

**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.*

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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