nutrition. It is also indicated in other situations where intravenous administration is required. Such situations include surgery, extensive burns, fractures and other trauma, severe infectious diseases, and comatose states, which may provoke a stress situation with profound alterations in the body's metabolic demands and consequent tissue depletion of nutrients. This product (administered in intravenous fluids under proper dilution) contributes intake of these vitamins that are necessary toward maintaining the body's normal resistance and repair processes.

The physician should not await the development of clinical signs of vitamin deficiency before initiating vitamin therapy.

Patients with multiple vitamin deficiencies or with markedly increased requirements may be given multiples of the daily dosage for 2 or more days, as indicated by the clinical status. Clinical testing indicates that some patients do not maintain adequate levels of certain vitamins when this formulation in recommended amounts is the sole source of vitamins.

(c) *Contraindications:*

Known hypersensitivity to any of the vitamins or excipients in this product or a preexisting hypervitaminosis. Allergic reaction has been known to occur following intravenous administration of thiamine and vitamin K. The formulation is contraindicated prior to blood sampling for detection of megaloblastic anemia, as the folic acid and the cyanocobalamin in the vitamin solution can mask serum deficits.

In addition, the following sections required by 21 CFR 201.57 should read as follows:

1. *Precautions:* (The following paragraph should be added and should appear in bold type.)

Caution should be exercised when administering this multivitamin formulation to patients on warfarin sodium-type anticoagulant therapy. In such patients, periodic monitoring of prothrombin time is essential in determining the appropriate dosage of anticoagulant therapy.

2. *Drug Reactions:* This section is revised to read ''Drug Interactions'' and to add aminophylline 125 mg and ampicillin 500 mg to this list.

Supplements to approved NDA's or ANDA's providing for appropriate revision of the labeling of drug products affected by this notice should be submitted on or before June 19, 2000.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 502, 505, 52 Stat. 1041, 1050–1053, as amended (21 U.S.C. 321(n), 352, 355)) and under the authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.70).

Dated: March 28, 2000.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 00–9848 Filed 4–19–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery Devices Panel of the Medical Devices 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: General and Plastic Surgery Devices Panel of the Medical Devices 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 May 8, 2000, 8 a.m. to 5 p.m.

Location: Marriott Washingtonian Center, Salons F and G, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12519. Please call the Information Line or access the Internet at http://www.fda.gov/cdrh/panelmtg.html for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on two premarket approval applications for: (1) An in situ polymerizable surgical mesh intended to be used to seal air leaks following thoracic cavity surgery; and (2) an interactive wound and burn dressing intended to be used for the treatment of diabetic foot ulcers.

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 May 1, 2000. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., 11:15 a.m. and 11:45 a.m., 1:15 p.m. and 1:45 p.m., and 4 p.m. and 4:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 1, 2000, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: April 14, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–9908 Filed 4–19–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Neurological Devices Panel of the Medical Devices 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: Neurological Devices Panel of the Medical Devices 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 May 11, 2000, 8:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, ext. 176, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12513. Please call the Information Line or access the Internet address at http://www.fda.gov/cdrh/upadvmtg.html for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations and vote on a premarket approval application for an embolization device.

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 April 24, 2000. Oral presentations from the public will be scheduled between approximately 9 a.m. and 9:30 a.m., and 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 24, 2000, 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.

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

Dated: April 14, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–9909 Filed 4–19–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

State Prevention Needs Assessments: Alcohol and Other Drugs, Cohort V

(New)—SAMHSA's Center for Substance Abuse Prevention (CSAP) has awarded contracts to three States (Cohort V) to collect data to assess the nature and extent of substance abuse prevention services needs. The data collection by these States will bring to 30 (Cohorts I–V) the number of States that have implemented a family of prevention needs assessment studies, and will constitute the third cohort to apply the core set of measures, instruments, and methodologies developed and standardized under prior State needs assessment State contracts.

Data will be collected in school surveys and community resource assessments (CRA). The information collected in this project will be combined with existing information from other sources; States may use multiple approaches to assess statewide and substate distributions of risk and protective factors for substance use, of prevention resources, and of prevention services needs. These needs assessment studies will permit cross-State comparison of risk and protection variables to assist State services planning and allocation of State Block Grant funds, and to assist Federal response to the Government Performance and Results Act (GPRA). The estimated annualized burden for the three-year project is shown below.

State/study	Estimates of number of respondents (3 year totals)	Number of responses per respondent (3 year totals)	Average burden per response (hours)	Total response burden (hours)
Alabama:				
Student Survey	6,500	1	0.75	4,875
School Survey Admin. (Contact)	60	1	0.50	30
School Survey Admin. (Teacher)	241	1	0.70	169
CRA	355	1	1.00	355
Michigan:				
Student Survey	12,000	1	0.75	9,000
Student Survey Admin. (Contact)	146	1	0.50	73
Student Survey Admin. (Teacher)	438	1	0.70	307
CRA	310	1	1.00	310
Tennessee:				
Student Survey	100,000	1	0.75	75,000
Student Survey Admin. (Contact)	250	1	0.50	125
Student Survey Admin. (Teacher)	3,333	1	0.70	2,333
CRA	1,100	1	1.00	1,100
Totals	124,733	.....	.....	93,677
3-year average	41,578	.....	.....	31,226

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Clarissa Rodrigues-Coelho, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.