between 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

Dated: October 7, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-28346 Filed 10-14-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82F-0300]

AB Casco.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that AB Casco has filed a petition proposing that the food additive regulations be amended to provide for the safe use of dialkyl (C_{16}-C_{18}) carbamoyl chloride as a sizing agent in the manufacture of paper and paperboard.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP OB3490) has been filed by AB Casco, Box 11010, 100 61, Stockholm, Sweden, proposing that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended to provide for the safe use of dialkyl (C_{16}-C_{18}) carbamoyl chloride as a sizing agent in the manufacture of paper and paperboard.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 1, 1982.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 82-28158 Filed 10-14-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82F-0295]

American Hoechst Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that American Hoechst Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of acesulfame potassium (potassium salt of 6-methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide) as a nonnutritive sweetener.

FOR FURTHER INFORMATION CONTACT: Patricia J. McLaughlin, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2A3659) has been filed by American Hoechst Corp., Route 202-206 North, Somerville, NJ 08876, proposing that the food additive regulations be amended to provde for the safe use of acesulfame potassium (potassium salt of 6-methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide) as a nonnutritive sweetener.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: October 1, 1982.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 82-28159 Filed 10-14-82; 8:45 am]

BILLING CODE 4160-01-M

Consumer Participation; Notice of Open Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following consumer exchange meetings:

San Francisco District Office, chaired by William C. Hill, District Director.

DATE: Wednesday, October 20, 1982, 1 p.m. to 3 p.m.

ADDRESS: Conference Room, Senior Citizens Center of Washoe County, 1155 E. Ninth St., Reno, NV 89720.

FOR FURTHER INFORMATION CONTRACT: Karen K. Erdman, Consumer Affairs Officer, Food and Drug Administration, 50 United Nations Plaza, San Francisco, CA 94102, 415-556-2062.

Kansas City District Officer, chaired by James A. Adamson, District Director.

DATE: Friday, November 5, 1982, 1 p.m.

ADDRESS: The Shepards Center, 5200 Oak St., Kansas City, MO 64112.

FOR FURTHER INFORMATION CONTACT: Lorena A. Meyers, Consumer Affairs Officer, Food and Drug Administration, 1009 Cherry St., Kansas City, MO 64106, 816-374-3817.

SUPPLEMENTARY INFORMATION: The purpose of these meetings is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance understanding and exchange information between local consumers and FDA's District Offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: October 6, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-28087 Filed 10-14-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82N-0240]

Merck Sharp & Dohme Research Laboratories; Reclassification of Lacrisert as an Approved New Drug

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the reclassification of Lacrisert from a medical device approved for marketing to an approved new drug. This reclassification is based on FDA's determination that Lacrisert is more properly classified as a drug product.

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Jr., National Center for Drugs and Biologics (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION: On December 31, 1979, Merck Sharp & Dohme, West Point, PA 19486, submitted to FDA an application for premarket

approval of Lacrisert (hydroxypropyl cellulose ophthalmic insert, MSD). Lacrisert is a rod-shaped, water soluble, ophthalmic preparation intended for moderate to severe dry eye syndrome and for other diseases of the eye. The application was reviewed by the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, and FDA advisory committee, which recommended approval of the application. On June 1, 1981, FDA approved the application by a letter to the sponsor from the Acting Director of the Bureau of Medical Devices.

This notice announces FDA's decision to reclassify Lacrisert from a medical device approved for marketing to an approved new drug product. The Division of Anti-Infective Drug Products of FDA's Office of New Drug Evaluation has reviewed the application approved by the Bureau of Medical Devices and has found Lacrisert to be safe and effective for use as recommended in its labeling.

FDA's determination that Lacrisert, like artificial tears and a product used as ocular demulcents and ocular emollients, is a drug product based on the definition of the terms "drug" and "device" in sections 201 (g) and (h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 (g) and (h)).

Under section 201(g)(1), the term "drug" is defined to mean, among other things, "* * * articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body." Section 201(h) of the act defines the term "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article * * * which is * * * intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or which is "intended to affect the structure or any function of the body," and "* * * which does not achieve any of its principal intended purposes through chemical action within or on the body * * * and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes."

The term "articles," appearing in the definition of "drug," is a broad category that contrasts with the list of specific types of products that are devices, appearing in the definition of "device." To be a device, a product must be "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article." Except for implants and in vitro reagents, most items in this list are mechanical products that generaly are constructed of solid materials such as metal or plastic. By contrast, a drug is a chemical or a combination of chemicals in liquid, paste, powder, or other drug dosage form that is ingested, injected, or instilled into body orifices, or rubbed or poured onto the body in order to achieve its intended medical purpose. Lacrisert is not an instrument, apparatus, implement, machine, contrivance, implant, or in vitro reagent nor is it similar or related to these products that are listed in the "device" definition; rather, Lacrisert is a combination of chemical entities, intended for in vivo use.

Under the last clause of the "device" definition, FDA may not regulate as a device an article that achieves any of its principal intended medical purposes through chemical action or by being metabolized. Congress has not, however, inserted any counterpart clause into the definition of "drug" that would make chemical or metaboilic action a prerequisite to a product's being regulated as a drug. Nor did Congress, in its 1976 revision of the "device" definition, substitute the broader term "article" for the listing of narrower categories of products to be regulated as devices found in the act since 1938. Rather, Congress simply updated and expanded this listing. There are a number of products that, like Lacrisert, are regulated as drugs even though they do not achieve their principal intended purposes through chemical action or by being metabolized. Among these are sunscreens, dandruff preparations, and various laxative preparations such as mineral oil and psyllium.

Dated: October 7, 1982.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-28345 Filed 10-14-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82F-0308]

Rexall Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Rexall Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aspartame as a sweetener in multivitamin food supplements.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2A3662) has been filed by Rexall Corp., 3901 North Kingshighway Blvd., St. Louis, MO 63115, proposing that § 172.804 *Aspartame* (21 CFR 172.804) be amended to provide for the safe use of aspartame (1-methyl *N-L-α*-aspartyl-*L*-phenylalanine) as a sweetener in multivitamin food supplements.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: October 1, 1982.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 82-28157 Filed 10-14-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82F-0305]

G. D. Searle & Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that G. D. Searle and Co., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aspartame as a sweetener in carbonated beverages.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2A3661) has been filed by the Searle Research and Development Division of G. D. Searle and Co. 4901 Searle Parkway, Skokie, IL 60077, proposing that § 172.804 *Aspartame* (21

CFR 172.804) be amended to provide for the safe use of aspartame (1-methyl *N*-*L*-α-aspartyl-*L*-phenylalanine) as a sweetener in carbonated beverages.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: October 1, 1982.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 82-28156 Filed 10-14-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket Nos. 81P-0094 and 82P-0092]

Varian Canada, Inc., and Garrett Manufacturing Co., Ltd.; Availability of Approved Variances for Aircraft Peripheral Vision Horizon Laser Device

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that variances from the performance standard for laser products have been approved by the Bureau of Radiological Health for two organizations that have manufactured and exported to the United States a peripheral vision horizon laser device for use in aircraft. One of the companies—Garrett Manufacturing Co., Ltd.—is now the primary, if not the sole, manufacturer and exporter of the product in question. The device projects a line of colored light onto an aircraft instrument panel, which line follows the aircraft's movement in pitch and roll, allowing the pilot to maintain attitude reference using peripheral vision.

DATES: The variance for Varian Canada, Inc., became effective September 23, 1981, and ends September 23, 1986; the variance for Garrett Manufacturing Co., Ltd., became effective June 7, 1982, and ends June 7, 1987.

ADDRESS: The applications and all correspondence on them, except for trade-secret information, have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Glenn E. Conklin, Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Under § 1010.4 (21 CFR 1010.4), Varian Canada, Inc., 45 River Dr., Georgetown, ON L7G 2J4, Canada, and Garrett Manufacturing, Ltd., 255 Attwell Dr., Rexdale, ON M9W 5B8, Canada, have been granted variances for the Peripheral Vision Horizon Laser Device from § 1040.10(f) (3), (4), and (5) (ii) and (iii) (21 CFR 1040.10(f) (3), (4), and (5) (ii) and (iii)) of the performance standard for laser products.

Section 1040.10(f) (3), (4) and (5) (ii) and (iii) require the product to be equipped with a remote control connector, a key control, an emission indicator delay, and dual emission indicators. However, these performance features are not appropriate for the Peripheral Vision Horizon Laser Device, which, by its physical design and conditions placed upon it by the variances, utilizes alternate means for providing radiation safety or protection equal to that provided by products meeting the four requirements. The conditions under which the variances are granted relate to additional instructions in the user information, constraints on the physical and optical design, and constraints on sales. All provisions of § 1040.10 other than those cited remain applicable to the laser product.

By letter to each manufacturer, the Director of the Bureau of Radiological Health approved the requested variances. The variances permit the manufacturers to introduce into commerce the Peripheral Vision Horizon Laser Device for use in governmental military and scheduled commercial aircraft. To identify each product by the variance approved for it, FDA requires that each product bear on the certification label required by § 1010.2(a) (21 CFR 1010.2(a)) a variance number (which is the docket number) and effective date of the variance. The product manufactured by Variance Canada, Inc., shall bear the variance No. 81P-0094 and the effective date of September 23, 1981. The product manufactured by Garrett Manufacturing Co., Ltd., shall bear the variance No. 82P-0092 and the effective date of June 7, 1982. Each variance expires 5 years after its effective date.

In accordance with § 1010.4, the application and all related correspondence, except information covered by the trade-secret provisions of section 360A(e) of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263i(e)), on the two applications have been placed on public display under the designated docket number in the Dockets Management Branch (address above) and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 7, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-28155 Filed 10-14-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 80N-0446]

Availability of Toxicological Standards for Food and Color Additive Safety Evaluation

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of a document entitled "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food." This document represents the agency's most recent effort at delineating a scientific framework for developing safety information for the approval of such new additives, and for maintaining an overview of the safety of approved additives.

DATES: Comments by January 13, 1983.

ADDRESS: A copy of this document is available for review at, and individual copies may be obtained from, the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD. 20857.

FOR FURTHER INFORMATION CONTACT:

For general information: A. M. Rulis, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5676.

For information relating specifically to toxicological criteria: Charles J. Kokoski, Bureau of Foods (HFF-156), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5705.

SUPPLEMENTARY INFORMATION: The approval of new food and color additives depends on the outcome of the agency's evaluation of appropriate information supplied by the sponsor of the additive. Upon finding that the proposed use of the additive is "safe" within the meaning of the statute and regulations, the agency publishes a regulation permitting such use.