Dated: April 13, 2000.

Nancy Cheal,

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

[FR Doc. 00–9886 Filed 4–19–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 79N–0113; DESI 2847]

Parenteral Multivitamin Products; Drugs for Human Use; Drug Efficacy Study Implementation; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the conditions for marketing an effective adult parenteral multivitamin drug product that published in the **Federal Register** of September 17, 1984 (49 FR 36446). The agency is notifying manufacturers of modifications in the adult formulation and certain portions of the labeling for the products.

DATES: Supplements to approved new drug applications (NDA's) and abbreviated new drug applications (ANDA's) are due on or before June 19, 2000.

ADDRESSES: Communication in response to this notice should be identified with the reference number DESI 2847 and directed to the attention of the appropriate office named below.

Supplements to full NDA's (identify with NDA number): Division of Metabolic and Endocrine Drug Products (HFD–510), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Original ANDA's: Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

Requests for opinion of the applicability of this notice to a specific product: Division of Prescription Drug Compliance and Surveillance (HFD–330), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 17, 1984 (49 FR 36446), FDA announced the conditions for marketing an effective parenteral multivitamin preparation. The effective 12-vitamin formulation set forth in the notice was based on the clinical evaluation of a guideline formulation recommended in 1975 by the American Medical Association (AMA). The notice also stated that, because parenteral multivitamin products are used and evaluated in patients with a variety of disease conditions, future adjustments to the formulation may be necessary.

On August 21, 1985, FDA's Division of Metabolic and Endocrine Drug Products and the AMA's Division of Personal and Public Health Policy sponsored a public workshop on ''Multivitamin Preparations for Parenteral Use.'' At the workshop, additional data from clinical testing of the 1975 AMA formulation and a variety of other data were presented and discussed in light of available information on parenteral vitamin therapy. After examining the data, the AMA–FDA workshop committee recommended that the dosage of vitamins B_1, B_6, C, and folic acid be increased and that vitamin K be added to the formulation. Based on a review of the committee's recommendations, the Director of the Center for Drug Evaluation and Research has concluded that the 1975 AMA formulation for parenteral multivitamins should be modified to reflect the advice of the committee.

Accordingly, this notice amends portions of the section *Conditions for Approval and Marketing* in the September 17, 1984, notice as follows (in accordance with current labeling practice, amounts previously listed in international units (IU) have been converted to weights):

Paragraph 1(a)(i) is revised as follows:

1. *Adult formulation (intended for ages 11 and older*)

Ingredient	Amount per Unit Dose
Fat Soluble Vitamins	
A (retinol)	1 milligram (mg)
D (ergocalciferol or cholecalciferol)	5 micrograms (µg)
E (alpha-tocopherol)	10 mg
K (phylloquinone)	150 µg
Water-Soluble Vitamins	
C (ascorbic acid)	200 mg
Folic acid	600 µg
Niacin	40 mg
B_2 (riboflavin)	3.6 mg
B_1 (thiamine)	6.0 mg
B_6 (pyridoxine)	6.0 mg
B_{12} (cyanocobalamin)	5 µg
Pantothenic acid	15.0 mg
Biotin	60 µg

2. *Labeling conditions.*

(a) The label must bear the statement ''Rx only.''

(b) *Indication.* Paragraph 2(b)(i)(a) is revised as follows (This language may be editorially adapted to a specific product's labeling, as appropriate.):

Adult. This formulation is indicated as a daily multivitamin maintenance dosage for adults and for children age 11 and above receiving parenteral

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.