

ACF will notify unsuccessful applicants after the award is issued to the successful applicant.

2. Administrative and National Policy Requirements

Grantees are subject to the requirements in 45 CFR Part 74 (non-governmental) or 45 CFR Part 92

Special Terms and Conditions of Awards: None.

3. Reporting Requirements

All grantees are required to submit semi-annual program reports with a final report due 90 days after the project end date. Grantees are also required to submit semi-annual expenditure reports using the required financial standard form (SF-269) with a final report due 90 days after the project end date. A suggested format for the program report will be sent to all grantees after the awards are made.

Special Reporting Requirements: None.

VII. Agency Contacts

Program Office Contact: Dr. Margaret Washnitzer, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Meyer Drive, Suite 300, Arlington, Virginia 22209, E-Mail: OCS@lcgnet.com, Phone: 1-800-281-9519.

Grants Management Office Contact: Barbara Ziegler Johnson, Team Leader, Office of Grants Management, Division of Discretionary Grants, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Meyer Drive, Suite 300, Arlington, Virginia 22209, E-Mail: OCS@lcgnet.com, Phone: 1-800-281-9519.

VIII. Other Information

Additional information about this program and its purpose can be located on the following Web site: <http://www.acf.hhs.gov/programs/ocs>.

Dated: April 27, 2004.

Clarence H. Carter,

Director, Office of Community Services.
[FR Doc. 04-10085 Filed 5-3-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0182]

Draft Guidance for Industry on Combination Products, Timeliness of Premarket Reviews, Dispute Resolution; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Combination Products, Timeliness of Premarket Reviews, Dispute Resolution Guidance." The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) delegates to the Office of Combination Products (OCP) responsibility for resolving disputes about the timeliness of premarket review of combination products. This guidance document provides information about presenting requests for resolution of disputes about the timeliness of premarket review of combination products.

DATES: Submit written or electronic comments on the draft guidance by July 6, 2004. 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 Combination Products, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Suzanne O'Shea, Office of Combination Products (HFG-3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301-827-9229; or

Sheryl Lard-Whiteford, Center for Biologics Evaluation and Research (HFM-4), 1401 Rockville Pike, Rockville, MD 20857, 301-827-5413; or

Les Weinstein, Center for Devices and Radiological Health (HFZ-5), 9200 Corporate Blvd., Rockville, MD 20850, 301-827-7991; or

Warren Rumble, Center for Drug Evaluation and Research, 5515 Security Lane, suite 500, Rockville, MD 20852, 301-594-5480.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Combination Products, Timeliness of Premarket Reviews, Dispute Resolution Guidance." MDUFMA delegated to OCP responsibility for resolving disputes about the timeliness of reviews of premarket applications covering combination products. This guidance document provides information on how an applicant submitting an application(s) covering a combination product can submit a request that OCP resolve such a dispute.

A timeliness dispute arises when FDA does not review and act on an applicant's combination product application within the applicable performance goal set by the Prescription Drug User Fee Act (PDUFA) or MDUFMA. Under PDUFA and MDUFMA, it is not expected that every application will meet every performance goal. Applications covering combination products in particular often present challenging review and regulatory issues. Nevertheless, because the PDUFA and MDUFMA performance goals reflect current review time expectations, it is appropriate to use them as guidelines.

The purpose of a timeliness dispute resolution request is to obtain the relevant review as quickly as possible, rather than to impose any sanction on the reviewing Center. In keeping with this perspective, upon receipt of a request for resolution of a timeliness dispute, OCP will contact the Center reviewing division and the Center Ombudsman to determine the current status of the review and what OCP can do to facilitate completion of the review as quickly as possible. If necessary and feasible, a plan for the completion of the review, including a target date for completion, will be developed.

This 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 combination products, timeliness of premarket reviews, and dispute resolution. 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 submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, 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. 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 document at either <http://www.fda.gov/oc/combinaton/default.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: April 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-10027 Filed 5-3-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Directorate of Science and Technology; Notice of Meeting of Homeland Security Science and Technology Advisory Committee

AGENCY: Office of the Under Secretary for Science and Technology; Department of Homeland Security.

ACTION: Notice.

SUMMARY: The Homeland Security Science and Technology Advisory Committee (HSSTAC) will meet in a partially closed session in New York, NY on May 20 & 21, 2004.

DATES: The HSSTAC will meet in closed session on May 20, 2004, from 7:30 a.m. to 5 p.m. and on May 21, 2004 from 8:15 a.m. to 12 p.m. HSSTAC will meet in open session on May 21, 2004 from 12:45 p.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Craig Wilson, Homeland Security Science and Technology Advisory

Committee, Department of Homeland Security, Directorate of Science and Technology, Washington, DC 20528; telephone (202) 205-5041; e-mail HSSTAC@dhs.gov.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App. 2). The HSSTAC will meet for purposes of: (1) Receiving briefings and examining initiatives and activities sponsored by the Directorate of Science and Technology; (2) receiving briefings on specific portfolios and activities from among the complement of the Directorate's portfolios and activities; (3) receiving a briefing on challenges for the Department; and (4) receiving status reports from HSSTAC subcommittees and discussing future committee actions. This meeting will be partially closed in compliance with Section 10(d) of FACA and Subsection (c) of 5 U.S.C. 552b, the Government in the Sunshine Act. The open portions of the meeting for purposes of (3) and (4) above will be held in the Environmental Measurement Laboratory from 12:45 p.m. to 4:30 p.m. on May 21, 2004. The Environmental Measurement Laboratory is located at 201 Varick Street, New York, NY 10014. The closed portions of the meeting, for purposes of (1) and (2) above will be held at various locations from 7:30 a.m. to 5 p.m. on May 20, 2004, and from 8:15 a.m. to 12 p.m. on May 21, 2004.

Public Attendance: Due to meeting space capacity restrictions, the maximum amount of public attendees will be twenty-five. Members of the public will be registered to attend the public session on a first-come, first-served basis per the procedures that follow. Any member of the public who wishes to attend the public session must provide his or her name, affiliation, social security number, and date of birth no later than 5 p.m. e.s.t., Monday, May 10, 2004. Please provide the required information to Craig Wilson via e-mail at HSSTAC@dhs.gov, or via phone at (202) 205-5041. Persons with disabilities who require special assistance should indicate so in their admittance request. Photo identification

will be required for entry into the public session, and everyone in attendance must be present and seated by 12:30 p.m. on May 21, 2004.

Basis for Closure: In accordance with section 10(d) of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App. 2), the Under Secretary for Science and Technology has issued a determination that portions of this HSSTAC meeting will concern matters sensitive to homeland security within the meaning of 5 U.S.C. 552b(c)(1)(a), (c)(7) and (c)(9)(B) and that, accordingly, these portions of the meeting will be closed to the public.

Public Comments: Members of the public who wish to file a written statement with the HSSTAC may do so by mail to Craig Wilson at the following address: Homeland Security Science and Technology Advisory Committee, Department of Homeland Security, Directorate of Science and Technology, Washington, DC 20528. Comments may also be sent via e-mail to HSSTAC@dhs.gov or via fax at (202) 772-9916.

Dated: April 29, 2004.

Charles E. McQueary,

Under Secretary for Science and Technology, Department of Homeland Security.

[FR Doc. 04-10226 Filed 5-3-04; 8:45 am]

BILLING CODE 4410-10-M

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Notice of Cancellation of Customs Broker National Permit

AGENCY: Bureau of Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: General notice.

SUMMARY: Pursuant to section 641 of the Tariff Act of 1930, as amended, (19 U.S.C. 1641) and the Customs Regulations (19 CFR 111.51), the following Customs broker national permits are canceled without prejudice.

Port	Permit No.	Name
Savannah	99-00012	D.J. Powers Company, Inc.
New York	99-00017	Freight Brokers International, Inc.
Minneapolis	99-00024	Lynx International, Inc.
Cleveland	99-00033	AW Fenton Company, Inc.
Champlain	99-00041	Trans-Border Customs Services, Inc.
Cleveland	99-00068	UPS Customhouse Brokerage, Inc.
Tampa	99-00073	Corie Louise Hall.
El Paso	99-00096	Rudolph Miles & Sons, Inc.
New York	99-00098	Rennie B. Alston.
Los Angeles	99-00111	Yamato Customs Brokers USA, Inc.