if any, of refusing administration of the product; and of the alternatives to AVA that are available, and of their benefits and risks.

With respect to condition (3), above, relating to the option to accept or refuse administration of AVA, the AVIP will be revised to give personnel the option to refuse vaccination. Individuals who refuse anthrax vaccination will not be punished. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation based on refusal of anthrax vaccination. There may be no penalty or loss of entitlement for refusing anthrax vaccination.

This information shall read in the trifold brochure provided to potential vaccine recipients as follows:

You may refuse anthrax vaccination under the EUA, and you will not be punished. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation, and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination.

The trifold brochure provided to potential vaccine recipients also shall state the following:

On October 27, 2004, the U.S. District Court for the District of Columbia issued an Order declaring unlawful and prohibiting mandatory anthrax vaccinations to protect against inhalation anthrax, pending further FDA action. The Court's injunction means you have the right to refuse to take the vaccine without fear of retaliation. A copy of the Court's Order and Opinion is available at *www.anthrax.mil* or from the vaccination clinic.

Other information, as outlined in your request of December 22, 2004, is not a condition of this EUA, but may be provided, including: That unvaccinated people are more vulnerable to lethal anthrax infection; morbidity or mortality due to anthrax could threaten the lives of others in the unit who depend on each other; and anthrax infections could jeopardize the success of the mission. Individuals subject to the vaccination program may be informed that their military and civilian leaders strongly recommend anthrax vaccination, but such individuals may not be forced to be vaccinated. In addition, the January 27, 2005, authorization notes that the issue of mandatory vaccination will be reconsidered by DoD after FDA completes its administrative process.[21]

As a condition of this authorization, DoD will provide to each potential AVA recipient, prior to vaccination, information that meets the requirements set forth above. Based on a review of DoD's trifold brochure, dated April 5, 2005,[22] I have concluded that this brochure continues to meet such requirements. DoD will obtain FDA's prior approval of any revision to the trifold brochure.

Conditions for the Monitoring and Reporting of Adverse Events Associated with the Emergency Use of AVA. DoD will, as a condition of this authorization, actively encourage health care providers or authorized dispensers and vaccine recipients to report adverse events to the Vaccine Adverse Events Reporting System (VAERS). In addition, we understand that DoD will conduct systematic monitoring of the health of recipients of AVA, e.g., cohort studies using the Defense Medical Surveillance System databases of active-duty military personnel; such monitoring is not a condition of this authorization.

Conditions Concerning Recordkeeping and Reporting, Including Records Access by FDA. DoD will, as a condition of authorization, record in individual medical records, including electronic immunization tracking systems, the names of individual recipients of AVA and the dates of vaccination. DoD will provide FDA access to such records.

Advertising and Promotional Descriptive Printed Matter. FDA has the authority, under section 564(e)(4) of the Act, to establish conditions on advertisements and other promotional descriptive printed matter that relate to the emergency use of AVA under this authorization. As a condition of this EUA, all advertising and promotional descriptive printed matter relating to the use of AVA shall be consistent with the trifold as well as the standards and requirements set forth in this authorization.

V. Duration of Authorization

This EUA will be effective for the duration of the declaration of emergency issued by Secretary of Health and Human Services, Tommy G. Thompson, on January 14, 2005. The EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Thank you in advance for your continued cooperation in implementing this EUA.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.

Commissioner of Food and Drugs

Dated: July 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–15233 Filed 7–28–05; 2:51 pm]

BILLING CODE 4160–01–S

[21] *See* Section I of this authorization.

[22] FDA approved a revision to the trifold brochure on February 15, 2005, and on April 6, 2005.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0355]

Critical Path Initiative; Developing Prevention Therapies; Planning of Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for Comments.

SUMMARY: The Food and Drug Administration (FDA) is planning a 2-day workshop to explore approaches and potential obstacles to developing drugs, disease biomarkers, medical devices, and vaccines to prevent or reduce the risk of illness. The agency plans to hold the workshop as part of its Critical Path Initiative. Speakers at the workshop will be asked to discuss the challenges in developing chemoprevention therapies (i.e., prevention therapies other than lifestyle changes, dietary supplements, or dietary choices that could reduce the risk of certain illnesses such as cancer, diabetes, and obesity). Because prevention of illness is widely recognized to be an important goal and the possible scope of this workshop is very broad, FDA welcomes comments related to the scope of this workshop.

DATES: Submit written or electronic comments by November 1, 2005. General comments are welcome at any time.

ADDRESSES: The FDA invites you to submit written comments on the proposed scope of the workshop. Please submit comments 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*.

FOR FURTHER INFORMATION CONTACT: Nancy Stanisic, Center for Drug Evaluation and Research (HFD–05), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–1660, FAX: 301–443–9718, e-mail: *Stanisicn@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The development of methods to prevent disease has been the single, most effective advance in healthcare in the past century, particularly in developed countries. The widespread ravages of smallpox, infantile diarrhea, plague, cholera, typhoid, and polio are gone from the United States.

The challenge that lies ahead is to prevent the diseases that still ravage our population, including: Heart disease, cancer, diabetes, Alzheimer's disease, and others. In recent decades, substantial effort has been made in the chemoprevention or early intervention for some of the top killers in the United States, notably cardiovascular disease and some cancers. Examples of effective preventive interventions include the aggressive treatment of hypertension to reduce the risk of stroke, statins to lower cholesterol and decrease the risk of a myocardial infarction, the use of low-dose aspirin and beta blockers to prevent death in patients after a myocardial infarction, tamoxifen to reduce the risk of recurrent breast

cancer, aggressive control of blood glucose to reduce the long-term consequences of diabetes, and flu and pneumonia vaccination programs to reduce morbidity and mortality.

Significant advances have also been made in the early identification of healthy individuals at risk of developing disease. Examples of predictors include genetic markers, such as BRCA 1 and 2 for malignancy; pap tests for identification of patients at risk for cervical cancer; genetic alpha–1–antitrypsin deficiency for lung disease; colonoscopy to identify polyps that predict an increased risk of colon cancer; and family history, obesity, and ethnicity for type II diabetes mellitus. Ongoing work in genomics and proteomics promises to identify additional markers to predict specific health risks and potential targets for intervention.

Although markers have been identified, candidate therapies require prospective testing in clinical trials. The design and conduct of chemoprevention trials offer substantial challenges. For example, in the Women's Health Initiative, we learned that the epidemiologic study results of the use of conjugated estrogens to prevent heart disease could not be replicated in the randomized, double-blind clinical trial setting. The Celebrex trial gives another example that prevention studies, in this case polyp prevention trials, must be of sufficient duration to ensure that the risks of long-term use of drugs are captured. These risks may be unexpected and the Data Safety Monitoring Boards need to pay careful attention as signals arise.

II. FDA Critical Path

On March 16, 2004, FDA published its Critical Path report,[1] aimed at identifying potential problems and solutions to ensure that breakthroughs in medical science can be efficiently translated to safe, effective, and available medical products. In the report, FDA underscored the importance of FDA collaboration with academic researchers, product developers, patient groups, and other stakeholders to make the critical path more predictable and less costly. This workshop and any activities that result from the workshop are part of that broad effort.

III. Topics Related to Planning the Public Workshop

Because the range of potential topics that could be discussed at such a workshop is so wide, we are seeking the public's input on what key topics should be addressed at this initial meeting.

Although the prefix ''chemo-'' is often used in relation to treatments for cancer, we are using the term ''chemoprevention'' in this notice to describe prevention therapies other than lifestyle changes, dietary supplements, or dietary choices that could reduce the risk of certain illnesses. We welcome comments on the use of the term ''chemoprevention.''

What follows is a list of topics and questions we have identified for possible discussion at the workshop. We welcome comment on whether these topics and questions are appropriate for discussion at a workshop on chemoprevention therapies? Are there other related issues that should be discussed at the workshop? What are they? Currently, we envision a 2-day workshop, with the first day devoted to identifying hurdles and challenges in designing and implementing chemoprevention studies from a broad perspective. The second day may consist of breakout sessions devoted to specific diseases or disease categories. We welcome input on the format for the 2-day workshop.

Does the following list of questions reflect the kinds of questions we should try to answer at a 2-day workshop on chemoprevention therapies? What questions would you be interested in having answered? In addition to the following topics, what other topics should be included in the scope of the meeting?

1. What have our successes been so far, and what lessons have we learned from past experience with regard to the development of the following preventive therapies:
   a. Vaccines
   b. Cardiovascular disease
   c. Cancer
   i Breast
   ii Colon polyps
2. Which diseases are the most promising with regard to development of chemoprevention therapies?
3. What options are available now for identifying populations at risk for those diseases?
   a. Screening
   b. Genomics
   c. Other
4. What techniques are available for assessing the risks and benefits of new therapies in prevention?
5. How much risk from the candidate therapy is acceptable?
6. Are there specific regulatory concerns in developing chemopreventions (e.g., Long trials, safety and efficacy issues, registries)? And what steps can FDA take to facilitate development in this area, such as the following?
   a. Mechanisms to streamline the regulatory process
   b. Mechanisms to facilitate the scientific process and clinical trials
   i. To better and more efficiently answer questions regarding product efficacy
   ii. To better and more efficiently answer questions regarding product safety
7. What are some of the obstacles facing manufacturers who wish to develop new or existing compounds for chemoprevention? For example, are there specific industry perspectives that need to be considered?
8. What patient perspectives are important to consider?

We have proposed the following topics and questions for discussion on the second day during breakout sessions. Are these appropriate? What other issues would you be interested in discussing at these breakout sessions?

1. Cancer prevention issues
   a. What characteristics of particular cancers make prevention promising?
   b. What characteristics from epidemiologic, early trials, or other models make particular drugs promising?
   c. What trial design issues should be addressed (e.g., endpoints, surrogates, population, adverse event data collection)?
   d. Are there obstacles to marketing prevention drugs?
2. Cardiovascular prevention issues
   a. What characteristics of cardiovascular disease make prevention promising?
   b. What characteristics from epidemiologic, early trials, or other models make particular drugs promising?
   c. What trial design issues should be addressed (e.g., endpoints, surrogates, population, adverse event data collection)?
   d. Are there obstacles to marketing prevention drugs?
3. Cerebrovascular prevention issues
   a. What characteristics of cerebrovascular disease make prevention promising?
   b. What characteristics from epidemiologic, early trials, or other models make particular drugs promising?
   c. What trial design issues should be addressed (e.g., endpoints, surrogates, population, adverse event data collection)?
   d. Are there obstacles to marketing prevention drugs?
4. What other conditions should be discussed?

[1] For the complete report, see *http://www.fda.gov/oc/initiatives/criticalpath*.

IV. Submission of Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. You can also view received comments on the Internet at *http://www.fda.gov/ohrms/dockets/dockets/dockets.htm*

Dated: July 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–15282 Filed 8–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 26 and 27, 2005, from 9 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Charles Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the following issues:

(1) Regulatory and nonregulatory mechanisms to enhance mammography quality while reducing the regulatory and inspection burden on facilities;

(2) Recommendations made by the Institute of Medicine regarding the current Mammography Quality Standards Act (MQSA) program, interventional mammography, and nonmammographic breast imaging procedures; and

(3) All relevant guidance documents issued since the last meeting.

The committee will also receive updates on recently approved alternative standards, voluntary stereotactic accreditation programs, and the radiological health program. MQSA regulations and guidance documents are available to the public on the Internet at *http://www.fda.gov/cdrh/mammography*.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 5, 2005. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 5, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks at 240–276–0450, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 27, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–15373 Filed 8–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Indian Health Service Loan Repayment Program

SUMMARY: The Department of Health and Human Services, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested date can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Indian Health Service (IHS) is providing a 60-day advance opportunity for public comment on a proposed extension of current information collection activity to be submitted to the Office of Management and Budget for review.

Proposed Collection: Title: 0917–0014, ''Indian Health Service Loan Repayment Program.'' *Type of Information Collection Request:* Extension, without revision, of currently approved information collection, 0917–0014, ''Indian Health Service Loan Repayment Program.'' *Form Number:* None. *Forms:* The IHS Loan Repayment Program Information Booklet contains the instructions and the application formats. *Need and Use of Information Collection:* The IHS Loan Repayment Program (LRP) identifies health professionals with pre-existing financial obligations for education expenses that meet program criteria and who are qualified and willing to serve at, often remote, IHS health care facilities. Under the program, eligible health professionals sign a contract under which the IHS agrees to repay part or all of their indebtedness for professional training education. In exchange, the health professionals agree to serve for a specified period of time in IHS health care facilities. Eligible health professionals that wish to apply must submit an application to participate in the program. The application requests personal, demographic and educational training information, including information on the educational loans of