

Dated: October 3, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97-26984 Filed 10-9-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0115]

SEF, P.A.; Revocation of U.S. License No. 1166

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. 1166) and the product licenses issued to SEF, P.A., doing business as National Health Guard, Inc., for the manufacture of Whole Blood and Red Blood Cells (RBC's). SEF, P.A., 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. 1166) and the product licenses is effective October 10, 1997.

FOR FURTHER INFORMATION CONTACT:

Dano B. Murphy, Center for Biologics Evaluation and Research (HFM-630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION: FDA is revoking the establishment license (U.S. License No. 1166) and product licenses issued to SEF, P.A., doing business as National Health Guard, Inc., 1885 West Commercial Blvd., suite 140, Fort Lauderdale, FL 33309, for the manufacture of Whole Blood (CPDA-1) and RBC's including frozen, deglycerolized, frozen rejuvenated, and rejuvenated deglycerolized RBC's.

On February 13, 1996, FDA attempted to inspect the SEF, P.A., facility located at 1820 North University Dr., Plantation, FL. The facility was found to be vacant. A visit that same day to the firm's previous business address, 1885 West Commercial Blvd., suite 140, Fort Lauderdale, FL, found that location to be vacant as well. On February 28, 1996, the owner of SEF, P.A., stated that all the firm's equipment was stored in a warehouse in Miami, FL. The owner also indicated that he would voluntarily surrender the firm's license because

SEF, P.A. was no longer in operation and there were no plans to resume operations. On June 17, 1996, FDA successfully contacted the owner by telephone and he indicated that he no longer desired to relinquish the license. Further attempts to contact the owner on July 2 and 29, 1996, were unsuccessful. On both occasions, messages were left with the answering party that were never replied to by the owner.

FDA sent a certified, return-receipt letter dated November 1, 1996, to the firm's owner. The letter stated that under 21 CFR 601.5(b) a license may be revoked when the Commissioner of Food and Drugs finds that: (1) Authorized FDA employees after reasonable efforts have been unable to gain access to an establishment or a location for the purposes of carrying out an inspection, or (2) manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made. The letter provided the firm's owner notice of FDA's intent to revoke U.S. License No. 1166 and announced FDA's intent to offer an opportunity for a hearing.

Under 21 CFR 12.21(b), FDA published in the **Federal Register** of April 9, 1997 (62 FR 17193), a notice of opportunity for a hearing on a proposal to revoke the licenses of SEF, P.A. In the notice, FDA explained that the proposed license revocation was based on the inability of 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 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.

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. 1166) and the product licenses issued to SEF, P.A. are revoked, effective October 10, 1997.

Dated: September 25, 1997.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 97-26987 Filed 10-9-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Center for Research Resources Special Emphasis Panel (SEP) meetings:

Name of SEP: Biomedical Research Technology (Telephone Conference Call).

Date: November 3, 1997.

Time: 12:00 p.m.

Place: National Institutes of Health, 6507 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965.

Contact Person: Dr. D.G. Patel, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda 20892-7965, (301) 435-0820.

Purpose/Agenda: To evaluate and review grant applications.

Name of SEP: Biomedical Research Technology (Telephone Conference Call).

Date: November 4, 1997.

Time: 12:00 p.m.

Place: National Institutes of Health, 6507 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965.

Contact Person: Dr. D.G. Patel, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda 20892-7965, (301) 435-0820.

Purpose/Agenda: To evaluate and review grant applications.

Name of SEP: Biomedical Research Technology (Telephone Conference Call).

Date: November 5, 1997.

Time: 12:00 p.m.

Place: National Institutes of Health, 6507 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965.

Contact Person: Dr. D.G. Patel, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda 20892-7965, (301) 435-0820.

Purpose/Agenda: To evaluate and review grant applications.

Name of SEP: Biomedical Research Technology (Telephone Conference Call).

Date: November 7, 1997.

Time: 12:00 p.m.

Place: National Institutes of Health, 6507 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965.