

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

### National Center for Infectious Diseases (NCID); Meeting

The National Center for Infectious Diseases (NCID), Hepatitis Branch of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

*Name:* Consultant Meeting to Update Recommendations for the Prevention and Control of Blood-Borne and other Pathogens in Hemodialysis Settings.

*Times and Dates:* 8 a.m.-5 p.m., October 5, 1999; 8 a.m.-5 p.m., October 6, 1999.

*Place:* Holiday Inn Select, 130 Clairmont Avenue, Decatur, Georgia, 30030 telephone 404/371-0204.

*Status:* Open to the public, limited only by the space available. Registration required. See contact person for more information. The meeting room accommodates approximately 150 people.

*Purpose:* The purpose of this working meeting is to review and discuss draft recommendations that will serve as a resource to individuals and organizations involved in prevention and control of blood-borne and other pathogens in hemodialysis settings.

*Matters To Be Discussed:* Participants will discuss recommendations for infection control and other practices to prevent transmission of hepatitis B virus, hepatitis C virus, and bacteria such as methicillin-resistant staphylococcus aureus (MRSA) and vancomycin-resistant enterococci (VRE) in hemodialysis settings.

The agenda will include an overview of issues related to prevention of transmission of these agents and management of infected patients in hemodialysis centers and work group sessions on current and updated recommendations for infection control practices including screening, vaccination, standard and dialysis unit precautions, isolation, and cleaning and disinfection.

The participants will consist of representatives from public, private, voluntary and non-governmental organizations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person(s) listed below prior to the opening of the meeting.

*Contact Person for More Information:* Mr. Wesley Hodgson or Mr. Rob Lyerla, Hepatitis Branch, NCID, CDC, M/S G-37, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-3048.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 2, 1999.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 99-20261 Filed 8-5-99; 8:45 am]

BILLING CODE 4163-18-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. 99N-0192]

### Agency Information Collection Activities; Announcement of OMB Approval; Infant Formula Recall Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Infant Formula Recall Regulations" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 17, 1999 (64 FR 26765), 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 0910-0188. The approval expires on July 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at "<http://www.fda.gov/ohrms/dockets>".

Dated: August 2, 1999

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 99-20258 Filed 8-5-99; 8:45 am]

BILLING CODE 4160-01-F

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. 99F-2535]

### Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp. has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with *o*-xylene as an antioxidant and/or stabilizer in olefin polymers, adhesives, pressure-sensitive adhesives, and ethylene-vinyl acetate copolymers intended for use in contact with food.

**FOR FURTHER INFORMATION CONTACT:** Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4680) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591-9005. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with *o*-xylene as an antioxidant and/or stabilizer for olefin polymers complying with § 177.1520, adhesives complying with § 175.105, pressure-complying with § 177.1520, adhesives complying with § 175.105, pressure-sensitive adhesives complying with § 175.125 and ethylene-vinyl acetate copolymers complying with § 177.1350 intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 13, 1999.

**Laura M. Tarantino,**

*Deputy Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.*

[FR Doc. 99-20256 Filed 8-5-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Amoxicillin Injection for Sheep; Availability of Data

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of effectiveness, target animal safety, and human food safety data that may be used in support of a new animal drug application (NADA) or supplemental NADA for veterinary prescription use of amoxicillin injection for treatment of bacterial pneumonia in sheep. The data, contained in Public Master File (PMF) 5433, were compiled under National Research Support Project-7 (NRSP-7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses.

**ADDRESSES:** Submit NADA's or supplemental NADA's to the Document Control Unit (HFV-199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

**FOR FURTHER INFORMATION CONTACT:** Naba K. Das, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7569.

**SUPPLEMENTARY INFORMATION:** Amoxicillin injection, used for the treatment of sheep for bacterial pneumonia due to *Pasteurella* spp. and *Haemophilis* spp., is a new animal drug under section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, amoxicillin is subject to section 512 of the act (21 U.S.C. 360b), requiring that its uses in sheep be the subject of an approved NADA or supplemental NADA. Sheep are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

The NRSP-7 Project, Western Region, University of California, Davis, CA 95616, has provided target animal safety, effectiveness, and human food safety data for veterinary prescription use of amoxicillin injection in sheep for

treatment of bacterial pneumonia due to *Pasteurella* spp. and *Haemophilis* spp. NRSP-7 did not provide information concerning potential environmental impacts of the manufacturing process. Such information is required upon submission of an application relying on this file to support approval.

Data and information on safety and effectiveness are contained in PMF 5433. Sponsors of NADA's or supplemental NADA's may, without further authorization, reference the PMF to support approval of an application filed under § 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other information needed for approval, such as data supporting extrapolation from a major species in which the drug is currently approved or authorized reference to such data, data concerning manufacturing methods, facilities, and controls, and information addressing potential environmental impacts of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA or supplement may contact Naba K. Das (address above).

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information provided in this PMF to support approval of an application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 29, 1999.

**George A. Mitchell,**

*Acting Deputy Director, Center for Veterinary Medicine.*

[FR Doc. 99-20255 Filed 8-5-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552(c)(4) and 552b(c)(6), Title 5 U.S.C., as

amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute of Child Health and Human Development Special Emphasis Panel MSCDA (U10) NETWORK APPLICATIONS.

**Date:** August 6, 1999.

**Time:** 12:30 PM to 2:00 PM.

**Agenda:** To review and evaluate grant applications.

**Place:** 6100 Executive Blvd. 5th Floor, Rockville, MD 20852 (Telephone Conference Call).

**Contact Person:** Gopal M. Bhatnagar, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, PHS, DHHS, 9000 Rockville Pike, 6100 Bldg., Room 5E01, Bethesda, MD 20892, (301) 496-1485.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: August 2, 1999.

**Anna Snouffer,**

*Acting Committee Management Officer, NIH*

[FR Doc. 99-20286 Filed 8-5-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; Notice of Closed Meeting

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The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which