

on this project along the US-Mexican border, by virtue of its extensive experience combating human trafficking, and its extensive institutional presence in that region. BSCC, a coalition of over 40 government and nonprofit agencies in the United States and Mexico, is the only bilateral project devoted to addressing the transient nature of human trafficking (anywhere in the world). BSCC will utilize its singular network of relationships with organizations in Mexican border communities to its implement this project, and will draw on its well-established public awareness and educational expertise, which focuses on "prevention" through community outreach to at-risk populations and groups, and "intervention" by educating and training legal and law enforcement personnel to locate and intervene in trafficking situations.

World Vision is deemed to be the only organization that has implemented a targeted international media campaign in partnership with travel and tourism companies and national governments targeting would-be sex tourists in destination countries with deterrent anti-trafficking messages. The project's ad campaign, designed to deter Americans who exploit children in the commercial sex trade overseas, now is placed in multiple media, including in-flight videos, billboards and street signs, printed ads in local tourist publications, and internet banner ads. World Vision has successfully implemented this anti-sex tourism project in Cambodia, Thailand and Costa Rica, drawing on its long-term presence on-the-ground in these countries, which helped it to establish extensive relationships with governments and local media companies. In addition to having the programmatic model for addressing sex tourism, World Vision is the only organization that possesses the capability and the institutional capacity to implement this same program simultaneously in Brazil and Mexico. World Vision has been operational in both countries for more than 40 years, and through this long-term presence on-the-ground, World Vision has established extensive relationships with governments and local media in these two countries as well. World Vision has the unique ability to effectively implement this program of its own design within in the very short time constraints of this project.

For more information regarding these awards, contact: Dr. Nguyen Van Hanh, Director, Office of Refugee Resettlement, Administration for Children and Families, 901 D Street, SW., 6th Floor

East, Washington, DC 20447, (202) 401-9246.

Dated: May 17, 2005.

Nguyen Van Hanh,

Director, Office of Refugee Resettlement.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0263]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified By the Environmental Protection Agency

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Channels of Trade Policy for Commodities with Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of October 28, 2003 (68 FR 61444), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0562. The approval expires on May 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: May 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 13 and 14, 2005, from 8:30 a.m. to 5 p.m. and on July 15, 2005, from 8:30 a.m. to 12 noon.

Location: Greenbelt Marriott Hotel, 6400 Ivy Lane Grand Ballroom, Greenbelt, MD.

Contact Person: Marcia L. Moore, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2397, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014510564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Food Advisory Committee is being asked to evaluate the Center for Food Safety and Applied Nutrition Threshold Working Group draft report "Approaches to Establish Thresholds for Major Food Allergens and Gluten." On July 13, 2005, the committee will discuss the draft report's approaches for food allergen thresholds. On July 14, 2005, the committee will discuss the draft report's approaches for gluten thresholds. On July 15, 2005, based on the charge and questions from FDA, the committee will determine whether the report is scientifically sound in its analyses and approaches and adequately considers available relevant data on allergens and gluten.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending

before the committee. Written submissions may be made to the contact person by July 8, 2005. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. on July 13 and 14, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 8, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Marcia Moore at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 16, 2005.

Sheila Dearybury Walcott,

Associate Commissioner for External Relations.

[FR Doc. 05-10251 Filed 5-20-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0467]

"Guidance for Industry: Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection;" 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: Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection," dated May 2005. The guidance document removes FDA's previous recommendation concerning deferral on the basis of a specific donor question related to West Nile Virus (WNV) infection. This

guidance pertains solely to this specific donor deferral recommendation; all other recommendations in the

"Guidance for Industry:

Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection," dated May 2003 remain in effect. This guidance applies to Whole Blood and blood components intended for transfusion, and blood components intended for use in further manufacturing into injectable products or noninjectable products, including recovered plasma, Source Leukocytes and Source Plasma. This guidance has an immediate implementation date due to the approaching season during which an outbreak of WNV can occur.

DATES: Submit written or electronic comments on agency guidances at any time.

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, Food and Drug Administration, 1401 Rockville Pike, suite 200N, 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:

Astrid Szeto, 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: Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection," dated May 2005. The guidance document removes FDA's previous recommendation to defer donors each year between June 1 and November 30 when the donor reports a history of fever with headache in the past week. We no longer recommend

asking this question as it relates to WNV. This donor deferral was originally recommended in the "Guidance for Industry:

Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection." Since the issuance of this May 2003 guidance, new data were presented at the October 22, 2004, Blood Products Advisory Committee Meeting indicating that self-reported fever with headache in the past week did not appear to be predictive of WNV infection and did not correlate with peak periods of WNV incidence as determined by WNV nucleic acid test prevalence in the donor pool.

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. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The information collection provisions in this guidance for 21 CFR 601.12 have been approved under OMB control number 0910-0338.

III. Comments

FDA is soliciting public comment, but is implementing this guidance immediately because the agency has determined that prior public participation is not feasible or appropriate. This is because blood establishments need to establish suitable standard operating procedures as soon as possible in preparation for the approaching season during which an outbreak of WNV can occur. 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