

the review committee. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailings.

Applications which do not meet the criteria in 1. or 2. above are considered late applications and will be returned to the applicant.

Where To Obtain Additional Information

All application procedures and guidelines are contained within the present announcement. Business management technical information may be obtained from David Elswick, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, N.E., Mailstop E-13, Atlanta, GA 30305, telephone (404) 842-6521.

Programmatic technical assistance may be obtained from Steven Adams, Project Officer, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Hwy, N.E., Mailstop F-35, Atlanta, GA 30341-3724, telephone (770) 488-7040.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone (202) 513-1800).

Dated: June 15, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0384]

Knickerbocker Biologicals, Inc.; Revocation of U.S. License No. 458-001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

revocation of the establishment license (U.S. License No. 458-001) and the product licenses issued to Knickerbocker Biologicals, Inc., for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Source Leukocytes. Knickerbocker Biologicals, Inc., did not respond to a notice of opportunity for a hearing on a proposal to revoke its licenses.

DATES: The revocation of the establishment license (U.S. License No. 458-001) and the product licenses is effective June 19, 1998.

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 revoking the establishment license (U.S. License No. 458-001) and the 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.

An attempted inspection of the facility by FDA revealed that the facility was no longer in operation at the location listed on the license. A certified, returned-receipt letter from FDA dated November 14, 1996, notifying the Responsible Head of the unsuccessful inspection and requesting the status of the firm was returned to the agency as "undeliverable; address unknown". A later attempt by FDA to visit three other known addresses of Knickerbocker Biologicals, Inc., New York, NY, verified that the company was no longer in business at these locations. The respective post office for each location was also visited and each verified that no information regarding either a forwarding address or address change was available. Based on the inability of authorized FDA employees to conduct a meaningful inspection of the facility, FDA initiated proceedings for the revocation of the licenses under 21 CFR 601.5(b)(1) and (b)(2). A certified, returned-receipt letter, dated January 24, 1997, to the firm's Responsible Head providing notice of FDA's intent to revoke the licenses and its intent to offer an opportunity for a hearing on the proposed revocation was returned as undeliverable.

Under 21 CFR 12.21(b), FDA published in the **Federal Register** of October 6, 1997 (62 FR 52135), a notice of opportunity for a hearing on a proposal to revoke the licenses of Knickerbocker Biologicals, Inc. In the notice, FDA explained that the proposed

license revocation was based on the inability of authorized FDA employees to conduct a meaningful inspection of the facility because it was no longer in operation and noted that documentation in support of the license revocation had been placed on file for public examination with the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The notice provided the firm 30 days to submit a written request for a hearing and 60 days to submit any data and information justifying a hearing. The notice provided other interested persons with 60 days to submit written comments on the proposed revocation. The firm did not respond within the 30-day time period with a written request for a hearing. The 30-day time period, prescribed in the notice of opportunity for a hearing and in the regulation, may not be extended. No comments were received from any other parties within the 60-day time period.

Accordingly, under 21 CFR 12.38, section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 458-001), and the product licenses issued to Knickerbocker Biologicals, Inc., are revoked, effective June 19, 1998.

Dated: May 28, 1998.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Studies of Adverse Effects of Marketed Drugs; Availability of Grants (Cooperative Agreements); Request for Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, is announcing \$1.4 million for cooperative agreements to study adverse effects of drugs marketed in Canada, the United States and its territories, subject to the availability of Fiscal Year 1999 funds. This amount is consistent with the level