reorganization proposals. Acts as liaison with the HHS Office of the Assistant Secretary for Management and Budget to coordinate organizational proposals requiring Secretarial approval; prepares functional statements and official organizational charts. Administers ACF's system for review, approval, and documentation of delegations of authority and maintains the guidelines related to the delegations of authority.

L. The Office of Administrative Services and Facilities Management (OASFM) directs and manages ACF's administrative support services, facilities management programs and activities.

Provides agency-wide guidance on administrative issues; prepares, coordinates and disseminates information, policy, and/or procedural guidance on administrative and facilities management issues. Directs and/or coordinates management initiatives to improve ACF administrative and facilities management services with the goal of continually improving services while reducing costs.

Maintains budgetary controls on administrative services accounts, reconciling accounting reports and invoices, and monitoring all spending. Controls OASFM Visa credit card for small purchases. Establishes and manages contracts and/or blanket purchase agreements (BPAs) for administrative support and facilities management services, including space design, building alteration and repair, telecommunications, reprographics, physical security, moving, labor, records and property management and inventory, systems furniture acquisitions and assembly, fleet management, and the Information Resource Center (library).

Provides management and oversight of ACF mail delivery services and activities, including Federal and contractor postal services nationwide, covering all classes of U.S. Postal Service mail, priority and express mail services, and courier services, etc.

Directs all activities associated with the ACF Master Housing Plan, including coordination and development of the agency long-range space budget; planning, budgeting, identification, solicitation, acceptance and utilization of office and special purpose space, repairs, and alterations; principal liaison with General Services Administration (GSA) and other Federal agencies, building managers and facilities engineers, architects and commercial representatives, for space acquisition, negotiation of lease terms, dealing with sensitive issues such as handicapped barriers, space shortages, and security. Develops and maintains space floor plans and inventories, directory boards, and locator signs. OASFM serves as the lead for ACF in coordination and liaison with Departmental, GSA, Federal Protective Service, and other Federal agencies on implementation of Federal security directives. Responsible for planning and executing the Agency's environmental health, safety, and physical security programs, ensuring that appropriate occupational health and safety and occupant emergency evacuation plans are in place. Serves as principal liaison with private and/or Federal building managers for all administrative services and facilities management activities. Responsible for issuing, and managing and controlling badge and cardkey systems to control access to agency space for security purposes.

Develops and/or implements agency telecommunications management policy in accordance with Federal regulations and procedures. Reviews and directs payment of all agency telephone invoices. Recommends and advises on the design and function of telecommunications systems, based on user needs, costs and technological availability. Communicates directly with private industry service providers to coordinate the acquisition, installation and maintenance of voice/data telecommunications equipment and systems. Responsible for other sources of communications capability such as pagers, cellular phone service, cable TV service, and audio conferencing equipment and service. Coordinates the implementation of personal video and video conferencing. Updates and maintains the ACF LAN-based telephone directory, handles the distribution of all commercial directories, and updates and maintains the databases for telephone lines, and equipment inventories.

Plans, manages/operates employee transportation programs, including shuttle service and fleet management, employee and visitor parking, and commuter services and programs including transit subsidies and ridesharing. Develops and implements ACF travel policies and procedures consistent with Federal requirements. Provides technical assistance and oversight; coordinates ACF use of the Travel Management System; manages employee participation in the American Express Credit Card program for travel.

Purchases and tracks common use supplies, stationery and publications; manages equipment repair services and reprographics management activities; controls and maintains equipment and personal property inventories; develops and coordinates records (paper) and forms management, and real property activities.

VIII. Within Chapter K, replace the term ''Deputy Assistant Secretary for Program Operations'' with ''Deputy Assistant Secretary for Administration.''

Dated: December 24, 1997.

Olivia A. Golden,

Assistant Secretary for Children and Families.

[FR Doc. 97–34217 Filed 12–31–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0521]

Richard-James, Inc.; Premarket Approval of SILIKON 1000-Silicone Oil

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Richard-James, Inc., Peabody, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the SILIKON 1000-Silicone Oil. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 25, 1997, of the approval of the application.

DATES: Petitions for administrative review by February 2, 1998.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2018.

SUPPLEMENTARY INFORMATION: On February 22, 1995, Richard-James, Inc., Peabody, MA 01960, submitted to CDRH an application for premarket approval of the SILIKON 1000-Silicone Oil. The device is an intraocular fluid and is indicated for use as a prolonged retinal tamponade in selected cases of complicated retinal detachments where other interventions are not appropriate

for patient management. Complicated retinal detachments or recurrent retinal detachments occur most commonly in eyes with proliferative vitreoretinopathy (PVR), proliferative diabetic retinopathy (PDR), cytomegalovirus (CMV) retinitis, giant tears, and following perforating injuries. SILIKON 1000 is also indicated for primary use in detachments due to acquired immune deficiency syndrome (AIDS) related CMV retinitis and other viral infections affecting the retina.

On January 13, 1997, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 25, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before February 2, 1998, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: December 1, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–34156 Filed 12–31–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0519]

Vitrophage, Inc.; Premarket Approval of VITREON®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Vitrophage, Inc., Lyons, IL, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of VITREON® . After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 30, 1997, of the approval of the application.

DATES: Petitions for administrative review by February 2, 1998.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744.

SUPPLEMENTARY INFORMATION: On December 6, 1991, Vitrophage, Inc., Lyons, IL 60534, submitted to CDRH an application for premarket approval of VITREON®. The device is a purified perfluorocarbon liquid and is indicated for use as an intraoperative surgical aid during vitreoretinal surgery in patients with primary and recurrent complicated retinal detachments. Complicated cases include giant retinal tear or retinal dialysis, proliferative vitreoretinopathy, proliferative diabetic retinopathy, tractional retinal detachments, and blunt or penetrating ocular trauma.

On October 19, 1995, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 30, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before February 2, 1998, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information,