morbidity and mortality among patients on TPN therapy, especially among premature neonates and patients with impaired kidney function.

The information collection reporting requirements resulting from this rulemaking are as follows:

21 CFR 201.323(b)—Requires that the package insert of all LVPs used in TPN therapy state that the drug product contains no more than 25 micrograms per liter (µg/L). This information must be contained in the ''Precautions'' section of the labeling of all LVPs used in TPN therapy.

21 CFR 201.323(c)—Requires that the maximum level of aluminum present at expiry be stated on the immediate container label of all SVP drug products and PBPs used in the preparation of TPN solutions. The aluminum content must be stated as prescribed in the regulation. The immediate container label of all SVP drug products and PBPs that are lyophilized powders used in the preparation of TPN solutions must contain the statement prescribed in the regulation.

21 CFR 201.323(d)—Requires that the package insert for all LVPs, SVPs, and PBPs used in TPN contain a warning statement, prescribed in the regulation, intended for patients with impaired kidney function and for neonates receiving TPN therapy. This information must be contained in the ''Warnings'' section of the labeling.

21 CFR 201.323(e)—Requires that applicants and manufacturers must use validated assay methods to determine the aluminum content in parenteral drug products. The assay methods must comply with current good manufacturing practice requirements. Applicants must submit to FDA both validation of the method used and release data for several batches. Manufacturers of parenteral drug products not subject to an approved application must make assay methodology available to FDA during inspections. Holders of pending applications must submit an amendment to the application.

Compliance with the information collection burdens under § 201.323(b), (c), and (d) (21 CFR 201.323(b), (c), and (d)) consists of submitting application supplements to FDA containing the revised labeling for each product. Based on data concerning the number of applications for LVPs, SVPs, and PBPs used in TPN received by the agency, FDA estimates that the labeling for approximately 200 products will be changed under § 201.323(b), (c), and (d). FDA estimates that it will take approximately 14 hours to prepare and submit to FDA each labeling change. FDA estimates that approximately 65 respondents will each submit one validated assay method annually under § 201.323(e). FDA estimates that it will take approximately 14 hours to prepare and submit to FDA each validated assay.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.323(b), (c), (d)	200	1	200	14	2,800
201.323(e)	65	1	65	14	910
Total					3,710

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 13, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–31995 Filed 12–18–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Tentative Schedule of Meetings for 2003

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 2003. During 1991, at the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. In its final report, one of the IOM's recommendations was for the agency to publish an annual tentative schedule of its meetings in the **Federal Register**. This publication implements the IOM's recommendation.

FOR FURTHER INFORMATION CONTACT: Theresa Green, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: The IOM, at the request of the Commissioner, undertook a study of the use of FDA's advisory committees. In its final report in 1992, one of the IOM's recommendations was for FDA to adopt a policy of publishing an advance yearly schedule of its upcoming public advisory committee meetings in the **Federal Register**; FDA has implemented this recommendation. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. Because the schedule is tentative, amendments to this notice will not be published in the **Federal Register**. However, changes to the schedule will be posted on the FDA advisory committees' Internet site located at http://www.fda.gov/oc/advisory/default.htm. The FDA will continue to publish a **Federal Register** notice 15 days in advance of each upcoming advisory committee meeting, to announce the meeting (21 CFR 14.20).

The following list announces FDA's tentatively scheduled advisory committee meetings for 2003. You may also obtain up-to-date meeting information by calling the Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area):

Committee Name	Dates of Meetings	Advisory Committee 5-Digit Information Line Code
OFFICE OF THE COMMISSIONER		
Science Board to the Food and Drug Administration	April 9, November 6	12603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH		
Allergenic Products Advisory Committee	April 8, November 18	12388
Biological Response Modifiers Advisory Committee	February 27–28, June 9–10, October 9–10	12389
Blood Products Advisory Committee	March 13–14, June 19–20, September 18–19, December 11–12	19516
Transmissible Spongiform Encephalopathies Advisory Committee	February 20–21, July 17–18, October 30–31	12932
Vaccines and Related Biological Products Advisory Committee	February 20–21, May 8–9, September 22–23, November 19–20	12391
CENTER FOR DRUG EVALUATION AND RESEARCH		
Advisory Committee for Pharmaceutical Science	February 12–13, March 12–13, September 17, October 21–23	12539
Advisory Committee for Reproductive Health Drugs	March 24–25, August 18–19, November 13–14	12537
Anesthetic and Life Support Drugs Advisory Committee	June 26–27, December 11–12	12529
Anti-Infective Drugs Advisory Committee	January 8–9, March 4–5, June 10–11, October 15–16	12530
Antiviral Drugs Advisory Committee	April 29–30, September 19	12531
Arthritis Advisory Committee	January 30–31, September 5	12532
Cardiovascular and Renal Drugs Advisory Committee	January 6–7, May 29–30, September 15–16, December 11–12	12533
Dermatologic and Ophthalmic Drugs Advisory Committee	March 6–7, April 15–16, July 17–18, September 10–11	12534
Drug Safety and Risk Management Advisory Committee	April 24–25, September 18–19	12535
Endocrinologic and Metabolic Drugs Advisory Committee	January 13–15, June 12–13, September 11–12	12536
Gastrointestinal Drugs Advisory Committee	July 17	12538
Nonprescription Drugs Advisory Committee	March 6–7, June 13–14, September 16–17	12541

Committee Name	Dates of Meetings	Advisory Committee 5-Digit Information Line Code
Oncologic Drugs Advisory Committee	March 3–4, March 12–13, June 10–11	12542
Peripheral and Central Nervous System Drugs Advisory Committee	July 18	12543
Psychopharmacologic Drugs Advisory Committee	February 27–28, September 4–5	12544
Pulmonary-Allergy Drugs Advisory Committee	May 15–16, November 6–7	12545
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		
Food Advisory Committee	February 24–26, August 18–20	10564
Biotechnology Sub-Committee	March 24–25, October 15–16	10564
Dietary Supplements Sub-Committee	March 27–28, September 22–23	10564
Contaminants and Natural Toxicants Sub-Committee	March 6–7, September 4–5	10564
Nutrition Sub-Committee	April 28–29, November 3–4	10564
Food Additives Sub-Committee	June 19–20	10564
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		
Device Good Manufacturing Practice Advisory Committee	No meetings planned	12398
Medical Devices Advisory Committee:		
Anesthesiology and Respiratory Therapy Devices Panel	March 27–28, May 7–8, September 4–5, November 10–11	12624
Circulatory System Devices Panel	February 21–22, April 24–25, June 26–27, August 28–29, October 23–24, December 11–12	12625
Clinical Chemistry and Clinical Toxicology Devices Panel	February 10–11, May 19, September 8–9, December 11–12	12514
Dental Products Panel	February 13–14, May 22–23, August 7–8, October 9–10	12518
Ear, Nose, and Throat Devices Panel	April 8–9, June 2–3, August 4–5, October 9–10, December 4–5	12522
Gastroenterology and Urology Devices Panel	January 17, April 4, July 25, October 17	12523
General and Plastic Surgery Devices Panel	February 27–28, April 10–11, July 23–24, October 23–24	12519
General Hospital and Personal Use Devices Panel	February 27–28, May 15–16, August 18–19, November 20–21	12520

Committee Name	Dates of Meetings	Advisory Committee 5-Digit Information Line Code
Hematology and Pathology Devices Panel	March 14, June 20, October 3	12515
Immunology Devices Panel	March 17–18, June 9–10, September 15–16	12516
Medical Devices Dispute Resolution Panel	No meetings planned	10232
Microbiology Devices Panel	March 27–28, May 5–6, August 7–8, October 16–17	12517
Molecular and Clinical Genetics Panel	April 24–25, July 17–18, November 13–14	10231
Neurological Devices Panel	March 6–7, June 23–24, September 18–19, December 8–9	12513
Obstetrics and Gynecology Devices Panel	March 3–4, June 9–10, September 8–9, November 3–4	12524
Ophthalmic Devices Panel	March 13–14, May 22–23, July 10–11, September 11–12, November 6–7	12396
Orthopaedic and Rehabilitation Devices Panel	February 20–21, May 29–30, August 27–28, November 20–21	12521
Radiological Devices Panel	February 4, May 20, August 12, November 18	12526
National Mammography Quality Assurance Advisory Committee	April 7–8, September 8–9	12397
Technical Electronic Product Radiation Safety Standards Committee	June 18	12399
CENTER FOR VETERINARY MEDICINE		
Veterinary Medicine Advisory Committee	May 15, September 15	12548
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants	February 10–13, June 23–25	12560
Science Advisory Board to the National Center for Toxicological Research	June 3–5	12559

Dated: December 12, 2002.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 02–31994 Filed 12–18–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P–0127]

Determination That PHENERGAN (Promethazine Hydrochloride Injection USP) 25 Milligrams/Milliliter, 10 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that PHENERGAN (promethazine hydrochloride (HCl) injection USP) 25 milligrams (mg)/milliliter (mL), 10 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for promethazine HCl injection USP 25 mg/mL, 10 mL.