

Promotion and Education (HCK) and substitute the following:

Center for Chronic Disease Prevention and Health Promotion (HCL)

Plans, directs, and coordinates a national program for the prevention of premature mortality, morbidity, and disability due to chronic illnesses and conditions and promotes the overall health of the population. In carrying out this mission, the Center: (1) Plans, directs, and conducts epidemiologic, behavioral, and laboratory investigations, technology translation, demonstrations, and programs directed toward the definition, prevention, and control of chronic diseases, promoting healthy behaviors and practices, and promoting reproduction health in conjunction with State health agencies; (2) provides leadership in the development, evaluation, and dissemination of effective health promotion, school health education, and risk reduction programs; (3) plans, develops, and maintains systems of surveillance for chronic diseases and conditions, and behavioral and other risk factors; (4) conducts epidemiologic and behavioral investigations and demonstrations related to major personal health practices and behaviors, including tobacco use, nutrition, family planning, alcohol use, and exercise in conjunction with State health agencies; (5) plans, directs, and conducts epidemiologic and evaluative investigations related to issues of access, utilization, and quality of health services aimed at the prevention and control of chronic diseases and conditions and selected adverse reproductive outcomes; (6) serves as the primary focus for assisting States and localities through grants, cooperative agreements, and other mechanisms, in establishing and maintaining chronic disease prevention and control and health promotion programs; (7) provides training and technical consultation and assistance to States and localities in planning, establishing, maintaining, and evaluating prevention and control strategies for selected chronic disease and health promotion activities; (8) plans, coordinates, and conducts laboratory activities related to selected chronic diseases with State and local health departments, other organizations, and other CDC programs; (9) provides technical consultation and assistance to other nations in the development and implementation of programs related to chronic disease prevention and control, health promotion, school health education, and selected adverse reproductive outcomes; (10) and in carrying out the above functions,

collaborates as appropriate with other Centers and offices of CDC, other PHS agencies, domestic and international public health agencies, and voluntary and professional health organizations.

2. Under the heading *Center for Environmental Health and Injury Control (HCN)*, the item (1), delete the words "and chronic disease;" and in item (8), insert the word "selected" before "chronic disease;" and in item (9), delete the words "chronic diseases and."

3. Under the heading *Center for Prevention Services (HCM)*, change item (4) to read: (4) Serves as the primary focus for assisting States and localities, through grants and other mechanisms, in establishing and maintaining prevention and control programs directed toward health problems such as vaccine-preventable diseases, acquired immunodeficiency syndrome and other sexually transmitted diseases, dental disease, and tuberculosis.

Effective Date: October 18, 1988

Otis R. Bowen,

Secretary.

[FR Doc. 88-24564 Filed 10-24-88; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 88C-0336]

Ciba Vision Corp.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Vision Corp. has filed a petition proposing that the color additive regulations be amended to provide for the safe use of C.I. Reactive Red 180 (5-(benzoylamino)-4-hydroxy-3-[[1-sulfo-6-[[2-(sulfoxy)ethyl]sulfonyl]-2-naphthalenyl]azo]-2,7-naphthalenedisulfonic acid, tetrasodium salt, CAS Reg. No. 98114-32-0) to color contact lenses.

FOR FURTHER INFORMATION CONTACT: Mary W. Lipien, Center for Food Safety and Applied Nutrition (HFF-335), 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. 706(d)(1), 74 Stat. 402-403 (21 U.S.C. 376(d)(1)), notice is given that a petition (CAP 7C0212) has been filed by Ciba Vision Corp., P.O. Box 105069, Atlanta, GA 30348, proposing that 21 CFR Part 73 of the color additive regulations be amended to provide for the safe use of C.I. Reactive Red 180 (5-

(benzoylamino)-4-hydroxy-3-[[1-sulfo-6-[[2-(sulfoxy)ethyl]sulfonyl]-2-naphthalenyl]azo]-2,7-naphthalenedisulfonic acid, tetrasodium salt, CAS Reg. No. 98114-32-0) to color contact lenses.

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).

Dated: October 17, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-24626 Filed 10-24-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0328]

Arakawa Chemical Industries, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Arakawa Chemical Industries, Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aromatic petroleum hydrocarbon resin, hydrogenated, as a component of paper and paperboard intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), 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 8B4072) has been filed by Arakawa Chemical Industries, Ltd., 1-21 Hiranomachi, Higashi-Ku, Osaka 541, Japan, 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 aromatic petroleum hydrocarbon resin, hydrogenated, as a component of paper and paperboard intended for use in contact with food.

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).

Dated: October 17, 1988.

Fred R. Shank,
Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-24621 Filed 10-24-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0325]

DuPont Canada, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that DuPont Canada, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of triisopropanolamine as an optional adjuvant substance in the production of olefin polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-335), 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 8B4104) has been filed by DuPont Canada, Inc., c/o Keller and Heckman, 1150 17th St. NW., Washington, DC 20036, proposing that § 177.1520 Olefin polymers (21 CFR 177.1520) be amended to provide for the safe use of triisopropanolamine as an optional adjuvant substance in the production of olefin polymers intended for use in contact with food.

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).

Dated: October 17, 1988.

Fred R. Shank,
Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-24622 Filed 10-24-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 83F-0029]

ICI Americas, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (FAP 7B3306) proposing that the food additive regulations be amended to provide for the safe use of toluene diisocyanate as a condensate modifier in the preparation of a modified cross-linked polyester resin for use in the fabrication of articles intended for repeated use in contact with foods.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 18, 1983 (48 FR 11514), FDA published a notice that it had filed a petition (FAP 7B3306) from ICI Americas, Inc., Wilmington, DE 19897, that proposed to amend the food additive regulations to provide for the safe use of toluene diisocyanate as a condensate modifier in the preparation of a modified cross-linked polyester resin for use in the fabrication of articles intended for repeated use in contact with foods. ICI Americas, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: October 17, 1988.

Fred R. Shank,
Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-24623 Filed 10-24-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0333]

Sandoz AG; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sandoz AG has filed a petition proposing that the food additive regulations be amended to include the use of di-tert-butylphenyl phosphonite condensation product with piperonyl as an antioxidant for 4-methylpentene-1 copolymers used in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (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 8B4100) has been filed by Sandoz AG, CH-442, Basel, Switzerland, proposing that § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) be amended to include the use of di-tert-butylphenyl phosphonite condensation product with biphenyl as an antioxidant for 4-methylpentene-1 copolymers used in contact with food.

The potential environmental impact of this section 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).

Dated October 14, 1988.

Fred R. Shank,
Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-24624 Filed 10-24-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0316]

Troy Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Troy Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 3-iodo-2-propynyl butyl carbamate as an antifungal preservative in adhesives for food contact applications.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Center for Food Safety and Applied Nutrition (HFF-335), 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 8B4088) has been filed by the Troy Chemical Corp., One Avenue L, Newark, NJ 07105-3895, proposing that § 175.105 Adhesives (21 CFR 175.105) be amended to provide for the safe use of 3-iodo-2-propynyl butyl carbamate as an

antifungal preservative in adhesives for food contact applications.

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).

Dated: October 7, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-24620 Filed 10-24-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88M-0292]

Behring Diagnostics, Inc.; Premarket Approval of the Enzygost® Anti-HBc Device

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Behring Diagnostics, Inc., Somerville, NJ, for premarket approval, under the Medical Device Amendments of 1976, of the Enzygost® anti-HBc device. After reviewing the recommendation of the Microbiology Devices Panel, FDA's Center for Biologics Evaluation and Research (CBER) notified the applicant, by letter of May 18, 1988, of the approval of the application.

DATE: Petitions for administrative review by November 25, 1988.

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

FOR FURTHER INFORMATION CONTACT: William Tyler, Center for Biologics Evaluation and Research (HFB-230), Food and Drug Administration, 88 Rockville Pike, Bethesda, MD 20892, 301-443-5433.

SUPPLEMENTARY INFORMATION: On October 26, 1986, Behring Diagnostics, Inc., Somerville, NJ 08876, submitted to CBER an application for premarket approval of the Enzygost® anti-HBc device. This in-vitro diagnostic device is indicated for detection of total antibody to hepatitis B core antigen (anti-HBc) in human serum or plasma and is to be used as an aid in the diagnosis of

ongoing or previous hepatitis B infection.

On February 8, 1988, the Microbiology Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. Subsequently, the regulatory responsibility for evaluation and approval of this device was transferred to CBER because the primary intended use of the device is for screening blood. On May 18, 1988, CBER approved the application by a letter to the applicant from the Director of the Center for Biologics Evaluation and Research.

A summary of the safety and effectiveness data on which CBER based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CBER—contact William Tyler (HFB-230), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (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 CBER'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 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 issue 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 November 25, 1988, 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.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10).

Dated: October 17, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-24627 Filed 10-24-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88M-0323]

Innovative Optics, Inc.; Premarket Approval of I.O.-18 (Kolfocon A) and I.O.-32 (Kolfocon B) Rigid Gas Permeable Contact Lenses (Clear and Tinted)

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Innovative Optics, Inc., Big Spring, TX, for premarket approval, under the Medical Device Amendments of 1976, of the I.O.-18 (kolfocon A) and I.O.-32 (kolfocon B) Rigid Gas Permeable Contact Lenses. The devices are to be manufactured under an agreement with Optacryl, Inc., Englewood, CO, which has authorized Innovative Optics, Inc., to incorporate information contained in its approved application for premarket approval for the Optacryl (polyacrylate-silicone) Rigid Gas Permeable Contact Lens (Clear and Tinted). FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 31, 1988, of the approval of the application.

DATE: Petitions for administrative review by November 25, 1988.

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

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 8757