DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0386]

Agency Emergency Processing Under the Office of Management and Budget Review; Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a notice that published in the **Federal Register** on January 26, 2005 (70 FR 3712).

DATES: This notice is withdrawn on February 24, 2005.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 26, 2005, FDA published a notice informing interested parties that the proposed collection of information entitled ''Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice'' had been submitted to the Office of Management and Budget (OMB) for processing in compliance with (44 U.S.C. 3507(j), of the Paperwork Reduction Act of 1995 and 5 CFR 1320.13). The notice contains a number of errors. Therefore, we are withdrawing both the notice itself and the request for OMB approval of the proposed collection of information.

Dated: February 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–3596 Filed 2–23–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0056]

Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated November 2004. The guidance document provides medical device manufacturers with information about performing studies to support modifying the indication for use of communicable disease tests to include testing of cadaveric blood specimens to screen donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The guidance document recommends a suggested protocol to modify the indication for use to include testing of cadaveric blood specimens.

DATES: Submit written or electronic comments on agency guidances at any time. In accordance with 21 CFR 10.115(g)(4)(i), FDA is immediately implementing this guidance.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Kathleen E. Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated November 2004. The guidance document provides information to medical device manufacturers of communicable disease tests used to screen donors of HCT/Ps for communicable diseases who plan to perform studies to validate the use of cadaveric blood specimens with their tests. The guidance supercedes the May 2, 1995, letter issued by FDA to manufacturers of communicable disease tests suggesting a minimum protocol for validation of use of cadaveric blood specimens with their donor screening tests.

The guidance recommends a minimum suggested protocol to validate an indication for use of cadaveric blood specimens with communicable disease tests used to screen donors of HCT/Ps. The guidance makes recommendations about: (1) Sensitivity and specificity studies, (2) reproducibility studies, (3) number of test kit lots to include in studies, (4) plasma dilution issues, and (5) information about specimen collection times to be included.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except

that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–3592 Filed 2–23–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0528]

Draft Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms'' dated February 2005. The draft document is intended to provide guidance to manufacturers using spore-forming microorganisms in the production of certain biological products. The draft guidance document provides recommendations to industry in response to changes made to the requirements for spore-forming microorganisms to allow greater flexibility in manufacturing.

DATES: Submit written or electronic comments on the draft guidance by May 25, 2005, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms'' dated February 2005. The draft document is intended to provide guidance to manufacturers using spore-forming microorganisms in the production of certain biological products. The draft guidance document provides recommendations to industry in response to changes made to the requirements for spore-forming microorganisms to allow greater flexibility in manufacturing.

In the **Federal Register** of December 30, 2003, FDA published the direct final rule entitled ''Revision of the Requirements for Spore-Forming Microorganisms'' (68 FR 75116) and the accompanying proposed rule entitled ''Revision of the Requirements for Spore-Forming Microorganisms; Companion to Direct Final Rule'' (68 FR 75179) to modify the regulatory requirements for the manufacturing of biological products with spore-formers to allow greater manufacturing flexibility. The modifications were intended to provide alternatives to the then-existing requirements for separate, dedicated facilities and equipment for work with spore-forming microorganisms. In the **Federal Register** of May 14, 2004 (69 FR 26768), FDA published the ''Revision of the Requirements for Spore-Forming Microorganisms; Confirmation of Effective Date'' confirming the effective date of June 1, 2004, for the direct final rule.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–3593 Filed 2–23–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections