	Respondent cost
Patients and their family members	1000	1	$20.00	$5,000.00
People at risk for diabetes	600	1	20.00	3,000.00
Physicians or other health care providers	600	1	75.00	11,250.00
Health care system	200	1	50	2,500.00
Total	.....	.....	.....	$21,750.00

(**Note:** On an annual basis, the average number of respondents is 800; the average number of hours is 200 and the average annual respondent cost is $5,437.50)

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 function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and aassumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimze 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 Joanne Gallivan, M.S., R.D., Director, National Diabetes Education Program, NIDDK, NIH, Building 31, Room 9A04, 31 Center Drive, Bethesda, MD 20892, or call non-toll-free number 301–494–6110 or E-mail your request, including your address to: *Joanne—Gallivan@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: February 26, 2004.

Barbara Merchant,

Executive Officer, NIDDK, National Institutes of Health.

[FR Doc. 04–5298 Filed 3–8–04; 8:45 am]

BILLING CODE 4140–01–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 contacting Brenda Hefti, Ph.D., Technology Licensing Specialist, Office