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,

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. 97–34157 Filed 12–31–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0514]

CDRH Interim Regulatory Policy for External Penile Rigidity Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is making available a policy from its Center for Devices and Radiological Health (CDRH) entitled ''CDRH Interim Regulatory Policy for External Penile Rigidity Devices.'' The document outlines several changes in how FDA regulates external penile rigidity devices including constriction rings, vacuum pumps, and penile splints.

DATES: Written comments concerning this guidance may be submitted at any time.

ADDRESSES: Written comments concerning this guidance must be submitted to the contact person. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the policy. Submit written requests for single copies of the ''CDRH Interim Regulatory Policy for External Penile Rigidity Implants'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

FOR FURTHER INFORMATION CONTACT: Donald St. Pierre, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Background

External penile rigidity devices are unclassified medical devices designed to promote or maintain sufficient penile rigidity for sexual intercourse. This document clarifies when premarket review is required for new external penile rigidity devices using a uniform approach. The new policy also allows manufacturers the option of marketing external penile rigidity devices as prescription and/or over the counter (OTC) devices.

This guidance document represents the agency's current thinking on regulation of external penile rigidity devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (61 FR 8961, February 27, 1997). This guidance is issued as Level 2 guidance consistent with GGP's.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the World Wide Web for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH Home Page includes the CDRH Interim Regulatory Policy for External Penile Rigidity Devices, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The CDRH Interim Regulatory Policy for External Penile Rigidity Devices will be available at http://www.fda.gov/cdrh/ode/expenrig.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Comments

Interested persons may at any time submit written comments on the guidance document to the contact person. Comments will be considered in determining whether to revise or revoke the guidance document.

Dated: December 1, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–34158 Filed 12-31-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1904–NC]

RIN 0938–AI24

Medicare Program; Schedule of Limits on Home Health Agency Costs Per Visit for Cost Reporting Periods Beginning on or After October 1, 1997

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice sets forth a revised schedule of limits on home health agency costs that may be paid under the Medicare program for cost reporting periods beginning on or after October 1, 1997. These limits replace the per visit limits that were set forth in our July 1, 1996 notice with comment period (61 FR 34344) and supersede those set forth in our July 1, 1997 notice with comment period (62 FR 35608). This notice also provides, in accordance with the Balanced Budget Act of 1997, that there be no changes in the home health per visit limits for cost reporting periods beginning on or after July 1, 1997 and before October 1, 1997 (that is, the cost limits set forth in our July 1, 1996 notice will apply to cost reporting