[Docket No. 83M-0215]

Precision-Cosmet Co., Inc.; Premarket Approval of SOFTMARK ™

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application for premarket approval under the Medical Device Amendments of 1976 of SOFTMARK ™, sponsored by Precision-Cosmet Co., Inc., Minnetonka, MN. After reviewing the recommendation of the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, and after listing, by regulation, the color additive contained in the device, FDA notified the sponsor that the application was approved because the device had been shown to be safe and effective for use as recommended in the submitted labeling.

DATE: Petitions for administrative review by August 19, 1983.

ADDRESS: Request for copies of the summary of safety and effectiveness data and petitions for administrative review may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles H. Kyper, National Center for Devices and Radiological Health (HFK-402), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7445.

SUPPLEMENTARY INFORMATION: On April 28, 1982, Precision-Cosmet Co., Inc, Minnetonka, MN, submitted to FDA an application for premarket approval of SOFTMARK ™, an identification marker containing the color aditive 2-[[2,5-diethoxy-4[(4-methylphenyl)thio]phenyl]-azo]-1,3,5-benzenetriol, for use to mark soft (hydrophilic) contact lenses with an "R" or an "L" to distinguish the right lens from the left and to aid in determining whether the lens is inverted. The application was reviewed by the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, an FDA advisory committee, which recommended approval of the application. In the **Federal Register** of May 20, 1983 (48 FR 22705), FDA published a regulation (21 CFR 73.3115) listing the color additive 2-[[2,5-diethoxy-4-[(4methylphenyl)thio]phenyl]azo]-1-3-5-benzenetriol for use in marking all soft (hydrophilic) contact lenses. The regulation became effective June 21, 1983. The use of 2-[[2,5-diethoxy-4[(4-methylphenyl)thio]phenyl]-azo]-1,3,5-benzenetriol in SOFTMARK ™ conforms to the color additive requirements in 21 CFR 73.3115. On June 22, 1983, FDA approved the application for premarket approval of this device by a letter to the sponsor from the Associate Director for Device Evaluation of the Office of Medical Devices.

Before enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295, 90 Stat. 539-583), soft contact lens accessories were regulated as new drugs. Because the amendments broadened the definition of the term "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(h)), soft contact lens accessories are now regulated as class III devices (premarket approval). As FDA explained in a notice published in the **Federal Register** of December 16, 1977 (42 FR 63472), the amendments provide transitional provisions to ensure continuation of premarket approval requirements for class III devices formerly regulated as new drugs. Furthermore, FDA requires, as a condition to approval, that sponsors of applications for premarket approval of soft contact lenses or accessories comply with the records and reports provisions of Subpart D of Part 310 (21 CFR Part 310) until these provisions are replaced by similar requirements under the amendments.

A summary of the safety and effectiveness data on which FDA's approval is based is on file with the Dockets Management Branch (address above), and is available upon request from that office. A copy of all approved final labeling is available for public inspection at the Office of Medical Devices—contact Charles H. Kyper (HFK-402), address above. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of FDA's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and FDA's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration of FDA's action under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register.** If FDA grants the petition, the notice will state the issues to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 19, 1983, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 13, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-19384 Filed 7-18-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82N-0166]

Orally Administered Drug Products for Relief of Symptoms Associated With Overindulgence in Alcohol and Food for Over-the-Counter (OTC) Human Use; Decision on Ingredients Intended To Minimize or Prevent Inebriation

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that fructose or any other ingredient intended to minimize or prevent inebriation is a new drug and as such is required to be the subject of an approved new drug application (NDA).

EFFECTIVE DATE: July 19, 1983.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFN-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 1, 1982 (47 FR 43540), FDA published under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph on OTC orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food, together with the recommendations of

the Advisory Review Panel on OTC Miscellaneous Internal Drug Products, which was the advisory review panel responsible for evaluating data on active ingredients in this drug class.

In preparing its recommendations to the agency, the Panel reviewed the available data relating to the use of fructose as an ingredient intended to minimize inebriation from alcoholic beverages. The Panel concluded, however, that there was insufficient evidence to make a final determination as to whether fructose was effective for this purpose and recommended that fructose be placed in Category III (insufficient data to determine whether the ingredient is generally recognized as safe and effective). The Panel also recommended that all claims for drug products intended for the prevention of inebriation be classified in Category II (not generally recognized as safe and effective or misbranded).

FDA is not aware of the marketing in the United States of any drug product containing fructose or any other ingredients for the claim "to minimize or prevent inebriation" prior to adoption of the Panel's report in August 1981, although at least one such product has entered the market since that time. The agency is concerned that such products may present a potential health hazard, particularly when motorists rely on unsubstantiated claims that the products will prevent or minimize an inebriated state. The National Highway Traffic Safety Administration has indicated that 25,000 of the highway deaths that occur annually, about 50 percent, involve an intoxicated driver (NHTSA Technical Report DOT–HS–806–269, May 1982). Products that claim to prevent or minimize inebriation could give persons who consume alcoholic beverages and then drive a motor vehicle a false sense of security, convincing them that they are capable of driving when in fact they are not.

The agency has determined that products containing fructose or any other ingredient claimed "to minimize or prevent inebriation" are new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 312(p)). A new drug is defined in the act as one not generally recognized by qualified experts as safe and effective for its intended uses or, if so recognized, one that has not been used to a material extent or for a material time. An indication that a drug is not generally recognized among qualified experts as effective for its intended use is the lack of a body of published or publicly available medical and scientific literature on the drug, including literature describing adequate and well-controlled studies demonstrating the safety and effectiveness of the drug. *United States* v. *41 Cases . . . Naremco,* 420 F.2d 1126 (5th Cir. 1970); *United States* v. *An Article of Drug . . . Mykocert,* 345 F. Supp. 571 (D.D.C. 1972); *United States* v. *An Article of Drug . . . Asper Sleep* CCH F.D. and Cosm. L. Rep., paragraph 40,821 Civil No. 70–C–196 (N.D. Ill. 1971); *United States* v. *An Article of Drug . . . Furestrol Vaginal Suppositories,* 294 F. Supp. 1307 (N.D. Ga. 1968). As noted above, the Panel found the available evidence insufficient to determine general recognition of safety and effectiveness. In addition, products claiming "to minimize or prevent inebriation" have not been marketed to a material extent and for a material time. For these reasons, the agency considers products claiming to minimize or prevent inebriation to be new drugs within the meaning of section 201(p) of the act. Such products may not be marketed until FDA has approved an NDA for such use (21 U.S.C. 355). The agency will initiate appropriate enforcement actions against drug products intended to prevent or minimize inebriation that are marketed without an approved NDA.

This action does not affect other marketed products containing ingredients reviewed by the Panel, including ingredients in drug products intended for the relief of symptoms of upset stomach due to overindulgence in the combination of alcohol and food, for the relief of hangover symptoms, or to minimize hangover symptoms.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

Dated: July 7, 1983.

[FR Doc. 83–19537 Filed 7–18–83; 8:45 am]

BILLING CODE 4160–01–M

Office of Human Development Services

Reallotment of Funds

AGENCY: Office of Human Development Services, HHS.

ACTION: Notice of reallotment of funds.

SUMMARY: The Administration on Developmental Disabilities in the Office of Human Development Services proposes to reallot funds which will not be utilized by American Samoa, Commonwealth of the Northern Marianas, and the Trust Territory of the Pacific Islands to forty-six of the States, the District of Columbia, Puerto Rico, Guam and the Virgin Islands.

DATE: Effective August 18, 1983.

ADDRESS: 200 Independence Avenue, S.W., Room 348F.5, Washington, D.C. 20201.

SUMMARY: Consideration will be given to any comments on this proposed reallotment of funds if received on or before August 18, 1983. Comments must be in writing and submitted to Jean K. Elder, Ph. D., Commissioner, Administration on Developmental Disabilities, Department of Health and Human Services, 200 Independence Avenue, S.W., Room 348F.5, Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: Nancy J. Stipa, Director, Division of Management and Administrative Services, Administration on Developmental Disabilities, Department of Health and Human Services, 200 Independence Avenue, S.W., Room 348F.5, Washington, D.C. 20201, telephone (202) 245–2904.

SUPPLEMENTARY INFORMATION: Section 132(d) of the Developmental Disabilities Assistance and Bill of Rights Act, Pub. L. 95–602, as amended, provides that the amount of a State's fiscal year allotment (as determined in accordance with 132(a)(1)) which will not be required by the State shall be available for reallotment to other States. Any reallotment shall be in proportion to the original allotments of such States for such fiscal year. The additional reallotment shall be reduced to the extent it exceeds the sum the Secretary estimates such State needs and will be able to use during such period; and the total of such reductions shall be similarly reallotted among the States whose proportionate amounts were not so reduced.

Notice is hereby given that the following allotments reserved for American Samoa, the Trust Territory of the Pacific Islands, and the Commonwealth of the Northern Marianas for Basic Support and Protection and Advocacy will not be required:

Basic support fiscal year 1983 allotment	$405,000
Protection and advocacy fiscal year 1983 allotment	82,500