for nonimpact-resistant lenses. Because most prescription orders are now filled by impact-resistant plastic lenses, and only one or two orders for nonimpact-resistant lenses are estimated to be completed annually, this de minimus burden is not included in the chart.

Dated: September 29, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–26451 Filed 10–3–97 ; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0384]

Knickerbocker Biologicals, Inc.; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 458–001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on a proposal to revoke the establishment license (U.S. License No. 458–001) and product licenses issued to Knickerbocker Biologicals, Inc., for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Source Leukocytes. The proposed revocation is based on the inability of authorized FDA employees to conduct an inspection of this facility, which is no longer in operation.

DATES: The firm may submit written requests for a hearing to the Dockets Management Branch by November 5, 1997, and any data and information justifying a hearing by December 5, 1997. Other interested persons may submit written comments on the proposed revocation by December 5, 1997.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is initiating proceedings to revoke the establishment license (U.S. License 458–001) and product licenses issued to Knickerbocker Biologicals, Inc., doing business as Knickerbocker Blood Bank, 272 Willis Ave., Bronx, NY 10454, for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Source Leukocytes. Proceedings to revoke the licenses are being initiated because an attempted inspection of the facility by FDA revealed that the firm was no longer in operation.

In a certified, return-receipt letter dated November 14, 1996, FDA notified the Responsible Head of the firm that its attempt to conduct an inspection at Knickerbocker Biologicals, Inc., at 272 Willis Ave., Bronx, NY 10454, was unsuccessful because the facility was apparently no longer in operation, and requested that the firm notify FDA in writing of the firm's status. This letter was returned to the agency marked ''undeliverable; address unknown.''

On December 3, 1996, FDA visited three other known addresses of Knickerbocker Biologicals, Inc., New York, NY, and attempted to conduct an inspection. These attempts were also unsuccessful. Upon consultation, the U.S. Postal Service reported no information regarding a forwarding address or change of address for any of the last known locations.

In a certified, return-receipt letter sent to Knickerbocker Biologicals, Inc., dated January 24, 1997, and returned as undeliverable, FDA indicated that the attempts to conduct an inspection at the facility were unsuccessful. The letter also advised the Responsible Head that, under 21 CFR 601.5(b)(1) and (b)(2), when FDA finds that authorized employees have been unable to gain access to an establishment for the purpose of carrying out an inspection or the manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection cannot be made, proceedings for license revocation may be instituted. In the same letter, FDA indicated that a meaningful inspection could not be made at the establishment and issued the firm notice of FDA's intent to revoke U.S. License No. 458–001 and announced its intent to offer an opportunity for a hearing.

Because FDA has made reasonable efforts to notify the firm of the proposed revocation and no response was received from the firm, FDA is proceeding under 21 CFR 12.21(b) and publishing this notice of opportunity for a hearing on a proposal to revoke the licenses of the above establishment.

FDA has placed copies of the documents relevant to the proposed revocation on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. These documents include the following: (1) FDA letters to the Responsible Head dated November 14, 1996, and January 24, 1997; and (2) memorandum regarding the investigation and inspection dated December 9, 1996. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Knickerbocker Biologicals, Inc., may submit a written request for a hearing to the Dockets Management Branch by November 5, 1997, and any data and information justifying a hearing must be submitted by December 5, 1997. Other interested persons may submit comments on the proposed license revocation to the Dockets Management Branch by December 5, 1997. The failure of the licensee to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation.

FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data to justify a hearing on proposed revocation of a license 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 factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, or if a request for a hearing is not made within the required time with the required format or 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 CFR 10.20(j)(2)(i), 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 section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502,

505, and 701 of the Federal Food, Drug, and Cosmetic Acts (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: September 17, 1997.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 97–26454 Filed 10–3–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97C–0415]

Zauder Bros., Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Zauder Bros., Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of zinc sulfide as a color additive in externally applied cosmetics.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 7C0251) has been filed by Zauder Bros., Inc., c/o Schiff & Co., 1129 Bloomfield Ave., West Caldwell, NJ 07006. The petition proposes to amend the color additive regulations to provide for the safe use of zinc sulfide as a color additive in externally applied cosmetics.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 11, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–26354 Filed 10–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95F–0040]

Chemie Research and Manufacturing Co., Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition filed by Chemie Research and Manufacturing Co., Inc., proposing that the food additive regulations be amended to provide for the safe use of a glycerin extract of dried grapefruit seeds and pulp as an antimicrobial agent in the processing of fresh or frozen poultry, fish, and shellfish.

FOR FURTHER INFORMATION CONTACT: Valerie M. Davis, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3181.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 16, 1995 (60 FR 14286), FDA announced that a food additive petition (FAP 2A4336) had been filed by Chemie Research and Manufacturing Co., Inc., 160 Concord Dr., P.O. Box 181279, Casselberry, FL 32718–1279. The petition proposed that the food additive regulations be amended to provide for the safe use of a glycerin extract of dried grapefruit seeds and pulp as an antimicrobial agent in the processing of fresh or frozen poultry, fish, and shellfish.

By letter dated May 10, 1995, the agency notified the petitioner that consideration of the petitioned use for the glycerin extract of dried grapefruit seed and pulp would require the submission and evaluation of specific additional data. By letter of June 1, 1995, the petitioner provided a partial response to the agency's request for information and stated an intent to provide a complete response within 180 days. However, no further information was submitted within the 180-day time period.

By letter of July 24, 1996, FDA again requested that the necessary data be submitted within 30 days and stated that a failure to respond would be considered to be an agreement by the petitioner to withdraw the petition. Because FDA has received no response from the petitioner, and the required information has not been submitted, the petition is now withdrawn without prejudice to a future filing (21 CFR 171.7(b)). Future consideration of the use of a glycerin extract of dried grapefruit seeds and pulp as an antimicrobial agent in the processing of fresh or frozen poultry, fish, and shellfish will require submission of a new food additive petition.

Dated: September 22, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–26413 Filed 10–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0412]

Mitsui Petrochemical Industries, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Mitsui Petrochemical Industries, Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ethylene/propylene copolymers that contain up to 20 mole-percent of polymer units derived from propylene, with the remainder of the polymer consisting of ethylene, and having a minimum viscosity-average molecular weight of 95,000 and a minimum Mooney viscosity of 13 at up to 30 percent of other regulated polymer blends.

DATES: Written comments on the petitioner's environmental assessment by November 5, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration,