Washington, DC 20201, telephone 202/245-0409.

Lillian K. Gibbons,

*Executive Director, Secretary's Commission on Nursing.*

[FR Doc. 88-14075 Filed 6-21-88; 8:45 am]

BILLING CODE 4150-04-M

## Food and Drug Administration

[Docket No. 88N-0025]

## Biological Resources, Inc.; Opportunity for Hearing on Intent To Revoke U.S. License No. 915

**AGENCY:** The Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** Food and Drug Administration (FDA) is announcing an opportunity for hearing on a proposal to revoke the establishment license (U.S. License No. 915) and product license issued to Biological Resources, Inc., for the manufacture of Source Plasma. The proposed revocation is based on significant noncompliance with certain provisions of the biologics regulations specified in this document.

**DATES:** The firm may submit a written request for a hearing to the Dockets 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 revocation by August 22, 1988.

**ADDRESS:** Written requests for hearing, data, and written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** JoAnn M. Minor, Center for Biologics Evaluation and Research (HFB-130), Food and Drug Administration, 8600 Rockville Pike, Bethesda, MD 20892, 301-295-8049 or 301-295-8101.

**SUPPLEMENTARY INFORMATION:** FDA is proposing to revoke the establishment license (U.S. License No. 915) and product license issued to Biological Resources, Inc., 16041 Woodward Ave., Highland Park, MI 48203, for the manufacture of Source Plasma. The proposed revocation is based on the failure of the firm and its responsible management to conform to the applicable standards and conditions established in its license and the requirements in 21 CFR Parts 600, 601, 610, and 640.

FDA inspections of Biological Resources, Inc., conducted on January 9 through 15, January 18 through 24, and March 5 through 21, 1985, revealed numerous and significant deficiencies from applicable standards in major areas of the plasmapheresis operation including: (1) Donor suitability determinations, (2) blood collection, (3) whole blood centrifugation and plasma processing, and (4) plasma storage and distribution. The deviations included, but were not limited to, the following:

### I. Donor Suitability Determinations and Related Quality Control Procedures

The establishment accepted individuals for plasmapheresis who did not meet the donor suitability criteria set forth in the biologics regulations for Source Plasma. For example: (a) An individual with a history of viral hepatitis was allowed to donate in violation of 21 CFR 640.63(c)(11); (b) donors were allowed to donate more than twice in a 7-day period in violation of 21 CFR 640.65(b)(5); (c) donors with abnormal results to serum protein electrophoresis testing were not temporarily deferred from participating in the plasmapheresis program in violation of 21 CFR 640.65(b)(2)(i); and (d) on at least six occasions reports of serum protein elecrophoresis tests for donor samples were not reviewed by a qualified licensed physician within 21 days of collection of the sample in violation of 21 CFR 640.65(b)(2)(i).

It was further noted that the establishment failed to maintain a donor identification system that positively identified each donor as required by 21 CFR 640.65(b)(3).

FDA investigators also found deficiencies in compliance with the required quality control procedures set forth in 21 CFR 606.60(a) and (b) designed to monitor equipment for proper performance. Three refractometers used in determining donor suitability had broken sight gates. Management instructed employees to improvise by using a glass slide in place of the broken sight gates. In addition, quality control logs for equipment and reagents used in plasmapheresis contained numerous inaccurate entries. Specifically, FDA investigators found entries for performance checks for reagents and equipment for dates, i.e., weekendes and holidays, when the establishment was reportedly closed.

### II. Blood Collection

FDA investigators observed that personnel did not consistently prepare the phlebotomy site to provide maximum assurance of a sterile container of blood as prescribed by 21 CFR 640.64(e). Blood collection scales were not always calibrated each day of use as required by 21 CFR 606.60(b).

Quality control logs for calibration of blood collection scales contained inaccurate entries. Specifically, the logs contained entries for dates, i.e., Sundays, when the establishment was reportedly closed.

### III. Whole Blood Centrifugation and Plasma Processing

The establishment did not maintain complete, concurrent, and accurate records as required by 21 CFR 606.160(a)(1) and 640.65(b)(4) and (6). For example, the whole blood and plasma log sheets frequently lacked entries relating to the amount of whole blood collected but the record indicated that such units were centrifuged and that the plasma obtained was pooled.

### IV. Plasma Storage and Distribution

FDA investigators noted numerous instances where storage temperatures were warmer than the temperatures required by 21 CFR 640.69(b). Adequate steps were not taken to assure that storage temperatures were consistently maintained as required. In addition, units of plasma were shipped without being relabeled in accordance with 21 CFR 640.76.

Source Plasma was shipped on at least one occasion prior to receipt of written test results for hepatitis B surface antigen (HBsAg).

FDA concluded that these violations demonstrated that the responsible head and other designated managers did not effectively fulfill their responsibilities to assure that the establishment was operated in compliance with the Federal regulations and the establishment's standard operating procedures.

Therefore, by letter dated April 5, 1985, FDA suspended the establishment license (U.S. License No. 915) and the product license for the manufacture of Source Plasma issued to Biological Resources, Inc.

By letter dated April 11, 1985, the establishment requested that the revocation be held in abeyance and outlined corrective actions. In considering the request, FDA comprehensively reviewed the establishment's recent inspectional history. FDA found significant and continued noncompliance with the applicable Federal regulations and the provisions of the establishment's license. Based on the willful nature of the violations, FDA denied the firm's request that license revocation be held in abeyance.

Accordingly, in a letter dated May 8, 1985, issued under § 601.5(b) (21 CFR 601.5(b)), FDA notified Biological Resources, Inc., and its responsible head

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

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**[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

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**[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

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[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

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[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

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[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