Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend § 71.123 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as republished (46 FR 409) as follows:

1. V-93 [Amended]
   By deleting the words "including an E alternate via the INT of Baltimore 034° and Lancaster 181° radials;"
2. V-499 [Amended]
   By deleting the words "From Lancaster, PA," and substituting the words "From Baltimore, MD, via INT of Baltimore 034° and Lancaster, PA, 181° radials; Lancaster,"
3. V-143 [Amended]
   By deleting the words "including an S alternate via Westminister, MD;"
4. V-457 [New]
   By adding "V-457 From Lancaster, PA, via Westminister, MD; to Martinsburg, WV."
5. V-162 [Amended]
   By deleting the words, "including a S alternate via INT Harrisburg 0.87° and East Texas 225° radials"
6. V-222 [Amended]
   By deleting the words "including an N alternate from Lynchburg via Gordonsville, VA."
7. V-476 [New]
   By adding "V-476 From Lynchburg, VA, via Gordonsville, VA, to INT Brooke, VA, 045° and Richmond, VA, 009° radials."
8. V-375 [Amended]
   By deleting the words "; including a N alternate via the INT Roanoke 035° and Montebello, VA, 250° and Montebello, VA."
9. V-473 [New]
   By adding "V-473 From Roanoke, VA, via INT Roanoke 035° and Montebello, VA, 250° radials; Montebello; Gordonsville, VA."
10. V-433 [Amended]
    By deleting the words, "including an E alternate via FATIMA 058° and Yardley 196° radials"
11. V-479 [New]
    By adding "V-479 From FATIMA, DE, via INT FATIMA 058° and Yardley, PA, 196° radials; to yardley."

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.65)

Note.—The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the critieria of the Regulatory Flexibility Act.

Issued in Washington, D.C., on November 19, 1981.

John W. Baier,

Acting Chief, Airspace and Air Traffic Rules Division.

[FR Doc. 81-33979 Filed 11-25-81; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 345

[Docket No. 78N-0024]

Vitamin and Mineral Drug Products for Over-the-Counter Human Use; Withdrawal of Proposed Monograph

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposed monograph (advance notice of proposed rulemaking).

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a proposed monograph (an advance notice of proposed rulemaking) of March 16, 1979 that would have established conditions under which over-the-counter (OTC) vitamin and mineral drug products are generally recognized as safe and effective and not misbranded. The proposed monograph was based on recommendations of the FDA Advisory Review Panel on OTC Vitamin, Mineral, and Hematinic Drug Products. The agency is taking this action because the proposal did not discuss what effects legislation that was enacted in 1976 would have on the agency's vitamin and mineral policies. Because of this omission, the proposal has been misinterpreted, resulting in considerable public confusion concerning the agency's intention to regulate vitamin and mineral drug products.

EFFECTIVE DATE: November 27, 1981.

FOR FURTHER INFORMATION CONTACT: Eileen Hodkinson, Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 11, 1972 (37 FR 9464), FDA issued final regulations for the review of all OTC drugs by independent advisory review panels (21 CFR Part 330). Acting under these regulations the agency issued in the **Federal Register** of October 15, 1973 (38 FR 28581), a request for data on all active ingredients used in OTC vitamin, mineral, and hematinic drug products. The Commissioner of Food and Drugs also appointed as an independent advisory committee the Advisory Review Panel on OTC Vitamin, Mineral, and Hematinic Drug Products. This Panel was directed to review the vitamin and mineral drug product data and to prepare a report on the safety, effectiveness, and labeling of these products. Also in 1973, in a separate and unrelated proceeding, FDA proposed to establish standards of identity and labeling requirements for vitamins and minerals sold as dietary supplements under the food provisions of the Federal Food, Drug, and Cosmetic Act. This proposal was made final in the **Federal Register** of August 2, 1973 (38 FR 20708, 20730).

On December 11, 1973, the Panel began reviewing the data, and on November 1, 1977, submitted its report to FDA. In the **Federal Register** of March 16, 1979 (44 FR 16126), FDA issued the Panel's report and a proposed monograph (advance notice of proposed rulemaking) which would, if adopted, establish conditions under which OTC vitamin and mineral drug products would be generally recognized as safe and effective and not misbranded. It should be noted that under the regulations in 21 CFR Part 330, the Panel's report, and the proposed monograph are the recommendations of the independent OTC advisory committee only: FDA had not at that stage evaluated either the report or proposed monograph. Therefore, the Panel's report on OTC vitamin and mineral products and the proposed monograph based on the Panel's recommendation did not represent the agency's position. The Panel's report and the proposed monograph were published to stimulate discussion, evaluation, and comment by interested persons before the agency conducted its evaluation. (Although the proposed monograph for OTC vitamin and mineral drug products was captioned in the **Federal Register** as a notice of proposed rulemaking, its actual status is that of an advance notice of proposed rulemaking. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final action occurs in the final monograph, a final rule.)

While the Panel was in the process of completing the OTC vitamin and mineral drug report, Congress on April 22, 1976, amended the act so as to restrict the agency's authority both to limit the maximum potency of vitamins and minerals when used as dietary supplements and to limit the ingredient composition of multinutrient

supplements that are offered for use by adults and are recognized as safe (Pub. L. 94–278, sec. 501 (a) (the "Proxmire Amendment"), which added section 411 to the Federal Food, Drug, and Cosmetic Act). In addition, the legislation precluded the agency from declaring a vitamin or mineral to be a drug solely because it exceeds the level of potency the agency has determined to be nutritionally rational or useful. The Proxmire Amendment essentially mandated that any regulation of the potency of vitamin and mineral products, whether sold as drugs or as dietary supplements, must be based on considerations of human toxicity rather than human need.

After enactment of the Proxmire Amendment, FDA issued in the **Federal Register** of October 19, 1976 (41 FR 46156), a revised final regulation establishing standards and labeling requirements for vitamin and mineral dietary supplements, conforming them to this new legislation. On February 16, 1978, the United States Court of Appeals for the Second Circuit vacated the October 19, 1976 regulation and remanded it to the agency for further proceedings. *National Nutritional Foods Association* v. *Kennedy*, 572 F. 2d 377 (2d Cir. 1978). The court held that the Proxmire Amendment had substantially changed the agency's authority over vitamins and minerals marketed as dietary supplements and, therefore, FDA had to provide opportunity for further public notice and comment. To comply with the decision of the court, FDA issued a notice in the **Federal Register** of March 16, 1979 (44 FR 16005), revoking the dietary supplement regulations. By coincidence, it was published the same day the OTC Panel's report and the proposed monograph on vitamin and mineral drug products were published (44 FR 16126).

The coincidence in publication dates in the **Federal Register** caused great confusion concerning FDA's intentions to regulate vitamin and mineral OTC drug products. Vitamins and minerals when used as dietary supplements—by far, the greatest number of currently marketed vitamin and mineral products—are regulated under the food provisions of the act. The OTC Panel's report and the proposed monograph, however, related only to vitamin and mineral products labeled with drug claims and sold as OTC drugs. Further, because of the Proxmire Amendment, the Panel report attempted to distinguish between vitamins and minerals subject to the drug provisions of the act and those subject to the food provisions of the act. Nevertheless, comments submitted in response to the Panel's report showed that many persons did not understand the distinction. Many letters from the public mistakenly expressed concern that vitamins and minerals would no longer be available over-the-counter and would require a prescription by a physician. Part of the confusion likely can be attributed to the agency's not explaining the effect of the Proxmire Amendment on the regulation of vitamin and mineral products at the time the OTC Panel's report and the proposed monograph were published. In the absence of any such discussion, many individuals and organizations interpreted the OTC Panel's report on vitamin and mineral drug products and the proposed monograph as an attempt to subvert the Proxmire Amendment. Certainly, FDA did not intend to subvert or circumvent the law.

Therefore, because of the confusion in the public's mind over FDA's intent, the unsuccessful attempts to correct the misinterpretations concerning the agency's jurisdiction over vitamins and minerals, and the significant change in FDA's legal authority over vitamins and minerals since the OTC Panel was first convened, the agency is withdrawing the proposed monograph (advance notice of proposed rulemaking). By this action, the agency formally recognizes and responds to the growing public sentiment expressed by the thousands of comments received from the public and by recent congressional interest in vitamin and mineral regulation. It is indicative also of an ongoing agency reassessment of all aspects of vitamin and mineral regulation.

The agency stresses, however, that it is withdrawing only the proposed monograph (advance notice of proposed rulemaking) and that this withdrawal does not in any way denigrate the scientific content of the report and the excellent work of the OTC Panel in its long efforts to produce it. FDA believes that the information in the report will provide valuable guidance to both the agency and industry in the area of vitamins and minerals.

The agency recognizes that OTC vitamin and mineral drug products constitute a very small segment of the marketplace and that withdrawal of the proposed monograph does not affect the agency's authority to take action against OTC vitamin or mineral drug products that are unsafe or misbranded.

Accordingly, the proposed monograph (advance notice of proposed rulemaking) published in the **Federal Register** of March 16, 1979 (44 FR 16126), which would have added new Part 345—Vitamin and Mineral Drug Products For Over-The-Counter Human Use (21 CFR Part 345) is hereby withdrawn, effective November 27, 1981. The Panel report will remain on public display in the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

This withdrawal is issued under authority of the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended (21 U.S.C. 321, 352, 355, 371)) and 21 CFR 5.11 and under authority delegated to the Commissioner (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)).

Dated: September 23, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: November 16, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 81–34165 Filed 11–25–81; 8:45 am]

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PANAMA CANAL COMMISSION

35 CFR Ch. I

Revised Shipping and Navigation Rules for the Panama Canal

AGENCY: Panama Canal Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: Upon entry into force on October 1, 1979, of the Panama Canal Treaty of 1977, the United States reliquished and Panama assumed plenary jurisdiction over what what was the Canal Zone. Under the Panama Canal Act of 1979, the statute implementing the new treaty, the Canal Zone Government was disestablished and the Panama Canal Company was replaced by the Panama Canal Commission, which will operate the waterway until the termination of the treaty on December 31, 1999. This document contains the proposed regulations of the Commission relating to shipping and navigation.

DATE: Written comments concerning the proposed regulations must be received by December 20, 1980.

ADDRESS: Send comments to: Mr. Michael Rhode, Jr., Secretary, Panama Canal Commission, Rm 312, Pennsylvania Bldg., 425 13th Street, NW., Washington, D.C. 20004 (Telephone: (202) 724–0104).