of the agency's intent to revoke U.S. License No. 915, setting forth grounds for the revocation, and offering an opportunity for a heading. In letters dated May 31, June 5, June 13, and July 19, 1985, the firm, through its legal counsel, requested the agency to reconsider its decision to pursue license revocation; challenged the findings of an agency investigation conducted concurrently with the inspections; and denied that the firm's management acted willfully. In a letter dated July 11, 1985, the agency advised the firm that the pervasiveness of the deficiencies and the failure of management personnel to correct and prevent the deficiencies represented willful disregard for prescribed standards. The agency also advised the firm that the determination documented during the 1985 inspections and on information obtained during FDA's investigation.

The agency has evaluated and considered all information submitted on behalf of Biological Resources, Inc., including the firm's the request that FDA reconsider its decision to proceed to revoke the firm's license, and has concluded that license revocation is appropriate. Accordingly, FDA is now issuing a notice of opportunity for hearing on the matter under § 12.21(b) (21 CFR 12.21(b)).

Copies of the List of Observations (Form FDA-483's) from the inspections of January 9 through 15, 1985, January 18 through 24, 1985, and March 5 through 21, 1985; FDA's April 5, May 8, and July 11, 1985, letters; and the firm's letters of April 11, May 31, June 5, June 13, and July 19, 1985, are on file at the Dockets Management Branch (address above).

This notice does not detail all the information in support of license revocation. Information from the time of the establishment's initial license application may be applicable to a hearing that may result from the publication of this notice.

The Commissioner of Food and Drugs is offering an opportunity for a hearing under § 12.21(a) on the proposed revocation of the establishment license (U.S. License No. 915) and product license issued to Biological Resources, Inc., for the manufacture of Source Plasma. The establishment may submit a written request for a hearing to the Docket Management Branch by July 22, 1988 and any data justifying a hearing must be submitted by August 22, 1988. Other interested persons may submit comments on the proposed license revocation to the Dockets Management Branch by August 22, 1988. The failure of a license to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity of a hearing concerning the proposed license revocation.

FDA procedures and requirements governing a notice of opportunity for hearing, notice of appearance and request for hearing, grant or denial of hearing, and submission of data and information to justify a hearing are contained in 21 CFR Parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials, but must set forth a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factural analyses in the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact that precludes the revocation of the license, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify the denial.

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Such submissions, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 351, 352, 355, 371 and under authority delegated to the Commission of Food and Drugs (21 CFR 5.10) and as redelegated (21 CFR 5.67).

Dated: June 7, 1988

Paul D. Parkman,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 88-13985 Filed 6-21-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88F-0193]

Bercen, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Cranston Print Works Co. has filed a petition on behalf of Bercen, Inc., proposing that the food additive regulations be amended to provide for the safe use of bis(methoxymethyl)tetrakis[(octadecyloxy)methyl] melamine resin as a water repellant in the manufacture of paper and paperboard for food-contact use.

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 6B3952) has been filed by Cranston Print Works Co., 1381 Cranston St., Cranston, RI 02920, on behalf of Bercen, Inc., proposing that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) of the food additive regulations be amended to provide for the safe use of bis(methoxymethyl)tetrakis[(octadecyloxy)methyl] melamine resin as a water repellant in the manufacture of paper and paperboard for food-contact use.

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: June 13, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-13977 Filed 6-21-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87F-0300]

Betz Laboratories, 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 7A4031) proposing that the food additive regulations be amended to provide for the safe use of hydroquinone as an additive in boilers producing steam that may come in contact with food.

FOR FURTHER INFORMATION CONTACT: Eric Flamm, Center for Food Safety and

Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–8950.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 7, 1987 (52 FR 37524), FDA published a notice that it had filed a petition (FAP 7A4031) from Betz Laboratories, Inc., 4636 Somerton Rd., Trevose, PA 19047, proposing that § 173.310 *Boiler water additives* (21 CFR 173.310) be amended to provide for the safe use of hydroquinone as an additive in boilers producing steam that may come in contact with food. The firm has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: June 13, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–13978 Filed 6–21–88; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88F–0182]

Dow Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Dow Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of styrene-butadiene-acrylonitrile copolymers as components of paper and paperboard 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 8B4083) has been filed by Dow Chemical Co., 1803 Bldg., Door 7, Midland, MI 48674, 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 styrene-butadiene-acrylonitrile copolymers, copolymerized with not more than 10 percent of one or more of the monomers of acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid and methacrylic acid, as components of paper and paperboard 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: June 13, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–13979 Filed 6–21–88; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88F–0196]

E.I. du Pont de Nemours & Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that E.I. du Pont de Nemours & Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of trimethyl trimellitate as an optional monomer in the manufacture of a certain polyester elastomer intended for repeated use in contact with food.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, 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 8B4089) has been filed by E.I. du Pont de Nemours & Co., 1007 Market St., Wilmington, DE 19898, proposing that § 177.2600 *Rubber articles intended for repeated use* (21 CFR 177.2600) be amended to provide for the safe use of trimethyl trimellitate as an optional monomer in the manufacture of a certain polyester elastomer derived from the reaction of dimethyl terephthalate, 1,4-butanediol and α-hydro-ω-hydroxypoly (oxytetramethylene) intended for repeated 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: June 13, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–13980 Filed 6–21–88; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88F–0177]

Velsicol Chemical Corp.; Filing of Food Additive Petitions

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Velsicol Chemical Corp. has filed two petitions proposing that the food additive regulations be amended to provide for the safe use of polypropylene glycol dibenzoate and propylene glycol dibenzoate, respectively, as components of adhesives in contact with food.

FOR FURTHER INFORMATION CONTACT: Richard H. White, 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 two petitions (FAP 8B4070 and FAP 8B4071) have been filed by Velsicol Chemical Corp., 5600 River Rd., Rosemont IL 60018–5119, proposing that § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of polypropylene glycol dibenzoate and propylene glycol dibenzoate, respectively, as components of adhesives 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: June 13, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–13981 Filed 6–21–88; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88N-0231]

Drug Export; Pneumopent ™ (Pentamidine Isethionate for Inhalation)

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Fisons Corp. has filed an application requesting approval for the export of the human drug Pneumopent ™ (Pentamidine isethionate for inhalation) to the United Kingdom. This drug is used in the treatment of *Pneumocystis carinii* pneumonia.

ADDRESS: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Rudolf Apodaca, Division of Drug Labeling Compliance (HFD-310), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8063.

SUPPLEMENTARY INFORMATION: The Drug Export Amendments Act of 1986 (Pub. L. 99-660) (section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382)) provides that FDA may approve applications for the export of drugs that are not currently approved in the United States. The approval process is governed by section 802(b) of the Act. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the Act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Fisons Corp., Two Preston Court, Bedford, MA 01730, has filed an application requesting approval for the export of the drug Pneumopent ™ (Pentamidine isethionate for inhalation), to the United Kingdom for use in the treatment of *Pneumocystis carinii* pneumonia. The application was received and filed in the Center for Drug Evaluation and Research on June 7, 1988, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by July 5, 1988, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802, Pub. L. 99-660 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: June 14, 1988.

Sammie R. Young,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research

[FR Doc. 88-13983 Filed 6-21-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88D-0050]

Investigation of Drugs in Humans; Availability of Revised Clinical Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guideline for the clinical evaluation of anti-inflammatory and antirheumatic drugs. The purpose of the guideline is to present acceptable approaches to the clinical study of drugs intended to treat arthritis and related conditions. The guideline was prepared by the Center for Drug Evaluation and Research. It revises a guideline for the clinical evaluation of anti-inflammatory drugs that was issued in September 1977.

ADDRESSES: Written comments may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockvile, MD 20857. Requests to purchase a copy of the guideline may be sent to the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. To order, reference GPO stock No. 017-012-00333-8.

FOR FURTHER INFORMATION CONTACT: Linda Carter, Center for Drug Evaluation and Research (HFN-100) Food and drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4330.

SUPPLEMENTARY INFORMATION: FDA is making available a revised guideline for the clinical investigation of anti-inflammatory drugs. The new guideline is entitled "Guidelines for the Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (Adults and Children)." The revisions represent an update of the guideline, which was originally issued in September 1977, entitled "Guidelines for the Clinical Evaluation of Anti-Inflammatory Drugs (Adults and Children)." This earlier guideline was issued under identification number HEW [FDA 78-3054]. The agency's action is consistent with its commitment to conduct periodic review of all clinical guidelines. The original guideline (HEW [FDA 78-3054]) is hereby revoked.

The new guideline applies to the clinical study of both nonsteroidal anti-inflammatory drugs (NSAID's) and disease-modifying antirheumatic drugs (DMRD's). The guideline was prepared by scientists in the Center for Drug Evaluation and Research with the assistance of the Arthritis Advisory Committee and its subcommittees.

This notice of availability of the revised guidelines is issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidelines to outline procedures or standards of general applicability that are acceptable to FDA for subject matter that falls within the laws administered by FDA. Although use of these guidelines is not a legal requirement, a person may be assured that in following an agency guideline the procedures and standards will be acceptable to FDA. A person may also choose to use alternative procedures or standards for which there is a scientific rationale even though they are not provided for in the guideline. A person who chooses to use procedures or standards not in the guideline may discuss the matter further with FDA to prevent the expenditure of money and effort on work that the agency may later determine to be unacceptable.

The guideline contains recommendations for the clinical study of drugs to treat anti-inflammatory conditions. Research begun in good faith in conformity with the recommendations contained in this guideline will be accepted for review by the agency. This, of course, does not mean that the data