SOPP 8010: Administrative Procedures for Emergency Use Authorization of Medical Products

Version #1

Effective Date: August 3, 2005

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1. Purpose

The purpose of this document is to describe the administrative procedures for authorizing the use of an unapproved product or for the unapproved use of an approved medical product (Emergency Use Authorization [EUA]) based on a declaration of an emergency by the Secretary of Health and Human Services.

2. Definitions

Emergency Use Authorization (EUA)

The EUA is an authorization by the Food and Drug Administration (FDA) for the use of medical products, i.e., an unapproved product or for the unapproved use of an approved product, when an emergency or a potential emergency exists.

A pre-EUA is a submission sent to FDA for review prior to the determination of an actual or potential emergency in order to reduce the time needed during an emergency to review the submission and consider authorization of the product.

3. Background

Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act (FD&C Act) was amended by the Project BioShield Act of 2004 to allow the Secretary of Health and Human Services (Secretary) to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency. The EUA may authorize an emergency use of an unapproved product or an unapproved use of an approved product. Before an EUA may be issued by FDA, the Secretary must declare an emergency justifying the authorization based on:

- A determination by the Secretary of Homeland Security that there is a domestic emergency or a significant potential for an emergency that involves a heightened risk of attack with a specified biologic, chemical, radiological or nuclear agent or agents, **or**
- A determination by the Secretary of Defense that there is a military emergency or a significant potential for an emergency that involves a heightened risk of attack with a specified biologic, chemical, radiological or nuclear agent or agents, **or**
- A determination by the Secretary of Health and Human Services of a public health emergency under section 319 of the Public Health Service Act (PHS Act) that affects or has the 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(s).

Once the Secretary declares an emergency, FDA may then authorize the emergency use of a particular product if the other statutory criteria and conditions are met. Based on the particular circumstances, the process for authorization can be expected to range in duration from hours to days. The Secretary has delegated his authority to issue an EUA under section 564 of the FD&C Act to the FDA Commissioner.

Section 564 states that a declaration of emergency will terminate one year after issuance or earlier if the Secretary determines that the circumstances that prompted the declaration have ceased. The Secretary must provide advance notice of termination sufficient to allow for disposition of unapproved product or any labeling or other information provided related to an unapproved use of an approved product. A declaration may be renewed at the discretion of the Secretary.

Criteria for issuance of an EUA for a medical product include:

- The agent specified in the declaration of emergency can cause a serious or life-threatening disease or condition;
- It is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition;
- The known and potential benefits 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;
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such serious or life-threatening disease or condition; and
- Any other criteria required by regulation.

Conditions of Authorization include:

- Health care providers or authorized dispensers administering the product are informed: 1) that FDA has authorized the emergency use of the product; 2) of the significant known and potential benefits and risks of the EUA product and the extent to which such benefits and risks are unknown; and, 3) of the available alternatives and their benefits and risks;
- Recipients of the product are informed: 1) that FDA has authorized emergency use of the product; 2) of the significant known and potential risks and benefits of the EUA product and the extent to which such benefits and risks are unknown; 3) of the option to accept or refuse administration of the product and consequences of refusing; and, 4) of available alternatives and their benefits and risks;
- Adverse event monitoring and reporting to FDA for EUA products;
- Maintaining records regarding the number of doses, devices, etc., that have been shipped or sold, the name and addresses of the facilities where the product was shipped, and relating to the monitoring of patients who have been administered the product; and,
- Any other conditions the Agency determines are appropriate and practicable given the circumstances of the emergency.

The Secretary/FDA will publish in the Federal Register each declaration of emergency, EUA issuance, advance notice of termination, and renewal.

4. Policy

It is CBER policy that:

1. EUAs, in general, will be:
    a. Administratively processed using Investigational New Drug (IND) review procedures, i.e., Managed Review Process;
    b. No Form FDA-1571 is required for EUAs or pre-EUAs;
    c. Tracked in BIRAMS with a BIRAMS number;
    d. Scientifically reviewed in accordance with the Emergency Use Authorization of Medical Products Guidance (Appendix 1); and
    e. Documented using specific EUA letter templates found on the CBER Review Template Letters web page.

    Note: During an emergency, non-critical administrative steps may be conducted retroactively with the exception of recommendations and management decisions for/against authorization.

2. When an investigational or marketing application is under review at CBER **and** a pre-EUA has been submitted for the same product with the potential for emergency use authorization, i.e., the product may be needed for use in an emergency **before** approval of the license/marketing application, the review team will concurrently review the product, both under its IND and under its pre-EUA submissions, to promote readiness should an emergency arise.
    a. If the sponsor has submitted a pre-EUA embedded in an investigational or marketing submission, then the review should continue but the sponsor should be notified to send in a separate submission for the pre-EUA and cross-reference appropriate IND/IDE numbers. Once received, the Application Division should then send an acknowledgement letter to the firm with the newly assigned EUA number, cross referencing the IND/IDE.
3. When the Secretary of Health and Human Services declares that an emergency exists potentially justifying an EUA, all affected Center personnel will prioritize and maximize activity to review and act on the EUA request in the most expeditious manner. All Center management in the review sign-off process must be proficient at using electronic signatures to accommodate signing off of an EUA action with maximum efficiency. This includes branch/laboratory chiefs up to the Center Director.
4. When an EUA request has been made to CBER for a CBER regulated product, CBER will be responsible for the overall coordination of responding to the request, with the exception that the Office of the Commissioner will determine the feasibility of consultation with NIH and CDC regarding the EUA request.

5. Responsibilities and Procedures

Note: For EUA requests received under emergency conditions, follow Procedure A. For pre-EUA requests received under non-emergency conditions, follow Procedure B.

Procedure A: Emergency Review of an EUA Request

1. When a request for Emergency Use Authorization is received by **anyone** in CBER:

    a. The person receiving the request will immediately deliver the EUA request by the most rapid means, e.g., hand-carry, email, fax, etc., to CBER's Document Control Center (DCC) for processing;

    b. DCC will immediately call to alert, then deliver, the EUA request by the most rapid means e.g., hand carry, email, fax, etc., to the appropriate Application Division for review; and

    c. The Application Division will verify that the submission is an EUA request and immediately notify by telephone the Office of the CBER Center Director of the receipt of the request (301-827-0636/0372).

2. The Center Director, or his designee, will immediately notify the Office of the Commissioner (301-827-2410) of the receipt of the request (if the request was not transferred to CBER from the Office of the Commissioner). The Center Director will determine if the Commissioner will be coordinating interagency consults and convey that information to the Application Division Director.

3. The Application Division will process the EUA request according to the above policy and treat it administratively as if it were an IND submission.

4. Note: In an emergency, processes and communication will be conducted at a pace proportionate to the emergency.

5. The Review Team will:

    a. Include all appropriate review disciplines including the Division of Epidemiology to assure that postmarketing strategies are fully considered prior to issuing the EUA;

    b. Consult with outside agencies according to the direction of the CBER Center Director;

    c. Consult within CBER and with Advisory Committee members and other FDA Centers as appropriate;

    d. Review and take action on the request based on the Emergency Use Authorization of Medical Products Draft Guidance (Appendix 1);

e. Issue information requests or otherwise correspond with the sponsor using template letters specific to EUAs found on the CBER Letter Template Page (Review), when the situation permits;

f. Prepare a review package in accordance with the Content of Review Memoranda (Appendix 2) to facilitate and expedite upper management review/approval; and

g. Consider conditions to impose on authorization, as appropriate.

6. When the review is complete, the Application Division will:

   a. Complete a sign-off package recommending or not recommending authorization including the appropriate template letter specific to EUAs found on the CBER Review Letter Template Web page;

   b. Include the additional correspondence described in 4.e. above;

   c. Include as appropriate,

      1. a talk paper and/or

      2. a press release and/or

      3. web posting forms and information; and,

   d. Obtain written concurrence from the Office Director and the CBER Center Director.

7. The Center Director will telephone alert and then hand deliver or otherwise immediately deliver the sign-off package to the Commissioner's Office, including electronic copies (i.e., CD-ROM, forward via email, etc.) of all documents in the sign-off package to facilitate editing by the Commissioner, if necessary.

8. The Application Division will:

   a. Obtain a copy of the signed letter issued by the Commissioner;

   b. Obtain copies of any associated documentation generated by the Commissioner, and

   c. File these documents and the completed sign-off package in the CBER file.

9. The CBER Associate Director for Policy will ensure that a Federal Register notice describing the action taken is prepared and forwarded to the Office of the Commissioner concurrently with or as soon as possible after the Commissioner issues the EUA letter.

Procedure B: Non-Emergency Review of a pre-EUA submission (prior to declaration of emergency):

Note: When a pre-EUA submission is received under non-emergency conditions (an emergency has not been declared), the following procedure applies:

10. For a pre-EUA received concurrently with the IND/IDE:

    a. If needed, notify DCC that the pre-EUA has been submitted and request a new BIMS number for the pre-EUA.

    b. Cross-reference both the pre-EUA and the appropriate INDs/IDEs in BIMS.

    c. Enter CBER generated pre-EUA documentation under the pre-EUA BIMS number and enter the CBER generated IND documentation under the IND BIMS number.

    d. Notify appropriate personnel of the receipt of the pre-EUA by emailing the CBER Counterterrorism Contact.

    e. If the extra review of the pre-EUA could cause the review of the IND/IDE to exceed 30 days, then the review of the pre-EUA portion can be suspended until the IND/IDE review is completed. The EUA review should resume immediately after the completion of the IND/IDE review.

    f. When the pre-EUA review is complete and supervisory concurrence has taken place, notify the Office of the Center Director (Counterterrorism Contact) of the status: authorizable or not authorizable (depending on the circumstances of a future declared emergency) and file the review in DCC and/or the EDR. If the status is "deficient (not authorizable)" due to lack of sufficient information, prepare the appropriate template letter specific to pre-EUAs/EUAs found on the CBER Review Letter Template web page and send to the sponsor.

    g. If an emergency is declared after the completion of the pre-EUA review, the product was deemed to be authorizable and the sponsor of the pre-EUA has requested an EUA, then proceed with Step 5, Procedure A, above.

11. For a stand-alone pre-EUA, with no associated IND/IDE submitted:

    a. Begin the review procedure at Procedure B, Step 1.c.

6. Effective Date

August 3, 2005

7. History

Written/Revised	Approved	Approval Date	Version Number	Comment
CTCCC	Robert A. Yetter, PhD	August 3, 2005	1	Original

Appendices

- Emergency Use Authorization of Medical Products [Appendix 1]
- Content of Review Memoranda for Management Review Package (PDF - 11KB) [Appendix 2]