DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Notice of Health Care Policy and Research Special Emphasis Panel Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of the following special emphasis panel scheduled to meet during the month of April 1997:

Name: Health Care Policy and Research Special Emphasis Panel.

Date and Time: April 28, 1997, 11 a.m.

Place; Agency for Health care Policy and Research, 2101 E. Jefferson Street, Suite 400, Rockville, MD 20852.

Open April 28, 1997, 11 a.m. to 11:10 a.m. Closed for remainder of meeting.

Purpose: This Panel is charged with conducting the initial review of grant applications proposing analytical and theoretical research on costs, quality, access, and efficiency of the delivery of health services for the research grant program administered by the Agency for Health Care Policy and Research (AHCPR).

Agenda: The open session of the meeting on April 28, from 11 a.m. to 11:10 a.m., will be devoted to a business meeting covering administrative matters. During the closed session, the panel will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6), the Acting Administrator, AHCPR, has made a formal determination that this letter session will be closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members or other relevant information should contact Carmen Johnson, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594–1449 x1613.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: March 31, 1997.

Lisa A. Simpson,

Acting Administrator.

[FR Doc. 97–9051 Filed 4–8–97; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) announces the following committee meeting.

Name: Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry (BSC, ATSDR).

Times and Dates: 8:30 a.m.–5 p.m., April 28, 1997; 9 a.m.–3 p.m., April 29, 1997.

Place: The Chattanooga Choo-Choo Holiday Inn, 400 Market Street, Chattanooga, Tennessee 37402.

Status: Open to the public, limited by the available space.

Purpose: The Board of Scientific Counselors, ATSDR, advises the Secretary; the Assistant Secretary for Health; and the Administrator, ATSDR, on ATSDR programs to ensure scientific quality, timeliness, utility, and dissemination of results. Specifically, the Board advises on the adequacy of the science in ATSDR-supported research, emerging problems that require scientific investigation, accuracy and currency of the science in ATSDR reports, and program areas to emphasize and/or to de-emphasize. In addition, the Board recommends research programs and conference support for which the Agency seeks to make grants to universities, colleges, research institutions, hospitals, and other public and private organizations.

Matters to be Discussed: Agenda items will include a visit to a hazardous waste site; an update on the ATSDR Child Health Initiative Work Group recommendations; a discussion on the Brownfields Initiative; the ATSDR response to the Community/Tribal Forum recommendations; an overview on environmental medicine and health promotion, partners in 3 health promotion, and medical monitoring criteria for the Hanford Nuclear Reservation; and a discussion on placing a site on inactive status.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Charles Xintaras, Sc.D., Executive Secretary, BSC, ATSDR, M/S E–28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–0708.

Dated: April 3, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–9067 Filed 4–8–97; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health: Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services, has been renewed for a 2-year period beginning February 3, 1997, through February 3, 1999.

For further information, contact Bryan D. Hardin, Ph.D., Executive Secretary, BSC, NIOSH, CDC, 200 Independence Avenue, SW., Washington, DC. 20201, telephone 202/401–0721 or fax 202/260–4464.

Dated: April 3, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–9043 Filed 4–8–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0115]

SEF, P.A.; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 1166

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. 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. The proposed revocation is based on the establishment's discontinuance of product manufacturing to the extent that a meaningful inspection cannot be made.

DATES: The firm may submit a written request for a hearing to the Dockets Management Branch by May 9, 1997

and any data and information justifying a hearing by June 9, 1997. Other interested persons may submit written comments on the proposed revocation by June 9, 1997.

ADDRESSES: Submit written requests for a hearing, and any data and information that would justify a hearing, including 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: 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 initiating proceedings to revoke 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 Red Blood Cells (RBC) including frozen, deglycerolized, frozen rejuvenated, and rejuvenated deglycerolized RBC's. 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 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. Later that same day, February 13, 1996, FDA contacted by telephone the person on file with the agency as being the responsible head of SEF, P.A. The individual informed FDA that he had resigned from the firm on July 12, 1995, because he lacked sufficient authority to bring the firm into compliance with FDA regulations. The individual also informed FDA that the person succeeding him as the responsible head had resigned in December 1995, and that the firm had ceased operations in January or February of 1996.

In a telephone conversation between FDA and the owner of SEF, P.A., on February 28, 1996, the owner stated that all the firm's equipment was stored in a Miami, FL, warehouse. During this conversation the owner indicated that he would voluntarily surrender the firm's license since SEF, P.A., was no longer in operation and there were no plans to resume operations. After this telephone conversation, FDA made several attempts to obtain the voluntary revocation of the firm's license. This effort included telephone calls on March 21 and 27, 1996, and April 9, 1996. On each occasion, a secretary or receptionist took a message from FDA requesting the owner to return FDA's calls. On April 15, 1996, FDA was contacted by the owner who verified that the firm was out of business and that a letter from him requesting the voluntary revocation of U.S. License No. 1166 would be forthcoming. On June 17, 1996, FDA successfully contacted the owner who 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. On August 1, 1996, the last two known locations of the SEF, P.A., were visited again by FDA investigators who determined that both locations were vacant and displayed no evidence of recent business activity. On October 10, 1996, FDA contacted the State of Florida, Agency for Health Care Administration, which reported that Florida License No. 800001631 held by SEF, P.A., had been terminated on July 2, 1996.

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 (the Commissioner) 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.

Because SEF, P.A., is no longer in operation and is not manufacturing any products, a meaningful inspection required under 21 CFR 600.21 cannot be conducted. Furthermore, FDA made reasonable efforts to obtain the voluntary revocation of the firm's licenses. Therefore, FDA is proceeding under to 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) Intention to revoke license letter dated November 1, 1996; (2) memorandum of investigation inspection March 5, 1996. These documents are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

SEF, P.A., may submit a written request for a hearing to the Dockets Management Branch by May 9, 1997 and any data and information justifying a hearing must be submitted by June 9, 1997. Other interested persons may submit written comments on the proposed revocation by June 9, 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 procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for 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 is not accompanied by the required analyses, the Commissioner 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 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 Act (21 U.S.C. 321, 351, 352, 355, and 371), and under the

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: March 27, 1997.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 97–8987 Filed 4–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

Part D, Chapter DB (Office of Operations) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 60 FR 56605, November 9, 1995, and in pertinent part at 56 FR 50126, October 3, 1991) is amended to reflect the reorganization of the Center for Veterinary Medicine (CVM), Office of Operations, in the Food and Drug Administration (FDA).

The Center for Veterinary Medicine will continue to develop and recommend the veterinary medical policy of the Agency with respect to the safety and effectiveness of animal drugs, feeds, feed additives, veterinary medical devices (medical devices for animal use), and other veterinary medical products. The restructuring of the Center is proposed to strengthen the delivery of services to our constituents and customer groups by streamlining the organization through delayering lines of authority and responsibility, and improving channels of communications at all levels within the Center.

1. Delete *Office of the Center Director (HFV1)*, Center for Veterinary Medicine (HFV), in its entirety and replace with the following:

Office of the Center Director (DBVA). Directs overall Center activities and coordinates and establishes Center policy in the areas of research, management, scientific evaluation, compliance and surveillance.

Approves new animal drug applications and issues notices of withdrawal of new animal drug approvals when the opportunity for a hearing has been waived.

Authorizes for use as edible products animals treated with investigational drugs and terminates exemptions for investigational trials. In conjunction with appropriate agency officials in the foods area, provides FDA policy development and direction on environmental impact matters.

Serves as focal point for operational review and compliance activity policy and legislative matters; serves as focal point for international harmonization and trade issues related to animal drugs and feeds; leads and provides oversight of research animal issues for FDA.

Plans, develops and implements the Center's Equal Employment Opportunity and Affirmative Action Program.

Develops, reviews, and coordinates all **Federal Register** publications pertaining to Center functions and coordinates requests and activities pertaining to the Regulatory Flexibility Act, Executive Orders on Regulations, Paperwork Reduction Act, and regulations planning and implementation.

2. Delete the *Office of Management (HFV1A)*, Center for Veterinary Medicine (HFV), in its entirety and replace with the following:

Office of Management and Communications (DBVB). Provides guidance and leadership in the analysis, planning, coordination and evaluation of administrative management activities including: personnel; employee orientation and development; procurement; travel; facilities; property; security; records management; performance management; awards; budget formulation and execution; information resources management; program analysis; and management analysis. Provides administrative assistance and support to the Veterinary Medicine Advisory Committee (VMAC) Executive Secretary.

Plans, develops, and implements Center management policies. Provides leadership and direction for the management and administrative interface with the Agency, the Department and other Federal agencies.

Serves as Center interface with the Agency and Department on budget issue resolutions.

Performs analysis, program assessments, or special studies of key issues relative to policy review and oversight. Directs a variety of short-range and long-range special projects or assignments of substantial significant to the Center.

Implements Internal Control Reviews in accordance with the Office of Management and Budget, Department and Agency guidelines. Provides direction in the preparation of responses to the Office of Inspector General and the General Accounting Office regarding audits and investigation.

Directs the Center's outreach efforts to consumers, professionals and the industry in communicating the program goals and priorities of the Center. Maintains the CVM Home Page on the World Wide Web. Provides automated scientific literature searches and retrieval support. Supports public and consumer affairs, including freedom of information.

Directs the Center's Strategic Plan and the efforts of Strategic Implementation Groups (SIG) to effectively accomplish Center goals and objectives. Facilitates implementation of SIG recommendations.

3. Insert *Administrative Staff (DBVB–1),* under the Office of Management and Communications (DBVB), reading as follows:

Administrative Staff (DBVB–1). Serves as the focal point in the Center for administrative management activities. Coordinates the administrative management activities in the Offices with designated Administrative Officers, i.e., personnel management, property acquisition and surplus, inventory, procurement, travel services, security procedures, records management, performance management, conflict of interest, special government employees, and telecommunications. Safeguards the administrative management services against waste, fraud and abuse.

Manages the Center's award systems through the Strategic Plan Awards Committee and the CVM Incentive Awards Committee. Manages CVM's participation in the Agency's Honor Award process, including the first and second tier ceremonies.

Provides budget execution and fiscal accounting services for the Center. Monitors and provides officials with continual awareness of obligated commitments and status of funds.

Directs, develops and implements the Center's overall professional, scientific, technical, clerical, and management training programs; formal career development programs and New Employee Orientation Program. Coordinates all Special training programs from the Agency and Department.

4. Insert *Communications Staff (DBVB–2),* under the Office of Management and Communications (DBVB), reading as follows:

Communications Staff (DBVB–2). Plans, produces, and publishes a bimonthly subscription newsletter entitled the *FDA VETERINARIAN* and other publications such as CVM UPDATES and consumer fliers.

Supports FDA public affairs/ consumer affairs initiatives, including