The estimated burden for § 803.19 is further adjusted to reflect the agency's actual experience with this type of submission.

Prior to the program change reflected in this rule, § 803.22(b)(2) provided that, if a manufacturer erroneously receives information about an adverse event concerning a device that they had not manufactured, the manufacturer must submit the report to FDA along with a cover letter explaining that the device in question was not manufactured by that firm. This final rule amends § 803.22(b)(2) to apply the same requirement to importers. The requirements of § 803.22(b)(2) were not previously reviewed by OMB under the PRA. Thus, the estimated burden reflects FDA's experience with this provision with regard to manufacturers and includes the estimated burden for both manufacturers and importers.

Prior to the program change reflected in this rule, § 803.33 required medical device user facilities to submit summary reports semiannually. Under this rule, user facilities are required to submit summary reports annually, thereby significantly decreasing the reporting burden on user facilities. The estimated burden for this section is also adjusted to reflect the agency's actual experience with this type of submission. FDA Form 3419 is being revised to reflect this change.

Under this rule the reporting requirement for importers of medical devices previously codified under § 804.25 is being transferred to § 803.40. The estimated burden for importer reporting is based upon the agency's actual experience with this type of submission. Section 803.40 requires importers to submit reports within 30 days after learning of the reportable event rather than 10 days as provided in § 804.25; this change does not affect the burden.

This rule does not amend § 803.55, but FDA is seeking approval for FDA Form 3417 on which baseline reports are to be submitted. The agency's estimate is based on FDA's actual experience with this type of submission.

Prior to the program change reflected in this rule, § 803.57 required medical device manufacturers to annually certify as to the number of reports submitted during the previous year, or that no such reports had been submitted. Distributors (including importers) were required to certify under § 804.30. As stated previously, FDA is also exempting manufacturers and distributors of cigarettes and smokeless tobacco products from the requirement of annual certification. Therefore, under this rule, §§ 803.57 and 804.30 are being eliminated.

Because distributors, including distributors of cigarettes and smokeless tobacco products, will no longer be required to report, the final rule also removes §§ 804.25 (distributor reporting), 804.32 (supplemental information), and 804.33 (alternative reporting requirements).

II. Recordkeeping Requirements

Prior to the program change reflected in this rule, § 803.17 required manufacturers and user facilities to establish written procedures for employee education, complaint processing, and documentation of information related to MDR's. Under this rule, the requirements for establishing written MDR procedures for importers of medical devices have been transferred to § 803.17. The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information related to MDR reporting as part of their internal quality control system. The agency has estimated that no more than 2,000 such entities would be required to establish new procedures, or revise existing procedures, in order to comply with this provision. For those entities, a one-time burden of 10 hours, annualized over a period of 5 years, is estimated for establishing written MDR procedures. The remainder of manufacturers, user facilities, and importers not required to revise their written procedures to comply with this provision are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

Prior to the program change reflected in this rule, § 803.18 required manufacturers and user facilities to establish and maintain MDR event files. Distributors (including importers) were required to establish and maintain MDR event files under § 804.35. Under this rule, § 803.18 is modified to transfer the recordkeeping requirements for importers and other distributors of medical devices, including cigarettes and smokeless tobacco products from § 804.35; therefore, § 804.35 is removed. As discussed previously, this recordkeeping may be done in an electronic format.

Under the proposed rule, distributors of cigarettes and smokeless tobacco products would have been required to establish written internal procedures for evaluating and reporting events. Because distributors of cigarettes and smokeless tobacco products will not be required to report under the final rule, § 804.34 is removed.

Dated: January 18, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–1786 Filed 1–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 91N–0101, 91N–0098, 91N–0103, and 91N–100H]

Food Labeling; Health Claims and Label Statements; Request for Scientific Data and Information; Reopening of Comment Period

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 below.

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for written comments; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 75 days the comment period for the submission of scientific data, research study results, and other related information on four substance-disease relationships that was announced in the **Federal Register** of September 8, 1999 (64 FR 48841). This action is being taken in response to requests for more time to submit data and information to FDA.

DATES: Written comments by April 3, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine J. Lewis, Center for Food Safety and Applied Nutrition (HFS–451), Food and Drug Administration, 200 C. St. SW., Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 8, 1999 (64 FR 48841), FDA requested scientific data, research study results, and other related information on four substance-disease relationships in order to reevaluate the scientific evidence for these relationships. FDA stated that it was taking this action to comply with a

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