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: June 5, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–18164 Filed 7–17–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0233]

Infinitech Inc.; Premarket Approval of Perfluoron™ (Highly Purified Perfluoro-n-Octane Liquid)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Infinitech Inc., Chesterfield, MO, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Perfluoron (highly purified perfluoro-n-octane liquid). After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of February 29, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 19, 1996.

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 April 28, 1995, Infinitech Inc., Chesterfield, MO 63005, submitted to CDRH an application for premarket approval of Perfluoron (highly purified perfluoro-n-octane liquid). The device, a perfluorocarbon liquid, is an intraoperative tool indicated for use during vitreoretinal surgery in patients with primary or recurrent retinal detachment which is complicated by penetrating ocular trauma, giant retinal tear(s) or proliferative vitreoretinopathy.

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 February 29, 1996, 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 part 12 (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 § 10.33(b) (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 August 19, 1996, 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: June 5, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–18283 Filed 7–17–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection Activity; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, (Pub. L. 104–13; 44 U.S.C.) the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed information dissemination activities for public comment. Interested persons are invited to send comments regarding the burden or any other aspect of this information dissemination activity, including any of the following subjects: (1) The necessity and utility of the proposed activity for the proper performance of the agency's functions; (2) ways to enhance the quality, utility, and clarity of the information being disseminated; and (3) the use of other automated techniques or other forms of information dissemination to minimize the burden of the information dissemination activity.

The Health Care Financing Administration is soliciting comments from the public on dissemination of information via an agency home page on the Internet. This service is a result of an ongoing process of creating a more customer-oriented, efficient government by improving public access to agency information electronically. The objective is to make releasable information available through the Internet when there is an important or substantial interest.

Examples of the information available include: (1) Program information overview; (2) HCFA strategic plan and 5-year Information Resource Management plan; (3) Laws and regulations; (4) Press information, including news releases, Administrator speeches and testimony; (5) Office of

Research initiatives; (6) Public Use Files which include data that supports the institutional payment rates; (7) Beneficiary publications, including the Medicare Handbook; and (8) Electronic interactive communication of inquiries. The availability of the above on the Internet does not eliminate the availability of this information from the agency in hardcopy, tape, or other currently available formats.

The Health Care Financing Administration will continue to apply the rules of the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 522a) when disclosing information via the home page. All graphic and table information displays will be converted to text format to ensure the content is accessible and readable for users with disabilities, as well as to accommodate various browser software packages and low-bandwidth access.

The Internet is a powerful tool for information dissemination and interactive communication which HCFA aims to use to improve program management and to provide improved services for program clients and customers.

On-line information available on HCFA's home page will be updated so documents represent a current resource rather than a historical artifact. When a publication is changed, its title page or the home page will include a modification date.

The intent is to continue to increase the presence of the agency data available on the Internet. Some of the areas for future consideration are: (1) Reporting of fraud and abuse; (2) Quality of care issues; (3) Request for Proposals; (4) Published statistics and evaluation reports; (5) Solicitations; (6) Increase the availability of the Public Use Files; (7) Additional Medicare and Medicaid program information; and (8) Managed Care information.

HCFA's home page may be accessed at http://www.hcfa.gov.

FOR FURTHER INFORMATION CONTACT: Malcolm Sneen, Chief, Information Processing Branch, 410–786–0163 or send an e-mail to MSneen @ hcfa.gov., or John Burke, HCFA Paperwork Clearance Officer, 410–786–1325.

Written comments and recommendations for the proposed information dissemination activity must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: John Burke, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 11, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–18241 Filed 7–17–96; 8:45 am]

BILLING CODE 4120–03–P

[HCFA–222, R–43]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Independent Rural Health Center/Freestanding Federally Qualified Health Center Cost Report; *Form No.:* HCFA–222; *Use:* The independent rural health clinic/freestanding federally qualified health center cost report is the cost report to be used by the mentioned clinics/centers to submit annual information to achieve a settlement of costs for health care services rendered to Medicare beneficiaries. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; *Number of Respondents:* 3,000; *Total Annual Responses:* 3,000; *Total Annual Hours Requested:* 150,000.

2. Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Conditions of Participation for Portable X-ray Suppliers (42 CFR 405 Subpart N); *Form No.:* HCFA-R–43; *Use:* This information is needed to determine if portable X-ray suppliers are in compliance with published health and safety requirements. *Frequency of Record keeping:* Retain records for two years; *Affected Public:* Business or other-for-profit; *Number of Respondents:* 554; *Total Annual Responses:* 554; *Total Annual Hours Requested:* 1,385.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 11, 1996

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–18242 Filed 7–17–96; 8:45 am]

BILLING CODE 4120–03–P

Substance Abuse and Mental Health Services Administration (SAMHSA)

Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of the following meetings of the SAMHSA Special Emphasis Panel I in August.

A summary of the meetings and a roster of the members may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: (301) 443–4783.

Substantive program information may be obtained from the individual named as Contact for each of the meetings listed below.

The meetings will include the review, discussion and evaluation of individual cooperative agreement and grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, these meetings are concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App.2, § 10(d).