Respondents	No. of respondents	No. of respondents/response	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Daily Diary with Peak Flow (Trial Period)	300	7 days	0.25	525
Compliance Calls During the Trial Period	300	2 phone calls	0.0833	50
Daily Dairy with Peak Flow (Weeks 1–6)	220	42 days	0.25	2310
Compliance Phone Calls (Week 1–6)	220	12 phone calls	0.0833	220

Dated: April 4, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–9192 Filed 4–9–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Advisory Committee on HIV and STD Prevention: Meeting

In accordance with section l0(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: CDC Advisory Committee on HIV and STD Prevention.

Times and Dates: 8:30 a.m.–4:30 p.m., May 1, 1997; 8:30 a.m.–4:30 p.m., May 2, 1997.

Place: Sheraton Colony Square Hotel, Midtown Atlanta, 188 14th Street, NE., Atlanta, Georgia 30361

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

Purpose: This committee is charged with advising the Director, CDC, regarding objectives, strategies, and priorities for HIV and STD prevention efforts including maintaining surveillance of HIV infection, AIDS, and STDs, the epidemiologic and laboratory study of HIV/AIDS and STDs, information/education and risk reduction activities designed to prevent the spread of HIV and STDs, and other preventive measures that become available.

Matters to be Discussed: Agenda items will include combined HIV and STD surveillance systems; impact of managed care on HIV and STD control efforts; prevention and treatment of persons co-infected with TB and HIV; and follow-up of CDC activities in response to the Institute of Medicine report ''The Hidden Epidemic—Confronting Sexually Transmitted Diseases.'' Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Beth Wolfe, Program Analyst, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., Mailstop E–07, Atlanta, Georgia 30333, telephone (404) 639–8008.

Dated: March 31, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–9193 Filed 4–9–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Infectious Diseases: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Board of Scientific Counselors, National Center for Infectious Diseases (NCID).

Times and Dates: 11 a.m.–5:30 p.m., May 1, 1997; 8:30 a.m.–2:30 p.m., May 2, 1997.

Place: CDC, Auditorium B, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Board of Scientific Counselors, NCID, provides advice and guidance to the Director, CDC, and Director, NCID, in the following areas: Program goals and objectives; strategies; program organization and resources for infectious disease prevention and control; and program priorities.

Matters To Be Discussed: The agenda will focus on:

1. NCID Update.
2. Scientific Updates:
   a. Opportunistic Infections
   b. CDC Genetics Initiative
   c. Vaccines
   d. Managed Care
3. Workgroup Sessions:
   a. Vaccines Issues
   b. Food Safety
   c. Blood Safety
   d. Antibiotic Resistance
   e. CDC Emerging Infections Plan 1998–2000
4. Workgroup Reports
5. Recommendations.

Other agenda items include announcements/introductions; follow-up on actions recommended by the Board in December 1996; and consideration of future directions, goals, and recommendations.

Agenda items are subject to change as priorities dictate.

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

Contact Person for More Information: Diane S. Holley, Office of the Director, NCID, CDC, Mailstop C–20, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone 404/639–0078.

Dated: March 31, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–9194 Filed 4–9–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Times and Dates: 8:30 a.m.–4:30 p.m., April 30, 1997; 8:30 a.m.–4:30 p.m., May 1, 1997.

Place: Sheraton Colony Square Hotel, Midtown Atlanta, 188 14th Street N.E., Atlanta, Georgia 30361.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: The Council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters to be Discussed: Agenda items include TB in children; TB in the foreign born; issues related to the laboratory

diagnosis of TB; impact of managed care on TB control efforts; and surveillance efforts relating to TB control. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Beth Wolfe, Program Analyst, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, M/S E–07, Atlanta, Georgia 30333, telephone 404/639–8008.

Dated: March 31, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–9195 Filed 4–9–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95F–0122]

Hempel Coatings (USA), Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 5B4457), proposing that the food additive regulations be amended to provide for the safe use of meta-xylylenediamine and 3-diethylaminopropylamine as components of articles intended for food-contact use.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 22, 1995 (60 FR 32526), FDA announced that a food additive petition (FAP 5B4457) had been filed by Hempel Coatings (USA), Inc., 6901 Cavalcade St., Houston, TX 77028. The petition proposed to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of meta-xylylenediamine and 3-diethylaminopropylamine as components of articles intended for food-contact use. Hempel Coatings (USA), Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 26, 1997.

Alan M. Rulis,

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

[FR Doc. 97–9168 Filed 4–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0029]

''Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies;'' 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 for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies.'' This document provides information regarding the manufacture and clinical study of combination vaccines. This document is intended to assist manufacturers and other interested parties with the development and licensure of combination vaccines.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies'' 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 that office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Persons with access to the Internet may obtain the document using the World Wide Web (WWW), or bounce-back e-mail. For WWW access, connect to CBER at ''http://www.fda.gov/cber/cberftp.html''. To receive the document by bounce-back e-mail, send a message to ''COMBVAC@A1.CBER.FDA.GOV''. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of this document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a document entitled ''Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies.'' In the **Federal Register** of June 25, 1993 (58 FR 34469), FDA announced the July 28 and 29, 1993, scientific workshop entitled ''Combined Vaccines and Simultaneous Administration: Current Issues and Perspectives.'' Issues discussed and information gathered in this workshop were considered in preparing this document. Prior to making this document available for industry use, FDA presented the issues discussed in this document at the October 27, 1995, Vaccines and Related Biological Products Advisory Committee meeting. FDA announced the advisory committee meeting and the availability of a draft guidance document in the **Federal Register** of October 2, 1995 (60 FR 51481 at 51482). Comments received from the meeting were considered in further preparation of this document.

For the purposes of this guidance document, a combination vaccine consists of two or more live organisms, inactivated organisms or purified antigens combined either by the manufacturer or mixed immediately before administration, and it is intended to: (1) Prevent multiple diseases, or (2) prevent one disease caused by different strains or serotypes of the same organism. Vectored vaccines and conjugated vaccines are combination vaccines, if the prevention of the disease caused by the vector organism or the carrier moiety is to be one of the combination's indication.

This guidance document discusses the approach manufacturers, sponsors, and investigators should follow in the