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: March 4, 1997.

**Joseph A. Levitt,**

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

[FR Doc. 97–8169 Filed 3–31–97; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 97M–0122]**

## Xillix Technologies Corp.; Premarket Approval of Xillix LIFE-Lung Fluoresence Endoscopy System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Hogan and Hartson, Washington, DC, U.S. representative for Xillix Technologies Corp., Richmond, B.C., Canada, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Xillix LIFE-Lung Fluoresence Endoscopy System. After reviewing the recommendation of the Ear, Nose, and Throat Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 19, 1996, of the approval of the application.

**DATES:** Petitions for administrative review by May 1, 1997.

**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:** Kirby J. Cooper, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

**SUPPLEMENTARY INFORMATION:** On December 21, 1995, Hogan and Hartson, Washington, DC, U.S. representative for Xillix Technologies Corp., Richmond, B.C. Canada, submitted to CDRH an application for premarket approval of Xillix LIFE-Lung Fluorescence Endoscopy System. The device is a fluorescence endoscopy system and is indicated for use as an adjunct to white light bronchoscopy, using an Olympus BF-20D bronchoscope, to enhance the physician's ability to identify and locate bronchial tissue, suspicious for moderate/severe dysplasia or worse, for biopsy and histologic evaluation in the following patient populations:

1. Patients with known or previously diagnosed lung cancer; and

2. Patients with suspected lung cancer including: (a) Patients with Stage I completely resected lung cancer, with no evidence of metastatic disease, who are at risk for secondary disease; and (b) patients suspected of having lung cancer because of clinical symptoms such as positive sputum cytology, hemoptysis, unresolved pneumonia, persistent cough, or positive x-ray.

On June 11, 1996, the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 19, 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 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 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 May 1, 1997, 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: March 4, 1997.

**Joseph A. Levitt,**

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

[FR Doc. 97–8170 Filed 3–31–97; 8:45 am]

**BILLING CODE 4160–01–F**

## Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 35, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

*Proposed Project: Program Data Report Form for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, Title III HIV Early Intervention Services Program*

(OMB No. 0915–0158)—Revision and Extension—Title III of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, as amended by the CARE Act Amendments of 1996, provides categorical funding to increase the capacity and capability of organizations that provide primary health care to provide HIV-related early intervention services to medically underserved persons who have, or are at high risk for, HIV infection. These services are provided as part of a continuum of HIV prevention and health care services.

This clearance request is for extension of OMB approval of the Title III Program Data Report form, which is submitted annually by Title III grant recipients. The bulk of the information being collected describes the epidemiologic and demographic data on the populations receiving early intervention services from grant recipients, and provides the basis for the annual report to the Secretary, which is legislatively mandated. It is also used to monitor the delivery of services, guide federal policy, and assist in program development and evaluation. Only minor revisions to the form are proposed, including deletion of some sections found to lack utility, revision of some data elements and instructions for clarity, and addition of data elements to improve the usefulness of the data.

The estimate of burden for the form is as follows:

| Form name | No. of respondents | Responses per respondent | Hours per response | Total burden hours |
|---|---|---|---|---|
| Program Data Report Form | 170 | 1 | 500 | 85,000 |

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 26, 1997.

**J. Henry Montes,**

*Director, Office of Policy and Information Coordination.*

[FR Doc. 97–8168 Filed 3–31–97; 8:45 am]

**BILLING CODE 4160–15–P**

## The Ryan White Comprehensive AIDS Resources Emergency Act of 1990, as Amended by the Ryan White CARE Act Amendments of 1996

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of a Pre-Application Technical Assistance Workshop for Ryan White Title III HIV Planning Grants.

**SUMMARY:** The Health Resources and Services Administration (HRSA) will hold a pre-application technical assistance workshop for competing applicants for Ryan White Title III HIV Planning Grants, of Part C of Title XXVI of the Public Health Service (PHS) Act. A Ryan White Title III HIV Planning Grant will assist health care service entities to qualify for grant support under the Ryan White Title III Early Intervention Services Program.

Eligible applicants for the Ryan White Title III HIV Planning Grants are public or nonprofit private entities. Grant recipients of the Ryan White Title III Early Intervention Services Program are not eligible to receive Ryan White Title III HIV Planning Grants.

It should be noted that eligible applicants for the Ryan White Title III Early Intervention Services Program are public or private, nonprofit entities that are: Current primary care service providers to populations at risk for HIV disease; community health centers under section 330 of the PHS Act; migrant health centers under section 330(g) of the PHS Act; health care for the homeless grantees under section 330(h) of the PHS Act; family planning grantees under section 1001 of the PHS Act, other than states; comprehensive hemophilia diagnostic and treatment centers; or federally qualified health centers under section 1905(1)(2)(B) of the Social Security Act.

**PURPOSE:** The purpose of the pre-application technical assistance workshop is to provide information about the Ryan White Title III HIV Planning Grant program, and to review application procedures. Information will also be provided about the Ryan White Title III Early Intervention Services Program. Participants will have the opportunity to review the program guidance and to receive technical assistance pertaining to all aspects of writing a Ryan White Title III HIV Planning Grant application.

**FOR FURTHER INFORMATION AND TO REGISTER:** Anyone interested in attending this workshop must contact Ms. Karin Martinsen, Professional and Scientific Associates, Inc., 8180 Greensboro Drive, Suite 1050, McLean VA 22102–3823 (phone: 703–442–9824). Costs of attending the workshop are the sole responsibility of the attendee. There is a nominal registration fee of $50 to cover the cost of materials, lunch and refreshments.

For general information, contact the HIV Primary Care Programs Branch, Division of Programs for Special Populations, Bureau of Primary Health Care, 4350 East West Highway, Bethesda, MD 20814 (telephone: 301–594–4444).

### Date, Time, and Location

Wednesday, April 9, 1997 (the due date for the Ryan White Title III HIV Planning Grant is May 1, 1997). 10:00 a.m.–5:00 p.m., St. Louis Airport Marriot, St. Louis, Missouri, (314) 423–9700.

The OMB *Catalog of Federal Domestic Assistance* number for this program is 93.918.

Dated: March 26, 1997.

**Claude Earl Fox,**

*Acting Administrator.*

[FR Doc. 97–8167 Filed 3–31–97; 8:45 am]

**BILLING CODE 4160–15–P**

## National Institutes of Health

## National Institute of Child Health and Human Development: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Development of a Microbial Screen for Anti-Virals Targeting PKR or Inhibitors of PKR

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The National Institutes of Health is seeking one or more CRADA partners for further development and evaluation of a microbial screen in yeast to identify anti-viral agents that target regulators of and/or the PKR kinase. The National Institute of Child Health and Human Development has established a system in yeast to identify and