recent court decision in which FDA was instructed to reconsider whether to authorize health claims for these relationships in dietary supplement labeling. The four health claims are: ''Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer,'' ''Consumption of fiber may reduce the risk of colorectal cancer,'' ''Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease,'' and ''0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.'' The agency stated that it will use the data and information to determine, for each substance-disease relationship, if an appropriate scientific basis exists to support the issuance of a proposed rule to authorize a health claim for the relationship.

The agency received requests to reopen the comment period on the September 8, 1999, notice to allow interested persons to comment after reviewing FDA's guidance on the ''significant scientific agreement'' standard for health claims in 21 U.S.C. 343(r)(3)(B)(i) and 21 CFR 101.14(c). The availability of that guidance was announced on December 22, 1999 (64 FR 71794). The agency has agreed to reopen the comment period on the September 8, 1999, notice for 75 days in response to the requests.

The agency has established four dockets to compile information relating to each of the four topic areas; docket numbers are specified in Table 1 below. FDA is allowing 75 days for the submission of additional data. Individuals and organizations submitting information or data relating to a specific topic should submit two copies of the information to the Dockets Management Branch (address above) by April 3, 2000. Separate submissions should be made for each topic area, and each submission should be identified with the appropriate docket number given below. Submissions received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Scientific data, research study results, and other related information on four substance-disease relationships that is submitted to the FDA must be considered publicly available. If used in the agency's scientific review, information submitted to FDA will become part of the public record for the evaluation of these relationships.

TABLE 1.

Topic	Docket No.
Antioxidant vitamins and cancer	91N–0101
Fiber and colorectal cancer	91N–0098
Omega-3 fatty acids and coronary heart disease	91N–0103
Folic acid (dietary supplement vs. food form) and neural tube defects	91N–100H

Dated: January 11, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–1127 Filed 1–18–00; 8:45 am]

BILLING CODE 4160–01–F

Editorial Note: Due to a printing error FR Document 00–1127 did not appear in the printed version of the **Federal Register** on Wednesday, January 19, 2000. It is printed in its entirety above.

[FR Doc. 00–1127 Filed 1–25–00; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 79N–0113; DESI 2847]

Pediatric Parenteral Multivitamin Products; Drug Efficacy Study Implementation; Announcement of Marketing Conditions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that pediatric parenteral multivitamin drug products that are formulated as set forth in this document are effective for treating certain vitamin deficiencies. FDA is further announcing the conditions for the approval and marketing of the drug products for the indications for which they are now regarded as effective.

DATES: Supplements to the conditionally approved new drug application (NDA) must be submitted by March 27, 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 the conditionally approved NDA (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 abbreviated new drug applications (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), Center for Drug Evaluation and Research, 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:

I. Background

In a notice published in the **Federal Register** of July 27, 1972 (37 FR 15027), FDA announced its evaluations of reports received from the National Academy of Sciences/National Research Council Drug Efficacy Study Group on certain parenteral multivitamin drug products. The agency stated that the products, as then formulated, lacked substantial evidence of effectiveness for their claimed indications. The conclusion was not based on any individual vitamin's lack of effectiveness; rather, certain essential vitamins in the available formulations were either not included or included in too great or too small amounts.

In a followup notice published in the **Federal Register** of December 14, 1972 (37 FR 26623), FDA granted parenteral multivitamin products a temporary exemption (paragraph XIV, category 11) from the time limits imposed for the implementation of the Drug Efficacy Study. The temporary exemption was based primarily on the recognized critical medical importance of

parenteral multivitamin therapy and the lack of alternative drugs. The agency allowed these products to remain on the market as then formulated, while complex technical and medical problems were being resolved and rational formulations were being developed and tested.

To facilitate the determination of rational multivitamin formulations and their evaluation, FDA accepted the assistance offered by the American Medical Association (AMA). In December 1975, the AMA submitted its ''Guidelines for Multivitamin Preparations for Parenteral Use,'' which recommended specific amounts of individual vitamins and procedures for evaluating the stability, safety, and effectiveness of the formulations.

The AMA report stressed that the guideline formulations were estimated from the existing Recommended Daily Allowance, which in turn is based on dietary population surveys. The assumptions applied by the AMA to correlate the established dietary allowances of the essential vitamins to the parenteral administration of vitamins to patients in various disease states required that clinical trials be conducted to evaluate the guideline formulations.

FDA accepted the AMA guidelines with minor reservations and, subsequently, in a **Federal Register** notice published July 13, 1979 (44 FR 40933), amended the terms of the December 1972 paragraph XIV temporary exemption to require conditional approval of an NDA or supplemental NDA within specific time frames as a condition for the continued marketing of a parenteral multivitamin drug product. The agency agreed not to initiate regulatory proceedings against these products under the following requirements: (1) Reformulation in accord with the AMA guidelines as to the number and quantities of vitamins in the formulation; (2) an outline of proposed studies along the lines set forth in the AMA report, to evaluate the stability and biological availability of the reformulated preparations; and (3) a plan or protocol for clinical effectiveness studies in accord with the AMA guidelines. A reformulated product could be marketed in place of the previous formulation after agency review and conditional approval of the submission. This procedure allowed continued marketing of parenteral multivitamins while clinical testing and evaluation of the AMA guideline formulations were being carried out.

After evaluating available data, FDA classified the AMA guideline adult formulations as effective in the **Federal Register** of September 17, 1984 (49 FR 36446). That notice also revoked the paragraph XIV exemption of all products listed in the notice, including the following pediatric product conditionally approved under the terms of the July 13, 1979, notice (in accordance with current labeling practice, amounts previously listed in United States Pharmacopeia units have been converted to weights):

NDA 18–920; M.V.I. Pediatric (lyophilized), each vial containing vitamin A (retinol) 0.7 milligrams (mg)/vial, vitamin D (ergocalciferol) 10 micrograms (µg)/vial, vitamin E (dl-alpha tocopherol acetate) 7 mg/vial, vitamin C (ascorbic acid) 80 mg/vial, folic acid 140 µg/vial, niacin (niacinamide) 17.0 mg/vial, vitamin B_2 (riboflavin-5′-phosphate sodium) 1.4 mg/vial, vitamin B_1 (thiamine hydrochloride) 1.2 mg/vial, vitamin B_6 (pyridoxine hydrochloride) 1.0 mg/vial, vitamin B_{12} (cyanocobalamin) 1 µg/vial, dexpanthenol (d-pantothenyl alcohol) 5.0 mg/vial, biotin 20 µg/vial, vitamin K (phytonadione) 200 µg/vial; Astra Zeneca, 50 Otis St., Westborough, MA 01581 (formerly held by Armour Pharmaceutical Co., P.O. Box 511, Kankakee, IL 60901).

The September 17, 1984, notice stated that further evaluation of pediatric parenteral multivitamin formulations containing vitamin E was required. The notice went on to state that until the time that such evaluation was completed, pediatric multivitamin products could be marketed only under the terms and conditions of the July 13, 1979, **Federal Register** notice.

The effectiveness of the AMA guideline pediatric formulations was considered by an AMA–FDA committee in the Workshop on Multivitamin Preparations for Parenteral Use on August 21, 1985, and by FDA's Endocrinologic and Metabolic Drugs Advisory Committee on March 3 and 4, 1986. Based on a review of the committees' recommendations and other available material, the Director of the Center for Drug Evaluation and Research has determined that the 1975 AMA guideline pediatric formulations are effective multivitamin preparations.

It should be noted, however, that although the intravenous preparation is properly formulated in composition and dosage amount of essential vitamins, it supplies inadequate amounts of vitamin A, particularly to low birth weight infants. In addition, the issue of whether the solubilizers used in pediatric preparations contribute to toxicity remains unresolved. Further study of the pediatric formulations is needed to determine a vehicle for administration of multivitamins to low birth weight infants that will provide adequate amounts of vitamin A and avoid possible toxicity associated with the use of solubilizers employed in pediatric preparations. Future approval of a more appropriate formulation for low birth weight infants may restrict the labeling of the current formulation to use in infants weighing more than 3 kilograms (kg).

The continuing exemption announced in the September 17, 1984, notice for pediatric parenteral multivitamin products is hereby revoked. These products are regarded as new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). Therefore, a fully approved NDA is required to market them. M.V.I. Pediatric (NDA 18–920) received conditional approval under the terms of the July 13, 1979, notice. A supplemental NDA is now required for M.V.I. Pediatric to revise the labeling and to update its conditionally approved NDA.

In addition to the product specifically named above, this notice applies to any product that is not the subject of an approved application and is identical or, under 21 CFR 310.6, is related or similar to M.V.I. Pediatric. It is the responsibility of all drug manufacturers and distributors to review this notice to determine whether it covers any drug product that they manufacture or distribute. Any person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Prescription Drug Compliance and Surveillance (address above).

II. Conditions for Approval and Continued Marketing of Formulations Evaluated as Effective

A. Effectiveness Classification

FDA has reviewed all available evidence and concludes that pediatric parenteral drug products formulated as listed below are effective for the applicable indication set forth in the labeling conditions below.

B. Conditions for Approval and Marketing

FDA is prepared to approve ANDA's and supplements to the conditionally approved NDA named above under conditions described here.

1. Form of Drug

(a) *Intravenous multivitamin preparations.* The preparation is an aqueous solution or lyophilized powder suitable for reconstitution and/or secondary dilution prior to intravenous

infusion and contains the specified amounts of the following individual vitamins, either as the moiety listed below or as the chemically equivalent salt or ester.

(i) *Pediatric formulation* (intended for infants and children under age 11)[1]

Ingredient	Amount per unit dose
Fat-Soluble Vitamins	
A (retinol)	0.7 mg
D (ergocalciferol or cholecalciferol)	10 µg
E (alpha-tocopherol)	7 mg
K_1 (phytonadione)	200 µg
Water-Soluble Vitamins	
C (ascorbic acid)	80 mg
Folic acid	140 µg
Niacin	17 mg
B_2 (riboflavin)	1.4 mg
B_1 (thiamine)	1.2 mg
B_6 (pyridoxine)	1.0 mg
B_{12} (cyanocobalamin)	1.0 µg
Pantothenic acid	5.0 mg
Biotin	20.0 µg

[1] For infants weighing less than 1 kg the daily dose is 30 percent of the indicated formulation. Do not exceed this daily dose. For infants weighing 1 to 3 kg the daily dose is 65 percent of the indicated formulation.

(b) *Intramuscular multivitamin preparations*. The preparation is a sterile solution suitable for intramuscular injection.

(i) *Pediatric formulation*. The vitamin composition of the pediatric intramuscular formulation shall be that of the pediatric intravenous preparation named above without the fat-soluble vitamins.

2. Labeling Conditions

(a) The label bears the statement ''Caution: Federal law prohibits dispensing without prescription.''

(b) The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The indication is as follows:

(i) *Intravenous Pediatric Multivitamin Preparations*. This formulation is indicated as a daily multivitamin maintenance dosage for infants and children up to 11 years of age receiving parenteral nutrition.

It is also indicated in other situations where administration by the intravenous route 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.

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

This product (administered in intravenous fluids under proper dilution) contributes intake of these necessary vitamins toward maintaining the body's normal resistance and repair processes.

Patients with multiple vitamin deficiencies or with markedly increased requirements may be given multiples of the daily dosage for two or more days as indicated by the clinical status.

(ii) *Intramuscular Pediatric Multivitamin Preparations*. This product is indicated for infants and children up to ll years of age for conditions in which: (1) Intake or absorption of the water-soluble vitamins is inadequate and oral intake must be supplemented; or (2) there is a known or suspected serious depletion of the water-soluble vitamins, and immediate treatment by the intramuscular route is advisable.

Conditions that may require parenteral administration of water-soluble vitamins may include disorders that can affect oral intake, gastrointestinal absorption, or utilization. Such conditions include comatose states, persistent vomiting, prolonged fever, severe infectious diseases, major surgery, extensive burns, fractures and other traumas, diarrhea, achlorhydria, or liver disease.

The physician should not await the development of clinical signs of vitamin deficiency before initiating therapy because there are few specific or pathognomonic signs of early vitamin deficiencies.

(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.

(d) PRECAUTIONS: (The following paragraph 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.

Adequate blood levels of vitamin E are achieved when this product is given to infants at the recommended dosage. Larger doses or supplementation with oral or parenteral vitamin E are not recommended because elevated blood levels of vitamin E may result.

Studies have shown that vitamin A may adhere to plastic, resulting in inadequate vitamin A administration in the doses recommended with this product. Additional vitamin A supplementation may be required, especially in low birth weight infants.

3. Marketing Status

(a) Marketing of the drug product that is now the subject of a conditionally approved NDA may be continued

provided that on or before March 27, 2000, the holder of the application has submitted: (i) A supplement for revised labeling necessary to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted; and (ii) a supplement to provide updated information with respect to the composition, manufacture, and specifications of the drug substance and the drug product as described in 21 CFR 314.50(d)(1)(i) and (d)(1)(ii). FDA will evaluate the submitted material and, if the material is adequate, will grant full approval to the conditionally approved NDA.

(b) Approval of an ANDA must be obtained in accordance with section 505(j) of the act (21 U.S.C. 355(j)) before marketing such products. Marketing prior to approval of an ANDA will subject such products, and those persons who caused the products to be marketed, to regulatory action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505 (21 U.S.C. 352, 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.70).

Dated: January 4, 2000.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 00–1787 Filed 1–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF INTERIOR

Office of the Secretary

Blackstone River Valley National Heritage Corridor Commission; Notice of Meeting

Notice is hereby given in accordance with Section 552b of Title 5, United States Code, that a meeting of the Blackstone River Valley National Heritage Corridor Commission will be held on Thursday, February 3, 2000.

The Commission was established pursuant to Public Law 99–647. The purpose of the Commission is to assist federal, state and local authorities in the development and implementation of an integrated resource management plan for those lands and waters within the Corridor.

The meeting will convene at 6:00 PM in the Great Hall of the Northbridge Town Hall, located on Main Street in Whitinsville, MA for the following reasons:

1. Approval of Minutes
2. Presentation of FY2000 Development Budget
3. Senator John H. Chafee Heritage Award

It is anticipated that about twenty people will be able to attend the session in addition to the Commission members.

Interested persons may make oral or written presentations to the Commission or file written statements. Such requests should be made prior to the meeting to: Michael Creasey, Executive Director, Blackstone River Valley National Heritage Corridor Commission, One Depot Square, Woonsocket, RI 02895, Tel.: (401) 762–0250.

Further information concerning this meeting may be obtained from Michael Creasey, Executive Director of the Commission at the aforementioned address.

Michael Creasey,

Executive Director BRVNHCC.

[FR Doc. 00–1629 Filed 1–25–00; 8:45 am]

BILLING CODE 4310–RK–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Exxon Valdez Oil Spill Public Advisory Group, Meeting

AGENCY: Department of the Interior, Office of the Secretary.

ACTION: Notice of meeting.

SUMMARY: The Department of the Interior, Office of the Secretary is announcing a public meeting of the Exxon Valdez Oil Spill Public Advisory Group.

DATES: February 10, 2000, at 1:00 p.m.

ADDRESSES: Fourth floor conference room, 645 ''G'' Street, Anchorage, Alaska.

FOR FURTHER INFORMATION CONTACT: Douglas Mutter, Department of the Interior, Office of Environmental Policy and Compliance, 1689 ''C'' Street, Suite 119, Anchorage, Alaska, (907) 271–5011.

SUPPLEMENTARY INFORMATION: The Public Advisory Group was created by Paragraph V.A. 4 of the Memorandum of agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska,* Civil Action No. A91–081 CV. The agenda will include discussions about the draft Gulf Ecosystem Monitoring program.

Willie R. Taylor,

Director, Office of Environmental Policy and Compliance.

[FR Doc. 00–1751 Filed 1–25–00; 8:45 am]

BILLING CODE 4310–RG–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Meeting of the Klamath Fishery Management Council

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces a meeting of the Klamath Fishery Management Council, established under the authority of the Klamath River Basin Fishery Resources Restoration Act (16 U.S.C. 460ss *et seq.*). The Klamath Fishery Management Council makes recommendations to agencies that regulate harvest of anadromous fish in the Klamath River Basin. This objectives of this meeting are to hear technical reports, review the 1999 fishery season, and discuss and plan management of the 2000 season. The meeting is open to the public.

DATES: The Klamath Fishery Management Council will meet from 1:00 p.m. to 5:00 p.m. on Wednesday, February 23, 2000; from 8:00 a.m. to 5:00 p.m. on Thursday, February 24, 2000; and from 8:00 a.m. to 12:00 p.m. on Friday, February 25, 2000.

PLACE: The meeting will be held at the Best Western Beachfront Harbor, 16008 Boat Basin Rd., Harbor, Oregon.

FOR FURTHER INFORMATION CONTACT: Dr. Ronald A. Iverson, Project Leader, U.S. Fish and Wildlife Service, P.O. Box 1006 (1215 South Main), Yreka, California 96097–1006, telephone (530) 842–5763.

SUPPLEMENTARY INFORMATION: For background information on the Klamath Council, please refer to the notice of their initial meeting that appeared in the **Federal Register** on July 8, 1987 (52 FR 25639).

Dated: January 14, 2000.

Elizabeth H. Stevens,

Acting Manager, California/Nevada Operations.

[FR Doc. 00–1761 Filed 1–25–00; 8:45 am]

BILLING CODE 4310–55–U

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–090–00–1430–BD; UTU–75494]

Emergency Road Closure

AGENCY: Bureau of Land Management, Interior.

ACTION: Order for temporary emergency closure of portions of the ''Moon