

concerning state plan disapproval. The Office contributes to the development of national policy based on regional perspectives on all ACF programs. It oversees ACF operations, the management of ACF regional staff; coordinates activities across regional programs; and assures that goals and objectives are met and departmental and agency initiatives are carried out. The Office alerts the Assistant Secretary for Children and Families to problems and issues that may have significant regional or national impact. The Office represents ACF at the regional level in executive communications within ACF, with the HHS Regional Director, other HHS operating divisions, other federal agencies, and public or private local organizations representing children and families.

Within the Office of the Regional Hub Director, the Program Coordination and Planning Unit (PCPU), headed by the Executive Officer and consisting of administrative staff, assists the Regional Hub Director in providing day-to-day support for regional administrative functions, including budget, internal systems, employee relations and human resource development activities. The PCPU develops and implements the regional planning process. Tracking, monitoring and reporting on regional progress in the attainment of ACF national goals and objectives are carried out. The PCPU coordinates public awareness activities, information dissemination and education campaigns in accordance with the ACF Office of Public Affairs and in conjunction with the HHS Regional Director. The unit also assists the Regional Hub Director in management of cross-cutting initiatives and activities among the regional components, and ensures effective and efficient management of internal automation processes.

For Regions 4 and 9, delete paragraph A and replace with the following:

KD.20 Functions. A. The Office of the Regional Hub Director is headed by a Director, who reports to the Assistant Secretary for Children and Families through the Director, Office of Regional Operations and State Systems. The Office is responsible for the Administration for Children and Families' key national goals and priorities. It represents ACF's regional interests, concerns, and relationships within the Department and among other Federal agencies and focuses on State agency culture change, more effective partnerships, and improved customer service. It provides executive leadership and direction to state, county, city, territorial and tribal governments, as well as public and private local grantees

to ensure effective and efficient program and financial management. The Office ensures that these entities conform to federal laws, regulations, policies and procedures governing the programs, and exercises all delegated authorities and responsibilities for oversight of the programs. The Office takes action to approve state plans and submits recommendations to the Assistant Secretary for Children and Families concerning state plan disapproval. The Office contributes to the development of national policy based on regional perspectives on all ACF programs. It oversees ACF operations, the management of ACF regional staff; coordinates activities across regional programs; and assures that goals and objectives are met and departmental and agency initiatives are carried out. The Office alerts the Assistant Secretary for Children and Families to problems and issues that may have significant regional or national impact. It represents ACF at the regional level in executive communications within ACF, with the HHS Regional Director, other HHS operating divisions, other federal agencies, and public or private local organizations representing children and families.

Within the Office of the Regional Hub Director, an administrative staff assists the Regional Hub Director in providing day-to-day support for regional administrative functions, including budget, internal systems, employee relations, and human resource development activities. The Staff develops and implements the regional planning process. It tracks, monitors and reports on regional progress in the attainment of ACF national goals and objectives. The Staff coordinates public awareness activities, information dissemination and education campaigns in accordance with the ACF Office of Public Affairs and in conjunction with the HHS Regional Director. It assists the Regional Hub Director in management of cross-cutting initiatives and activities among the regional components, and ensures effective and efficient management of internal automation processes.

IV. Within Chapter KD, replace the term "Regional Administrator" with "Regional Hub Director" in Regions 2, 4, 5, 6 and 9.

Dated: April 17, 1996.

Mary Jo Bane,

Assistant Secretary for Children and Families.

[FR Doc. 96-10008 Filed 4-23-96; 8:45 am]

BILLING CODE 4184-01-P

Food and Drug Administration

[Docket No. 96N-0015]

Personal Blood Storage of Memphis, Inc.; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 1131

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. 1131) and the product licenses issued to Personal Blood Storage of Memphis, Inc., for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Platelets. The proposed revocation is based on the establishment's discontinuing of manufacturing of products to the extent that a meaningful inspection or evaluation cannot be made.

DATES: The firm may submit a written request for a hearing to the Dockets Management Branch by May 24, 1996, and any data and information justifying a hearing by June 24, 1996. Other interested persons may submit written comments on the proposed revocation by June 24, 1996.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any 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: Gloria J. Hicks, 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 initiating proceedings to revoke the establishment license (U.S. License No. 1131) and product licenses issued to Personal Blood Storage of Memphis, Inc., formerly located at 5182 East Raines Rd., Memphis, TN 38118, for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Platelets. Proceedings to revoke the licenses are being initiated because an inspection of the facility by FDA revealed that the firm was no longer in operation.

On May 23, 1995, an FDA investigator attempted to conduct an inspection of Personal Blood Storage of Memphis, Inc., and found that the facility was vacant. Communication with the person listed as the responsible head indicated that all of the firm's employees were

dismissed on March 3, 1995. During a June 1, 1995, telephone conversation with FDA staff at the Center for Biologics Evaluation and Research (CBER), one of the owners of the firm stated that the firm ceased operations in December 1994. FDA explained that it could move to revoke the license if the firm remained inoperative. FDA requested a written response within 30 days regarding whether the owners intended to reopen the establishment. As of July 24, 1995, none of the owners had contacted FDA regarding the firm's intentions. In addition, messages left by FDA staff on one owner's telephone answering machine were not answered. An FDA investigator, from the Nashville District Office, was permitted to visit the unoccupied facility by the property owner on August 3, 1995. The investigator documented that the office space and two walk-in freezers were empty and that there was no electrical or water service at the facility. The U.S. Postal Service supplied FDA with the firm's forwarding address, and FDA sent a certified letter, dated September 8, 1995, to the firm's responsible head. The certified letter stated that, under 21 CFR 601.5(b), a license may be revoked if the Commissioner finds that after reasonable efforts authorized FDA employees have been unable to gain access to an establishment for the purposes of conducting an inspection, or that the manufacturing of a product has been discontinued to an extent that a meaningful inspection cannot be made. The letter also stated that following repeated attempts to conduct an inspection, FDA had determined that a meaningful inspection could not be made. The letter provided the firm's responsible head notice of FDA's intent to revoke U.S. License No. 1131 and announced FDA's intent to offer an opportunity for a hearing. The responsible head responded by telephone on September 12, 1995, and said that she was no longer employed by Personal Blood Storage of Memphis, Inc. She also sent a copy of a March 3, 1995, letter to CBER in which she had stated that she was no longer the Technical Director or responsible head for Personal Blood Storage of Memphis, Inc. A copy of FDA's letter of intent to revoke U.S. License No. 1131 was also sent to one owner's address in Texas and was returned by the U.S. Postal Service as unclaimed.

Because FDA made reasonable efforts to notify the firm of the proposed revocation and no response was received from the firm, FDA is proceeding pursuant to 21 CFR 12.21(b) and publishing this notice of an

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 license 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) Record of teleconference dated June 1, 1995; (2) letter to FDA from responsible head dated March 3, 1995; (3) Summary of Findings dated August 3, 1995, (Endorsement-Form FDA 481); (4) FDA certified letter to responsible head dated September 8, 1995; (5) copy of information returned from the U.S. Postal Service showing that the copy of FDA certified letter of September 8, 1995, sent to one owner's Texas address, was unclaimed; and (6) record of teleconference dated September 12, 1995. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Personal Blood Storage of Memphis, Inc., may submit a written request for a hearing to the Dockets Management Branch by May 24, 1996, and any data and information justifying a hearing must be submitted by June 24, 1996. Other interested persons may submit comments on the proposed revocation by June 24, 1996. 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 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 and information to justify a hearing on a 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 requested time, or in the required format or with the required analyses, the Commissioner of Food and Drugs will deny the hearing request, making available the 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. The public availability of information in submissions is governed by 21 CFR 10.20(j)(2)(i). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 351 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 Act (21 U.S.C. 321, 351, 352, 355, and 371), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of CBER (21 CFR 5.67).

Dated: April 12, 1996.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 96-10025 Filed 4-23-96; 8:45 am]

BILLING CODE 4160-01-F

Food and Drug Administration

Grassroots Regulatory Partnership Meeting; Southeast Region, Atlanta District Office; Turkey/Broiler Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of External Affairs, Office of Regulatory Affairs, Office of the Southeast Region, and Center for Veterinary Medicine) is announcing a free public meeting. FDA's Atlanta District Office (Southeast Region) and the Center for Veterinary Medicine will meet with interested persons in the Southeast Region to address specific issues related to the turkey/broiler industry. The agency is holding this meeting to promote the President's initiative for a partnership approach with front-line regulators and the people affected by the work of the agency, and to create local partnerships.

DATES: The public meeting will be held on Tuesday, May 14, 1996, from 8 a.m. to 5 p.m.

ADDRESSES: The public meeting will be held at the Sheraton Inn—Raleigh at Crabtree Valley, 4501 Creedmoor Rd., Raleigh, NC 27812. Attendees requiring overnight accommodations may contact the hotel at 919-787-7111.

FOR FURTHER INFORMATION CONTACT: JoAnn M. Pittman, FDA Atlanta District, 60 Eighth St. NE., Atlanta, GA 30309, 404-347-7355, or FAX 404-347-1912.