Please check the NCVHS website, where a detailed agenda will be posted prior to the meeting.

Contact Person for More Information: Substantive information as well as summaries of NCVHS meetings and a roster of committee members may be obtained by visiting the NCVHS website (http://aspe.os.dhhs.gov/ncvhs) where an agenda for the meeting will be posted when available. Additional information may be obtained by calling James Scanlon, NCVHS Executive Staff Director, Office of the Assistant Secretary for Planning and Evaluation, DHHS, Room 440–D. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201, telephone (202) 690–7100, or Majorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050.

Note: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, individuals without a government identification card may need to have the guard call for an escort to the meeting room.

Dated: August 21, 1998.

James Scanlon,

Director, Division of Data Policy.

[FR Doc. 98–23042 Filed 8–26–98; 8:45 am]

BILLING CODE 4151–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Vaccine Advisory Committee Meeting

The National Vaccine Advisory Committee, Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: National Vaccine Advisory Committee (NVAC) Immunization Registries Workgroup.

Time and Date: 8 a.m.–5 p.m., September 2, 1998.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue, Washington, DC 20036, 202/347–3000.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 30 people.

Purpose: To discuss and explore the development of a Plan of Action for community and state based immunization registries.

Matters to be Discussed: Agenda items will include and address the following: themes and issues identified during public meetings; special issues such as Immigration and Naturalization Services, Privacy and Confidentiality; Plan of Action (format, goals/recommendations and roles); and an outline of a timeline.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Robb Linkins, Ph.D., M.P.H., Chief, Systems Development Branch, Data Management Division, NIP, CDC, 1600 Clifton Road, NE, M/S E–62, Atlanta, Georgia 30333, telephone 404/639–8728, e-mail rxl3@cdc.gov.

Dated: August 20, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–22973 Filed 8–26–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0706]

BASF Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BASF Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2,9-bis(3,5-dimethylphenyl)anthra(2,1,9-def:6,5,10-d′e′f′)diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Red 149) as a colorant for all polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 8B4620) has been filed by BASF Corp., 3000 Continental Dr. North, Mt. Olive, NJ 07828–1234. The petition proposes to amend the food additive regulations in § 178.3297 *Colorants for polymers* to provide for the safe use of 2,9-bis(3,5-dimethylphenyl)anthra(2,1,9-def:6,5,10-d′e′f′)diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Red 149) as a colorant for all polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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: August 5, 1998.

George H. Pauli,

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

[FR Doc. 98–23032 Filed 8–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0705]

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 tris(2,4-di-*tert*-butylphenyl)phosphite as a stabilizer in polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 8B4618) has been filed by Ciba Specialty Chemicals Corp., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. 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 tris(2,4-di-*tert*-butylphenyl)phosphite as a stabilizer for polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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 31, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–23031 Filed 8–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0645]

Medical Device Warning Letter Draft Pilot; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is planning to initiate a pilot program involving the medical device industry that is a continuation of the ''medical device industry initiatives.'' This draft pilot concerns the issuance of warning letters for quality system, premarket notification submission (510(k)), and labeling violations. This draft pilot is intended to optimize resource utilization, enhance communication between industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. The draft pilot includes eligibility criteria and procedures for the issuance of warning letters and will not be implemented until after the public comment period has expired.

DATES: Written comments on the draft pilot may be submitted by October 13, 1998.

ADDRESSES: Submit written comments on the draft pilot to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft pilot.

FOR FURTHER INFORMATION CONTACT:

Device quality system warning letter draft pilot: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411, FAX 301–827–0482.

Premarket notification (510(k)) and labeling warning letter draft pilot: Chester T. Reynolds, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4618, FAX 301–594–4610.

SUPPLEMENTARY INFORMATION:

I. Background

During recent FDA/medical device industry grassroots forums, several issues were discussed concerning FDA's interaction with the medical device industry. After considering these issues, the agency plans to initiate a pilot program that will last for 18 months, and then be formally evaluated. The draft pilot includes procedures for the issuance of warning letters for quality system (21 CFR part 820), 510(k) (part 807, subpart E) (21 CFR part 807, subpart E), and labeling (e.g., 21 CFR part 800, subpart B; part 801, and part 809, subparts B and C) violations. This draft pilot is currently restricted to the medical device industry and is a continuation of the medical device industry initiatives.

FDA currently maintains contracts with the States of California, Colorado, and Texas that will expire on September 30, 1998, to conduct medical device inspections on behalf of FDA. This draft pilot does not include those inspections done under State contract for FDA. However, noncontract medical device inspections done by FDA personnel in these States will be eligible for this draft pilot.

The purpose of this draft pilot is to optimize resource utilization, enhance communication between the medical device industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. Implementation of this draft pilot will not impact on violative situations where enforcement action is necessary to protect the public health.

The medical device warning letter draft pilot is being issued as a guidance document and represents the agency's current thinking on the subject. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This pilot is being issued as a draft level 1 guidance consistent with GGP's.

The draft pilot consists of two parts that are described as follows:

I. Device Quality System Warning Letter Draft Pilot

Dates: (insert initiation and ending dates 18 months apart)

This draft pilot is restricted to the medical device industry and is a continuation of the medical device industry initiatives.

Following a domestic device quality system inspection which finds current good manufacturing practice (CGMP) deficiencies (situation 1, compliance program (CP) 7382.830—part V) that warrant a warning letter, the establishment is to be given 15 working days to respond from the issuance date of the list of inspectional observations (FDA–483). If the firm's written response to the FDA–483 is deemed to be satisfactory by the district office, then a warning letter should not be issued.

This draft pilot does not apply to:

1. Nonquality system inspections such as mammography, radiological health, and bioresearch inspections;

2. Establishments that manufacture devices as well as other FDA regulated products;

3. Establishments that manufacture devices that are regulated by the Center for Biologics Evaluation and Research (CBER);

4. Recidivous establishments as defined in CP 7382.830;

5. An inspection that uncovered CGMP, premarket notification submission (510(k)), or labeling deficiencies that may cause serious adverse health consequences;

6. A compliance followup inspection when the previous inspection resulted in a warning letter or regulatory action for quality system, 510(k), or labeling violations;

7. An inspection that disclosed other significant device violations (e.g., medical device reporting or premarket approval) in addition to quality system, 510(k), or labeling violations which warrant the issuance of a warning letter or regulatory action; or

8. A situation where the firm's management failed to make available to FDA personnel all requested information and records required by regulations or laws enforced by FDA.

If the district is essentially satisfied with the written response to the FDA–483 but needs further clarification, it may seek additional information via untitled correspondence, meetings, or telephone.

If the firm fails to respond to the FDA–483, a warning letter should be sent to the establishment once the 15 working day period has expired. If the district receives a response to the FDA–483 within 15 working days, the district has 15 working days from the receipt date to determine whether the response is satisfactory. If it is necessary for the district to consult with the Center for Devices and Radiological Health's Office of Compliance for technical assistance, the latter office has 15 working days to respond to the district and then the district has 15 working days to respond to the establishment. If the written response to the FDA–483 is determined to be unsatisfactory, the district should send a warning letter to the establishment.

When no warning letter is issued by the district office due to the firm's satisfactory written response, the postinspectional notification letter (see attachment 1 of this