SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance is designed to assist sponsors and CDRH to oversee post-approval studies. These studies are oftentimes mandated at the time the Center approves a Premarket Approval Application (PMA) to address additional concerns. This guidance aims to assure that:

- Sponsors submit clear, consistent and timely study reports;
- CDRH can track the status of the studies;
- CDRH staff reviews the studies and holds discussions with the sponsors in a timely manner;
- CDRH stakeholders can quickly learn about the status of these studies; and
- CDRH can take appropriate and timely action based on study results.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Procedures for Handling Post-Approval Studies Imposed by PMA Order.'' 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 ''Procedures for Post-Approval Studies Imposed by PMA Order'' by fax machine, call the 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 (1516) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet.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. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft 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 collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910–0231).

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 or two paper copies of any mailed comments except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18372 Filed 9–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0251]

Guidance for Industry, Food and Drug Administration Staff, and Food and Drug Administration-Accredited Third Parties; Requests for Inspection by an Accredited Person Under the Inspections by Accredited Persons Program Authorized by the Medical Device User Fee and Modernization Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002.'' The Medical Device User Fee and Modernization Act of 2002 authorizes FDA to establish a voluntary inspection program under which manufacturers of class II or class III devices who meet certain eligibility criteria as defined by the statute can elect to have FDA-accredited third parties conduct some of their establishment inspections instead of FDA. This guidance document describes the establishment eligibility criteria and the process for establishments to follow when requesting FDA's approval to have an accredited person (AP) conduct an inspection of their establishment instead of FDA under the new Inspections by Accredited Persons Program (AP Program).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002'' 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:

For medical device issues: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD

20850, 240–276–0106.
For biologics issues: Carol Rehkopf, Center for Biologics Evaluation and Research (HFM–650), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6202.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) was signed into law. Section 201 of MDUFMA amends the Federal Food, Drug, and Cosmetic Act (the act) by adding new provisions authorizing FDA to establish a voluntary inspection program under which eligible manufacturers of class II or class III devices can elect to have FDA-accredited third parties conduct some of their establishment inspections instead of FDA. Certain technical corrections were subsequently made to these provisions by the Medical Devices Technical Corrections Act (MDTCA) (Public Law 108–214), which was enacted on April 1, 2004. FDA announced in the **Federal Register** of June 3, 2004 (69 FR 31397), the availability of a draft guidance document entitled ''Requests for Inspection by an Accredited Person under the Inspections by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002,'' and invited interested persons to comment by September 1, 2004.

One person submitted a comment in response to the draft guidance. The comment suggested, among other things, that partial inspections during a 2-year period should be permitted without the need for establishments to have to reapply to participate in the AP Program after each partial inspection. The comment further suggested that the guidance be revised to explicitly state that complete inspections conducted by APs under the new program which result in either a ''No Action Indicated'' or ''Voluntary Action Indicated'' classification can satisfy FDA's biennial establishment inspection requirement under section 510(h) of the act (21 U.S.C. 360(h)). The agency carefully considered the comment while finalizing the guidance and has revised the document accordingly.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on implementation of a new program that allows third-party inspections of eligible device establishments as authorized by section 201 of MDUFMA (as amended by MDTCA). 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 ''Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002'' by fax, call the 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 1532 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. The Center for Devices and Radiological Health (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. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

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 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing the agency request or requirement that members of the public submit reports, keep records, or provide information to a third party. The provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0569. This approval expires on August 31, 2008. 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.

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 or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18364 Filed 9–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Bureau of U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Desktop Scanners

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that the Bureau of Customs and Border Protection (CBP) has issued a final determination concerning the country of origin of certain desktop scanners to be offered to the United States Government under an undesignated government procurement contract. The final determination found that, based upon the facts presented, the United States is the country of origin of the Kodak i600 line of desktop scanners for purposes of U.S. Government procurement. The Kodak i600 series includes the i620, i640, and i660 models.

DATES: The final determination was issued on September 9, 2005. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within 30 days of September 15, 2005.