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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Date 01-31-2005 11:39A
Action Date 2-2-2005
L. CLAWSON

Food and Drug Administration

[Docket No. 2005N–0040]

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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for Anthrax Vaccine Adsorbed (AVA) 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. FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic Act (the act), as requested by DoD. The Authorization contains, among other things, conditions on the emergency use of AVA. The Authorization follows the determination by DoD that there is a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax. On the basis of such determination, Secretary of Health and Human Services Tommy G. Thompson (the Secretary) declared an emergency justifying the authorization of the emergency use of AVA. The Authorization, which includes an explanation of the reasons for its issuance, is reprinted in this Notice.

DATES: The Authorization is effective as of January 27, 2005.

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ADDRESSES: Submit written requests for single copies of the Emergency Use 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: Margaret O'K. Glavin, 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 act (21 U.S.C. 360bbb–3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA 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. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives to protect the American people and the U.S. military.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

(1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;

(2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or

(3) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act (PHS Act) that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

Once the Secretary has declared an emergency justifying an authorization under section 564 of the act, FDA may authorize the emergency use of a drug, device, or biological product if the agency concludes, based on the information and data available to the agency, that the statutory criteria of section 564(c) of the act are satisfied. Under section 564(h)(1) of the act FDA is required to publish in the **Federal Register** notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. The explanation may include a summary of data submitted to FDA in an application under section 505(i) or 520(g) of the act (21 U.S.C. 355(i) or 21 U.S.C. 360j(g)).

Section 564 of the act permits FDA to authorize, during the effective period of the declaration, the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency. Products appropriate for emergency use may include products and

uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the act (21 U.S.C. 355, 21 U.S.C. 360(k), 21 U.S.C. 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) (to the extent feasible and appropriate given the circumstances of the emergency), FDA concludes:

(1) That the agent specified in the declaration of emergency can cause a serious or life-threatening disease or condition;

(2) That, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing—(a) the serious or life-threatening disease or condition referred to in paragraph (1); or (b) a serious or life-threatening disease or condition caused by a product authorized under section 564, or approved, cleared, or licensed under the act or PHS Act, for diagnosing, treating, or preventing the disease or condition referred to in paragraph (1) and caused by the agent specified in the declaration of emergency;

(3) That the known and potential benefits of the product outweigh the known and potential risks of the product when used to diagnose, prevent, or treat the serious or life-threatening disease or condition that is the subject of the declaration; and

(4) That there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such serious or life-threatening disease or condition.

II. EUA Request for AVA

On December 10, 2004, pursuant to section 564(b)(1)(B) of the act (21 U.S.C. 360bbb–3(b)(1)(B)), the Deputy Secretary of Defense determined that

there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax. On January 14, 2005, pursuant to section 564(b) of the act, and on the basis of such determination, 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 is published elsewhere in this issue of the **Federal Register**.

III. Significance of Notice

The issuance of this Authorization for the emergency use of AVA is the first time that the EUA authority is being used. FDA intends to explain clearly the reasons for each issuance, termination, or revocation of an EUA. The agency wishes to make its decision-making understandable to help ensure that members of the public, and particularly those individuals who may be eligible to receive a medical product authorized for emergency use, are informed about the basis of an EUA determination. The amount of information that will be provided regarding each authorization will depend on the circumstances of the emergency. We anticipate that in some circumstances, an EUA will be issued very quickly, and time may not permit the agency to prepare supplementary documents beyond the letter of authorization and the notice required by section 564(h)(1) of the act. Other circumstances may afford greater opportunity to produce materials in addition to those prepared and disseminated as a condition of authorization under section 564(e) of the act. Thus, the amount of additional information that we will provide will necessarily vary on a case-by-case basis. The agency will publish notice of each EUA and intends also to make the notice and certain supplementary

information available on its website and in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, which is open to the public between 9 a.m. and 4 p.m., Monday through Friday.

Because the statute is self-executing, FDA does not require regulations or guidance to implement the EUA authority. However, we believe that it would be helpful for stakeholders and the public to have more information about the EUA authority, and the process that the agency is proposing to adopt for the consideration of EUA requests. Accordingly the agency is planning to issue draft guidance on this topic in the near future.

IV. Electronic Access

An electronic version of this notice and the full text of the Authorization are available on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm.*

V. The Authorization

Having consulted with NIH and CDC, and having concluded that the criteria for issuance of this Authorization under section 564(c) of the act are met, FDA has 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. The Authorization follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

William Winkenwerder, Jr., M.D.

Assistant Secretary of Defense for Health Affairs

The Pentagon

Washington, D.C. 20301–1200

Re: Request for 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 December 22, 2004, requesting that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) regarding the use of Anthrax Vaccine Adsorbed (AVA) for the prevention of inhalational anthrax, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act).

On December 10, 2004, pursuant to section 564(b)(1)(B) of the Act, 21 U.S.C. § 360bbb–3(b)(1)(B), 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.[1] On January 14, 2005, pursuant to section 564(b) of the Act, and on the basis of such determination, Secretary of Health and Human Services, Tommy G. Thompson declared an emergency justifying the authorization of the emergency use of AVA. Having consulted with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), and having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I

[1] You state in your letter that the Deputy Secretary of Defense has assigned authority from the Secretary of Defense to make the statutory determination under section 564(b)(1)(B) of the Act.

am authorizing the emergency use of AVA for prevention of inhalation anthrax,[2] subject to the conditions established herein.[3]

I. Background

AVA was first licensed by NIH in November 1970.[4] 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.[5] Under this review, independent advisory panels evaluated the safety and effectiveness data of vaccines to assure 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).[6]

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,[7] FDA published a final rule and final order in response to the report and recommendations of the

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[2] The Secretary of Health and Human Services has delegated his authority to issue an EUA under section 564 to the FDA Commissioner.

[3] The terms "inhalation anthrax" and "inhalational anthrax" are used interchangeably.

[4] Biological products are licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

[5] *See* 21 C.F.R. § 601.25.

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

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

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.[8] 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.

II. Criteria for Issuance of Authorization

Having considered the December 10, 2004, determination by the Deputy Secretary of Defense that there is a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax, and the January 14, 2005, declaration of emergency by the Secretary of Health and Human Services, and after consultation with NIH and CDC, I have concluded that the use of AVA to prevent inhalation anthrax meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

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

(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.[9]

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. The fatality rate for inhalation anthrax in the United States is estimated to be approximately 45 percent to 90 percent. From 1900 to October 2001, there were 18 identified cases of inhalation anthrax in the United States, the latest of which was reported in 1976, with an 89 percent (16/18) mortality rate. Most of these exposures occurred in industrial settings, i.e., textile mills. From October 4, 2001, to December 5, 2001, a total of 11 cases of inhalation anthrax linked to intentional dissemination of *Bacillus anthracis* spores were identified in the United States. Five of these cases were fatal. These fatalities occurred despite aggressive medical care, including antibiotics.

I have concluded that, based on the totality of scientific evidence available to FDA, 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,

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

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 the following:

- A well-controlled efficacy field study using an earlier version of a protective antigen-based anthrax vaccine was conducted in mill workers from 1955-1959. In a comparison of anthrax cases between the placebo and vaccine groups, including both inhalation and cutaneous cases in those who were completely vaccinated, the calculated vaccine efficacy level against all reported cases of anthrax combined was 92.5 percent (lower 95 percent CI = 65 percent). The efficacy analysis included all cases of anthrax disease regardless of the route of exposure or manifestation of disease.

- Epidemiological surveillance data on the occurrence of anthrax disease in at-risk industrial settings for the years 1962-1974 provides further supportive evidence of the effectiveness of AVA. In that time period, individuals received either AVA, or an earlier version of anthrax vaccine. Of the 24 anthrax cases that occurred in mill employees during that period, no cases occurred in those who had received the full vaccination series.

- The safety of AVA was evaluated in a 5-year (1967-1971) open-label safety study in which 15,907 doses of AVA were administered to approximately 7,000 textile employees, laboratory workers, and other at-risk individuals. Severe local reactions were reported in 0.15 percent of doses administered (24 reports). There were 150 reports (0.94 percent of doses administered) of moderate local reactions and 1,373 reports (8.63 percent of doses administered) of mild local reactions. In the same open label study, four cases of systemic reactions were reported during a 5-year reporting period

(<0.06 percent of doses administered). These reactions, which were reported to have been transient, included fever, chills, nausea, and general body aches.

- Recently (1996-1999), an assessment of safety was conducted as part of a randomized clinical study conducted by the U.S. Army Medical Research Institute of Infectious Diseases. Four of the 28 volunteers reported seven acute adverse events within 30 minutes after the subcutaneous administration of AVA. These adverse events included erythema (3), headache (2), fever (1), and elevated temperature (1). Of these events, a single patient reported the simultaneous occurrence of headache, fever, and elevated temperature (100.7°F). The most common local reactions reported after the first dose in this study were tenderness (71 percent), erythema (43 percent), subcutaneous nodule (36 percent), induration (21 percent), warmth (11 percent), and local pruritus (7 percent). Local reactions were found to occur more often in women. No abscess or necrosis was observed at the injection site.

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 is 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 scientific evidence available to FDA, 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. FDA has reviewed the scientific information available, including the studies described in Section II above, and concludes 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 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:

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

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

(3) of the alternatives to AVA that are available, and of their 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 assure 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:

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

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

Other information, as outlined in your request, 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 issue of mandatory vaccination will be reconsidered by DoD after FDA completes its administrative process, which DoD expects to occur later this year.[10]

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

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. FDA has reviewed DoD's trifold brochure, submitted on January 19, 2005, and concludes that this brochure meets 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 6 months from the date of issuance. However, this EUA may be extended within the duration of the declaration of emergency if the criteria under section 564(c) of the Act for issuance of such authorization are still met. Moreover, the EUA will cease to be effective when the declaration of emergency is terminated under section 564(b) of the Act or the EUA is revoked under section 564(g) of the Act.

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

Sincerely,

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

Dated: 1/28/05
January 28, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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

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