DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0199]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Importer's Entry Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Importer's Entry Notice'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 28, 2003 (68 FR 51787), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0046. The approval expires on August 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: March 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5862 Filed 3–15–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0082]

Guidance for Industry and Food and Drug Administration Staff: Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled, ''Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems.'' This guidance document describes a means by which Factor V Leiden deoxyribonucleic acid (DNA) mutation detection systems may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify the Factor V Leiden DNA mutation detection system into class II (special controls). This guidance document is immediately in effect as the special control for Factor V Leiden DNA mutation detection systems, but it remains subject to comment in accordance with the agency's good guidance practices regulation (GGPs).

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Mansfield, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the Factor V Leiden DNA mutation detection system into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for Factor V Leiden DNA mutation detection systems. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving a written notice of the classification of the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments we receive in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs. The guidance represents the agency's current thinking on Factor V Leiden DNA mutation detection systems. 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 requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems'' by fax machine, call FDA's Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1236) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a

personal computer with Internet access. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number. 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 2004.

Beverly Chernaik Rothstein,

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

[FR Doc. 04–5865 Filed 3–15–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[HRSA–04–078]

Special Projects of National Significance: An Evaluation of Innovative Methods for Integrating Buprenorphine Opioid Abuse Treatment in HIV Primary Care Settings; CFDA 93.928

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of fiscal year (FY) 2004 funds to be awarded under the Special Projects of National Significance (SPNS) Program for the development and evaluation of innovative methods for integrating buprenorphine opioid abuse treatment in HIV primary care settings.

Program Purpose: The purpose of this new grant initiative is to support and examine the effectiveness of the integration of advancements in substance abuse treatment (buprenorphine) in HIV primary care settings. Grantees are expected to participate in multi-site evaluation activities as well as accomplish a local evaluation of interventions. An Evaluation and Technical Assistance Center (ETAC) will be responsible for coordinating and conducting a multi-site analysis, providing clinical expertise, developing guidelines for integrated programs, conducting cost-effectiveness analysis, and dissemination of results.

Program Requirements: The demonstration projects will focus on the development and evaluation of interventions that examine a number of relevant issues including (a) barriers and facilitators for clients successfully engaging in integrated substance abuse treatment using buprenorphine while also being treated for HIV, (b) how delivery of care is impacted by an integrated approach, and (c) how continuity of both HIV primary care and substance abuse (buprenorphine) treatment will be affected. The Center will work with SPNS and demonstration sites to develop an overall multi-site evaluation of the initiative. Subsequently, the Center will assist grantees on program development and evaluation issues. The Center will be responsible for describing the methods, theoretical framework, and principles of the evaluation design. The Center must also develop a technical assistance plan for grantees. Throughout the initiative, the SPNS Program expects the Center to describe the roles and characteristics of the clients, providers, and practitioners who participate in the projects, and the interventions used by grantees. In addition, the Center will gather information that will describe the effect of integrating buprenorphine treatment into primary care structures and health care systems.

Eligible Applicants: The statute, Section 2691(a) of the Public Health Service Act specifies that grants may be awarded to public and non-profit private entities to fund special programs for the care and treatment of people with HIV disease. Eligible applicants may include, but are not limited to, State, local, or tribal public health, mental health, housing, or substance abuse departments; public or non-profit hospitals and medical facilities; faith-based and community-based organizations, institutions of higher education, and national service provider and/or policy development associations and organizations. With regard to this initiative, all applicants must have significant experience evaluating substance abuse treatment programs, HIV primary care and treatment, and the integration of these endeavors.

Funding Priorities: This SPNS Initiative is designed to demonstrate and evaluate innovative and replicable models with regard to HIV treatment and care in various settings. The authorizing legislation specifies three SPNS program objectives: (1) To support the development of innovative models of HIV care; (2) to evaluate the effectiveness of innovative program designs; and (3) to promote replication of effective models.

Authorizing Legislation: The SPNS Program is authorized by section 2691 of the Public Health Service (PHS) Act, (42 U.S.C. 390ff–101).

Availability of Funds: The program has $3.5 million dollars available for this initiative. The Health Resources and Services Administration (HRSA) expects to make up to ten (10) awards for demonstration projects (Category A) and one award for an Evaluation and Program Support Center (Category B). It is anticipated that each Category A project site will be awarded up to $300,000 per year for 5 years. The Category B Evaluation and Support Center will be awarded up to $500,000 per year for 5 years. The budget and project periods for approved and funded projects will begin on or about September 1, 2004. Funds must be requested for all 5 years of the initiative.

Cost Sharing/Matching: There are no cost sharing/matching requirements under this grant initiative.

Application Deadline: Applications must be received in the HRSA GAC by the close of business April 15, 2004, to be considered for competition. Applications will meet the deadline if they are either (1) received on or before the deadline date or (2) postmarked or E-marked on or before the deadline date, and received in time for submission to the objective review panel. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted instead of a postmark. Private metered postmarks shall not be accepted as proof of timely mailing.

Late Applications: Applications which do not meet the criteria above are considered late applications. HRSA shall notify each late applicant that its