TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801	3,406	1,089	3,709,134	.14	519,279

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

Dated: July 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–15371 Filed 8–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0564]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Temporary Marketing Permit Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of July 26, 2005 (70 FR 43159). The document announced Office of Management Budget approval for State petitions for exemption from preemption. The document was published with an incorrect title and an incorrect docket number. This document corrects those errors.

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

SUPPLEMENTARY INFORMATION: In FR Doc. 05–14697, appearing on page 43159 in the **Federal Register** of Tuesday, July 26, 2005, the following corrections are made:

1. On page 43159, in the third column, in the heading of the document, ''[Docket No. 2004N–0565]'' is corrected to read ''[Docket No. 2004N–0564]''.

2. On page 43159, in the third column, in the heading of the document, ''Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; State Petitions for Exemption From Preemption'' is corrected to read ''Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Temporary Marketing Permit Applications''.

3. On page 43159, in the third column, in the **SUMMARY** section of the document, beginning in the fourth line, ''State Petitions for Exemption From Preemption'' is corrected to read ''Temporary Marketing Permit Applications''.

Dated: July 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–15369 Filed 8–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0299]

Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Extension; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an extension of the Emergency Use Authorization (EUA) (the Authorization) for Anthrax Vaccine Adsorbed (AVA), issued on January 27, 2005, for prevention of inhalation anthrax for individuals between 18 and 65 years of age who are deemed by the Department of Defense (DoD) to be at heightened risk of exposure due to attack with anthrax. The FDA Commissioner is extending the term of this Authorization on the request of DoD.

DATES: The extension of the Authorization was effective as of July 22, 2005.

ADDRESSES: Submit written requests for single copies of the extension of the Authorization to the Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Boris D. Lushniak, Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows the FDA Commissioner, by delegation from the Secretary of Health and Human Services (the Secretary), to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces. As a result of an October 27, 2004, order by the U.S. District Court for the District of Columbia, the use of AVA by DoD for the prevention of inhalation anthrax is deemed an unapproved use of an approved product for purposes of section 564(a)(2) of the act.

On December 10, 2004, under section 564(b)(1)(B) of the act, the Deputy Secretary of Defense determined that there is a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax. On December 22, 2004, DoD requested an EUA for AVA for protection against inhalation anthrax. DoD asked for a 6-month authorization and indicated that, if necessary, it might ask for an extension of the duration of the EUA.

Under section 564(b) of the act, and on the basis of the Deputy Secretary of Defense's determination of a significant potential for a military emergency, on January 14, 2005, the Secretary of Health and Human Services, Tommy G. Thompson, declared an emergency justifying the authorization of the emergency use of AVA. Notice of the determination of the Deputy Secretary of Defense and the declaration of the Secretary of Health and Human Services

was published in the **Federal Register** of February 2, 2005 (70 FR 5450).

On January 27, 2005, after consulting with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), and after concluding that the criteria for issuance of an authorization under section 564(c) of the act were met, the FDA Commissioner authorized the emergency use of AVA for prevention of inhalation anthrax for individuals between 18 and 65 years of age who are deemed by DoD to be at heightened risk of exposure due to attack with anthrax. As requested, the Authorization was effective for 6 months from the date of issuance on January 27, 2005. Notice of the Authorization was published in the **Federal Register** of February 2, 2005 (70 FR 5452).

II. Request for Extension

On July 11, 2005, DoD requested an extension of the Authorization and stated that the information presented in its December 22, 2004, request for an EUA for AVA is still accurate.

III. Electronic Access

An electronic version of this notice is available on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*.

IV. Extension of the Authorization

Having confirmed that the declaration of emergency issued under section 564(b)(1) of the act currently remains in effect and having concluded that the criteria for issuance of the Authorization under section 564(c) of the act continue to be met, the FDA Commissioner, on July 22, 2005, granted DoD's request for an extension of the Authorization for the emergency use of AVA for prevention of inhalation anthrax. This EUA will be effective for the duration of the declaration of emergency issued on January 14, 2005.

The letter granting the extension follows:

William Winkenwerder, Jr., M.D.
Assistant Secretary of Defense for Health Affairs
The Pentagon
Washington, D.C. 20301–1200
Re: Request for Extension of the Emergency Use Authorization for the Armed Forces Pending Re-determination on the Licensed Use of Anthrax Vaccine Adsorbed for Protection Against Inhalational Anthrax
Dear Dr. Winkenwerder:

This is in response to your letter of July 11, 2005, requesting an extension of the above-referenced Emergency Use Authorization (EUA), which was issued on January 27, 2005,[1] pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360bbb–3.[2] You requested an extension of the EUA ''for such time as necessary pending the upcoming FDA re-determination of the licensed use of AVA for protection against inhalational anthrax.''

The declaration of emergency[3] justifying the EUA for AVA remains in effect. The Secretary of Health and Human Services, Tommy G. Thompson, issued this declaration of emergency on January 14, 2005.[4] Pursuant to section 564(b)(2)(A)(ii) of the Act, the declaration of emergency will terminate by expiration on January 14, 2006, which is the end of the one year period that began on the date that the declaration was made.[5]

Having confirmed that the declaration of emergency, issued under section 564(b)(1) of the Act, currently remains in effect and having concluded that the criteria for issuance of this authorization under section 564(c) of the Act continue to be met, I am granting your request to extend the authorization for the emergency use of AVA for prevention of inhalation anthrax.[6] The extension of the EUA is for the duration of the existing declaration of emergency,[7] subject to the conditions established herein. These conditions shall be the same as those that currently apply to the EUA for AVA, issued on January 27, 2005.

I. Background

AVA was first licensed by the National Institutes of Health (NIH) in November 1970.[8] Upon the delegation of vaccine regulation to FDA in 1972, FDA undertook a comprehensive review of the safety, effectiveness, and labeling of all vaccines licensed prior to July 1, 1972.[9] Under this review, independent advisory panels evaluated the safety and effectiveness data of vaccines to ensure that they met appropriate standards. The advisory panel that reviewed AVA concluded that it is safe, effective, and not misbranded, and FDA issued a proposal to adopt the panel's recommendation (the Bacterial Vaccines and Toxoids Efficacy Review).[10]

In March 2003, six plaintiffs, known as John and Jane Doe 1 through 6, filed suit in the United States District Court for the District of Columbia (the Court) seeking the Court to enjoin the Anthrax Vaccine Immunization Program (AVIP) of the Department of Defense (DoD) and to declare AVA an investigational drug when used for protection against inhalation anthrax. On December 22, 2003, the Court issued a preliminary injunction barring inoculations under the AVIP in the absence of informed consent or a Presidential waiver of the informed consent requirement.

In the **Federal Register** of January 5, 2004,[11] FDA published a final rule and final order (January 2004 final rule and final order) in response to the report and recommendations of the independent advisory panel that reviewed the safety and effectiveness data pertaining to AVA. Following FDA's issuance of the final rule and final order, the Court lifted the preliminary injunction on January 7, 2004, except as it applied to the six Doe plaintiffs.

On October 27, 2004, the Court issued a memorandum opinion vacating and remanding the January 2004 final rule and final order to FDA for reconsideration, following an appropriate notice and comment period. The Court also enjoined operation of the AVIP for inoculation using AVA to prevent inhalation anthrax. On December 29, 2004, FDA published a proposed rule and proposed order reopening the comment period on the Bacterial Vaccine and Toxoids Efficacy Review for 90 days.[12] As a result of the Court's order of October 27, 2004, the use of AVA by DoD for the prevention of inhalation anthrax under the AVIP is deemed an unapproved use of an approved product for purposes of section 564(a)(2) of the Act. But for the Court's order, FDA would not consider the use of AVA for inhalation anthrax to be an unapproved use.

On December 10, 2004, pursuant to section 564(b)(1)(B) of the Act, the Deputy Secretary of Defense determined that there is a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax.[13] On December 22, 2005, you requested an EUA to use AVA for protection against inhalation anthrax. You requested an authorization for a period of six months, pending completion of FDA's Bacterial Vaccine and Toxoids Efficacy Review.[14] You also indicated that, if necessary, you might ask for an extension of the duration of the EUA.

On January 14, 2005, pursuant to section 564(b) of the Act, and on the basis of the Deputy Secretary of Defense's determination

[1] Notice of the issuance of the EUA for AVA was published in the **Federal Register** on February 2, 2005 (70 Fed. Reg. 5452).

[2] The Secretary of Health and Human Services (HHS) has delegated the authority to issue an EUA under section 564 of the Act to the Commissioner of Food and Drugs.

[3] Notice of the HHS Secretary's declaration of emergency and of the Deputy Secretary of Defense's determination of military emergency under section 564(b)(1) of the Act was published in the **Federal Register** on February 2, 2005 (70 Fed. Reg. 5450).

[4] The declaration of emergency was not issued on January 10, 2005, as is stated in your letter of July 11, 2005.

[5] It is possible, under section 564(b)(2) of the Act, that the declaration of emergency may terminate or be renewed prior to its expiration.

[6] The terms ''inhalation anthrax'' and ''inhalational anthrax'' are used interchangeably.

[7] The EUA may be revoked, pursuant to section 564(g) of the Act, prior to the termination of the declaration of emergency if the criteria for issuance of the authorization are no longer met or other circumstances make revocation appropriate to protect the public health or safety.

[8] Biological products are licensed under section 351 of the Public Health Service Act, 42 U.S.C. § 262.

[9] *See* 21 C.F.R. § 601.25.

[10] Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 50 Fed. Reg. 51002 (Dec. 13, 1985).

[11] Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 69 Fed. Reg. 255 (Jan. 5, 2004).

[12] Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Proposed Rule and Proposed Order, 69 Fed. Reg. 78281 (Dec. 29, 2004).

[13] *See supra* note 3.

[14] *See supra* note 12.

of a significant potential for a military emergency, the Secretary of Health and Human Services, Tommy G. Thompson, declared an emergency justifying the authorization of the emergency use of AVA.[15] On January 27, 2005, after consulting with the NIH and the Centers for Disease Control and Prevention (CDC), and after concluding that the criteria for issuance of an authorization under section 564(c) of the Act were met, I authorized the emergency use of AVA for prevention of inhalation anthrax, subject to conditions of authorization set out in the authorization.[16]

II. Criteria for Issuance of Authorization

The January 14, 2005, declaration of emergency by the Secretary of Health and Human Services remains in effect. After consultation with NIH and CDC, I have concluded that the use of AVA to prevent inhalation anthrax continues to meet the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) anthrax (*Bacillus anthracis*) can cause a serious or life-threatening disease or condition;

(2) based on the totality of scientific evidence available to FDA, AVA is effective in preventing inhalation anthrax; therefore, it is reasonable to believe that AVA may be effective in preventing inhalation anthrax pursuant to section 564(c)(2)(A) of the Act; and that the known and potential benefits of AVA, when used to prevent inhalation anthrax, outweigh the known and potential risks of the product; and

(3) there is no adequate, approved, and available alternative to AVA for preventing inhalation anthrax.[17]

Specifically, I have concluded, pursuant to section 564(c)(1) of the Act, that anthrax (*Bacillus anthracis*) can cause inhalation anthrax, which is a serious or life-threatening disease or condition. FDA incorporates by reference the information concerning inhalation anthrax contained in Section II, p. 3, of the authorization issued on January 27, 2005. 70 Fed. Reg. 5454 (February 2, 2005).

I have concluded that, based on the totality of scientific evidence available to FDA,[18] including data from at least one well-controlled field study, AVA is effective in preventing inhalation anthrax; therefore, it is reasonable to believe that AVA may be effective in preventing inhalation anthrax pursuant to section 564(c)(2)(A) of the Act. In addition, pursuant to section 564(c)(2)(B) of the Act, I have concluded that it is reasonable to believe that the known and potential benefits of AVA outweigh the known and potential risks of the product. The available scientific evidence that supports these conclusions includes data and information described in Section II of the authorization issued on January 27, 2005,[19] which is hereby incorporated by reference.

I have concluded, pursuant to section 564(c)(3) of the Act, that there is no adequate, approved, and available alternative to AVA for preventing inhalation anthrax. No other drugs are approved for the prevention (pre-exposure) of anthrax infection. Antibiotics are effective against the germinated form of *Bacillus anthracis*, but are not effective against the spore form of the organism. Although antibiotics are available to treat anthrax infection, their effectiveness is limited, in part due to delays from the time of exposure to the initiation of treatment. Delays in the treatment of exposed persons are possible, considering the potential scenarios of exposure, and the difficulties that exist in identifying anthrax as the etiology of illness.

III. Scope of Authorization

Pursuant to section 564(d)(1) of the Act, this authorization continues to be limited to the use of AVA for the prevention of inhalation anthrax for individuals between 18 and 65 years of age who are deemed by DoD to be at heightened risk of exposure due to attack with anthrax.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of AVA, when used to prevent inhalation anthrax, outweigh the known and potential risks of the product for the population described above.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of available scientific evidence reviewed by FDA,[20] that AVA is effective in preventing inhalation anthrax, and therefore, it is reasonable to believe that AVA may be effective in preventing inhalation anthrax pursuant to section 564(c)(2)(A) of the Act.

Accordingly, I have concluded that AVA, when used for preventing inhalation anthrax, meets the standards set forth in section 564(c) of the Act.

FDA understands that DoD recognizes that the current AVA license describes an immunization schedule consisting of six doses. Certain details of DoD's December 22, 2004, EUA request are not specifically addressed in the package insert, however. DoD notes that for some personnel, the vaccination schedule was unavoidably disrupted, and DoD intends for such personnel to resume vaccinations at the point in the dosing schedule where they left off, for individuals eligible under the EUA. While this practice is not addressed in the package insert, the practice is consistent with the general recommendations of the Advisory Committee on Immunization Practices. When it is impracticable to provide a dose on a specific date recommended by the schedule, DoD intends to provide the vaccine dose as soon as practicable thereafter. Based on the totality of the scientific evidence available to FDA, it is reasonable to believe that such administration of AVA may be effective in preventing inhalation anthrax. Furthermore, the known and potential benefits of AVA, when used to prevent inhalation anthrax in the manner described above, outweigh the known and potential risks of the product. DoD also acknowledges that during the course of the EUA, the risk status of individuals initially eligible for vaccination under the EUA may change (e.g., changes in deployment or other circumstances). In such cases, DoD must determine whether such individuals continue to be at heightened risk of exposure due to attack with anthrax, and therefore, whether they continue to be eligible for vaccination with AVA under this EUA.

The use of AVA under this EUA must be consistent with and not contrary to the conditions of authorization set forth below. Subject to the foregoing limitations and under the circumstances set forth in the Deputy Secretary of Defense's determination of military emergency, AVA may be administered for the prevention of inhalation anthrax to individuals determined by DoD to be at heightened risk of exposure due to attack with anthrax.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Conditions Designed to Ensure that Health Care Providers or Authorized Dispensers Administering the Product Are Informed. DoD will conduct an educational and information program under appropriate conditions designed to ensure that health care providers or authorized dispensers administering AVA under this authorization are informed of the following:

(1) that FDA has authorized the emergency use of AVA for preventing inhalation anthrax;

(2) that significant known and potential benefits and risks exist with the emergency use of AVA, and that the extent to which such benefits and risks exist is unknown; and

(3) that alternatives to AVA are available, and that there are benefits and risks.

With respect to condition (2), above, relating to provision of the significant known and potential benefits and risks of the emergency use of AVA, DoD will ensure that the manufacturer's package insert is available to all health care providers or authorized dispensers who administer AVA. DoD will also provide to all such health care providers or authorized dispensers the same information provided to potential vaccine recipients described immediately below.

Conditions Designed to Ensure that Individuals to Whom the Product is Administered Are Informed. DoD will conduct an educational and information program under appropriate conditions designed to ensure that individuals to whom AVA is administered are informed of:

(1) the fact that FDA has authorized the emergency use of AVA for preventing inhalation anthrax;

(2) the significant known and potential benefits and risks of the emergency use of AVA, and of the extent to which such benefits and risks are unknown; and

(3) the option to accept or refuse administration of AVA; of the consequences,

[15] *See supra* note 3.

[16] *See supra* note 1.

[17] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

[18] The available scientific evidence includes FDA's review of adverse event reports concerning AVA submitted to the Vaccine Adverse Event Reporting System

[19] 70 Fed. Reg. 5454 (February 2, 2005).

[20] The scientific evidence available to the Agency includes studies referred to in Section II above.

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