

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 FDA announced in the **Federal Register** of June 3, 2004 (69 FR 31397), the availability of a draft guidance document entitled "Requests for Inspection by an Accredited Person under the Inspections by Accredited Persons Program Authorized by Section 201 of the Medical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One person submitted a comment in response to the draft guidance.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.

FOR FURTHER INFORMATION CONTACT: Ed Caldwell, Valuation and Special Programs Branch, Office of Regulations and Rulings (202-572-8872).

SUPPLEMENTARY INFORMATION: Notice is hereby given that on September 9, 2005, pursuant to subpart B of part 177, Customs Regulations (19 CFR part 177, subpart B), CBP 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 CBP ruling number is HQ 563294. This final determination was issued at the request of Eastman Kodak Company under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-18).

The final determination concluded that, based upon the facts presented, the assembly in the United States of parts of various origins to create the Kodak i600 scanners substantially transformed the imported parts used in production.

Section 177.29, Customs Regulations (19 CFR 177.29), provides that notice of final determinations shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, Customs Regulations (19 CFR 177.30), states that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: September 9, 2005.

Michael T. Schmitz,

Assistant Commissioner, Office of Regulations and Rulings.

Attachment

HQ 563294

September 9, 2005.

MAR-2-05 RR:CR:SM 563294 EAC

Category: Marking.

Mr. Alan W.H. Gourley, Crowell & Moring LLP, 1001 Pennsylvania Avenue, NW., Washington, DC 20004-2595

RE: U.S. Government Procurement; Final Determination; country of origin of desktop scanners; substantial transformation; 19 CFR part 177

Dear Mr. Gourley:

This is in response to your letter dated June 3, 2005, requesting a final determination on behalf of Eastman Kodak Company ("Kodak"), pursuant to subpart B of part 177, Customs Regulations (19 CFR 177.21 *et seq.*). Under these regulations, which implement Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2411 *et seq.*), U.S. Customs and Border Protection ("CBP") issues country of origin advisory rulings and final determinations on whether an article is

or would be a product of a designated foreign country or instrumentality for the purpose of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

This final determination concerns the country of origin of certain desktop scanners that Kodak is considering selling to the U.S. Government. We note that Kodak is a party-at-interest within the meaning of 19 CFR 177.22(d)(2) and is entitled to request this final determination.

Facts:

I. Background

We are advised that the scanners under consideration consist of the three models within Kodak's i600 line of scanners, the i620, i640, and i660. The Kodak i600 Series Scanners are desktop scanners that have the primary function of creating electronic images from paper documents. Paper documents of various sizes, dimensions, and types may be fed into the scanners, viewed through cameras, and converted into electronic images. The scanners can process these images at a rate of up to 480 per minute. In addition, the scanners have a number of features to enhance their performance and improve the quality of the images they produce, such as skew angle determination, which detects and corrects images fed at an angle, and electronic color dropout, which removes irrelevant background color from images.

The primary difference between these models is the speed at which they are able to process images, with the i660 able to process images most quickly. The mechanical components and manufacturing processes used to build the different models are nearly identical. The differences in processing speed are attributable to differences between the programming solutions that are installed on the scanners. Kodak developed the programming for the i600 line of scanners in the United States.

II. Component Parts and Subassemblies

Kodak has manufactured its i600 series scanners both in its Rochester, New York facility and in a facility located in Shanghai, China. Many, but not all, of the parts used in the manufacture of the scanners are obtained from Chinese sources. The i600 scanners are comprised of 13 major subassemblies. Regardless of whether the scanners are manufactured to completion in the United States or China, the Shanghai facility also assembles three of the thirteen major subassemblies for the scanners from parts of U.S., Chinese, and other origins.

The present ruling request pertains only to Kodak i600 scanners to be manufactured in the United States from parts shipped from China, but sourced from various countries abroad.

Each subassembly performs a specific function and together, with miscellaneous other components and hardware, constitute a finished product capable of electronically scanning a variety of paper images. The finished scanners consist of approximately 600 individual parts. The major subassemblies are identified and described as follows.

Operator Control Panel ("OCP") Assembly: This assembly provides the interface between the user and scanner, including wiring and the power switch used to turn the machine on and off.

Elevator Assembly: This assembly lifts the paper to the proper height to be fed into the machine for scanning without jamming the feed.

Carriage Assembly: This assembly is located at the front of the machine where paper is fed, and includes a metal tray upon which paper rests as it is fed into the scanner. The carriage assembly also includes the lead edge of the paper transport system which has a separation roller that ensures the top sheet of paper is separated from those below.

Feed Module Assembly: This assembly is set above the carriage assembly where it grabs the top sheet of paper and feeds it into the scanner.

Image Baffle Assembly: Each scanner includes two image baffle assemblies. Each assembly has a glass plate through which a camera module views paper for scanning. There are two such assemblies because separate cameras view the front and back of each document as it moves through the scanner.

Backup Baffle Assembly: Each scanner includes two backup baffle assemblies. Each assembly is adjacent to the paper path where it guides the paper through the scanner and helps assure the paper feeds cleanly through the machine and does not jam. Each assembly also includes a backup strip, which provides a background for documents as they are viewed by a camera. There is one backup baffle assembly for each of the image baffle assemblies.

Camera Modules (Upper and Lower): Each scanner includes two camera modules. The camera modules include mirrors and lenses used to view documents as they are fed through the scanner. Each camera module views and electronically captures a different side of the document. The upper camera module is part of the pod assembly. The lower camera module is located below the paper path. As the camera modules view a document, the light images they detect are converted into raw electronic data using a charge couple device. That raw data is amplified and forwarded to the "E-box", where the data is converted into an electronic image.

Pod Assembly: The pod assembly is the top portion of the machine, which can be opened to provide access to the paper path. The components in this assembly operate together to feed a document through the machine and to view one side of the document during scanning. This assembly includes numerous parts, as well as the following major subassemblies: (a) The upper camera module; (b) an image baffle assembly; and (c) a backup baffle assembly.

E-Box Assembly: This assembly contains the central "brain" of the machine, and it converts raw electronic data from the camera assembly into high quality electronic images. The E-box Assembly incorporates two circuit boards, the machine control board ("MCB") and the image processing board ("IPB").

Shroud Assembly and Cabinetry: These pieces are the cosmetic cabinetry that

encompass and form the outside of the machine.

Under the proposed production scenario, Kodak will purchase the two "camera modules" and the "feed module" as assembled units from its Shanghai facility. The Shanghai facility will assemble these modules using various parts, including a charge couple device for each camera module, which is purchased from the United States. The other major subassemblies will be manufactured in Rochester, New York, using component parts purchased from inventory at the Shanghai facility. It is envisioned that the Rochester facility will purchase the necessary number of parts, but that they would not be packaged or inventoried as kits. The parts inventoried at the Shanghai facility are sourced primarily from China, but include components from such designated countries as the United States, Canada, Japan, and Korea.

III. The Assembly Process

We are informed that assembly of the scanners at the Rochester facility requires approximately four to six hours of work encompassing essentially five stages: (a) manufacturing most of the major subassemblies; (b) building the pod assembly; (c) performing the "main build"; (d) performing "end of line" procedures; and (e) packaging. During these stages, the machine is built, the firmware that allows the machine to work as a scanner is loaded, the major subassemblies and the integrated circuit are tested, and the scanner's parameters are set to enable proper operation.

1. Manufacture of Major Subassemblies

The first step of production involves assemblage of most of the scanner's major subassemblies. In order to demonstrate the complexity of these operations, a description of the operations undertaken to assemble the E-box assembly has been provided. As noted above, the E-box Assembly contains the central brain of the machine and is a key component for ensuring the proper function and quality of the scanning operation. It contains approximately 50 individual parts that technicians in the United States must assemble. The building process includes, among other things, mounting a CPU board to a base and adding to that CPU board a programmed chip that enables and controls processing speed. Other operations performed include mounting gaskets and a card cage, installing electromagnetic interference ("EMI") gaskets, installing the machine control board ("MCB") and image processing board ("IPB") circuit boards, attaching a power supply to the CPU board, mounting a fan and installing an air duct, and attaching a cover to the base.

During this stage of production, technicians also build the OCP, elevator, carriage, image baffle, backup baffle, and shroud assemblies. At the end of this production stage, these subassemblies are complete and ready to undergo further processing.

2. Building the Pod Assembly

After completing the major subassemblies set forth above, the technicians begin assembling the pod assembly, which is the

top of the scanner. The technicians use the upper camera module, image baffle assembly, backup baffle assembly, and approximately 180 additional parts to build the pod assembly. Additional parts that must be integrated during this manufacturing stage include lamp inverters, air ducts, dust seals, video cables, blowers, air filters, rollers, support baffles, lamps, clutches, gears, and shafts. Special fixtures and tooling are used to build the pod assembly.

3. Main Build

After building the pod assembly, the technicians manufacture the bottom of the scanner, integrate the pod assembly, make fine adjustments to the unit, and perform certain testing operations. This stage of production is referred to as the "main build."

During the main build, technicians integrate the elevator, carriage, image baffle, backup baffle, E-box, shroud, OCP, and lower camera subassemblies, along with literally hundreds of additional parts. The additional parts include components such as camera mounts, lamp inverters, latch handles, bumpers, stops, slide blocks, bushings, brackets, gaskets, wires, air ducts, UDDS emitter boards (a circuit board for the ultrasonic double document sensor, which is used to detect misfeeds), electronic grounding jacks, elevator position sensors, carriage plates, motors, lamps, shafts, belts, blowers, air filters, foam seals, bearings, cables, switch actuators, and exterior cabinetry. The technicians also attach the pod assembly with a special fixture during this stage.

Technicians perform quality assurance checks throughout the main build and also use special fixtures designed to test electrical grounding.

4. End of Line Procedures

During this phase of production, additional quality control checks are conducted to ensure, for example, that the OCP cover is correctly installed, that all wires are dressed correctly, that the pod latches operate properly, and that glass and roller components are clean and ready for operation. The feeder module is then installed along with a separation roller and a separation pad. It is stated that the core elements of this stage of production, however, are operations such as programming, testing, and calibration of the machine.

The technicians program the equipment by inputting Kodak's proprietary firmware designed for the i600 line of scanners. This firmware was developed by Kodak's Software Engineering Group within the United States and is considered the "intelligence" of the scanner. The firmware provides the programming that will control machine function and the algorithms to process images.

The technicians load the firmware using Kodak's Scanner Validation Tool ("SVT"), which is a software package also developed and provided by Kodak's Software Engineering Group. In order to perform this task, technicians connect the scanner to a computer with the SVT and firmware already loaded. They then use the SVT to transfer the

firmware onto the scanner. This process installs the firmware onto the IPB circuit board and CPU circuit board, which the technicians previously installed during manufacture of the E-box subassembly.

Once the firmware is loaded onto the scanner, the technicians use the SVT and the firmware to calibrate and test the responses of the machine for specific inputs. These testing and calibration operations include procedures such as calibration of the UDDS system, calibration of the scanner for brightness, calibration of the scanner's speed, and measurement of image quality.

5. Packaging

Once the end of line procedures are completed, the assembled scanners are visually inspected and packaged for shipment.

Issue: Whether the assembled Kodak i600 line of scanners are considered to be products of the United States for purposes of U.S. Government procurement.

Law and Analysis: Pursuant to Subpart B of Part 177, 19 CFR 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations on whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also, 19 CFR 177.22(a).

In determining whether the combining of parts or materials constitutes a substantial transformation, the determinative issue is the extent of operations performed and whether the parts lose their identity and become an integral part of the new article. *Belcrest Linens v. United States*, 573 F. Supp. 1149 (CIT 1983), *aff'd*, 741 F.2d 1368 (Fed. Cir. 1984). Assembly operations that are minimal or simple, as opposed to complex or meaningful, will generally not result in a substantial transformation. *See*, C.S.D. 80-111, C.S.D. 85-25, C.S.D. 89-110, C.S.D. 89-118, C.S.D. 90-51, and C.S.D. 90-97. In C.S.D. 85-25, 19 Cust. Bull. 844 (1985), CBP held that for purposes of the Generalized System of Preferences ("GSP"), the assembly of a large number of fabricated components onto a printed circuit board in a process involving a considerable amount of time and skill resulted in a substantial transformation. In that case, in excess of 50 discrete fabricated components (such as resistors, capacitors, diodes, integrated circuits, sockets, and connectors) were assembled.

CBP has held in a number of cases involving similar type equipment that

complex and meaningful assembly operations involving a large number of components will generally result in a substantial transformation. For example, in Headquarters Ruling Letter ("HRL") 562495 dated November 13, 2002, color ink jet printers were assembled in Singapore of components imported from a number of other countries. CBP determined that the imported components were substantially transformed during assembly such that the country of origin of the assembled ink jet printers was Singapore. In support of this position, CBP recognized that the processing operations that occurred within Singapore were complex and extensive, required the integration of 13 major subassemblies to the chassis, and that the resulting product was a new and distinct article of commerce that possessed a new name, character, and use.

In HRL 561734 dated March 22, 2001, published in the **Federal Register** on March 29, 2001 (66 FR 17222), CBP held that certain multi-functional machines (consisting of printer, copier, and fax machines) assembled in Japan were a product of that country for purposes of U.S. Government procurement. The multi-functional machines were assembled from 227 parts (108 parts obtained from Japan, 92 from Thailand, 3 from China, and 24 from other countries) and eight subassemblies, each of which was assembled in Japan. One of the subassemblies produced in Japan, referred to as the scanner unit, was described as the "heart of the machine." In finding that the imported parts were substantially transformed in Japan, CBP stated that the individual parts and components lost their separate identities when they became part of the multi-functional machine. *See also*, HRL 561568 dated March 22, 2001, published in the **Federal Register** on March 29, 2001 (66 FR 17222).

By contrast, assembly operations that are minimal or simple will generally not result in a substantial transformation. For example, in HRL 734050 dated June 17, 1991, CBP held that Japanese-origin components were not substantially transformed in China when assembled in that country to form finished printers. The printers consisted of five main components identified as the "head", "mechanism", "circuit", "power source", and "outer case." The circuit, power source and outer case units were entirely assembled or molded in Japan. The head and mechanical units were made in Japan but exported to China in an unassembled state. All five units were exported to China where the head and mechanical units were assembled with screws and screwdrivers. Thereafter, the head, mechanism, circuit, and power source units were mounted onto the outer case with screws and screwdrivers. In holding that the country of origin of the assembled printers was Japan, CBP recognized that the vast majority of the printer's parts were of Japanese origin and that the operations performed in China were relatively simple assembly operations.

The programming operations performed in the instant case must also be considered. In

Data General Corporation v. United States, 4 CIT 182 (1982), the Court of International Trade held that a PROM (programmable read-only memory) fabricated in a foreign country but programmed in the United States for use in a computer circuit board assembled abroad was substantially transformed. In *Data General*, the court stated that the electronic pattern introduced into the circuit by programming gave the PROM the function as a read only memory and that the essence of the article, its pattern of interconnection or stored memory, was established by programming.

As applied, we find that the various foreign-origin parts are substantially transformed within the United States when assembled to form the Kodak i600 line of scanners in the manner set forth above. In making this determination we note that the scanners are comprised of approximately 600 parts and thirteen subassemblies. Ten of the subassemblies are assembled to completion within the United States during a complex and meaningful process. Illustrative examples of two major subassemblies built to completion in the United States are the E-Box assembly (comprised of approximately 50 parts) and the pod assembly (comprised of more than 180 parts). During the main build phase of production, the various subassemblies and literally hundreds of additional parts are assembled together to form the scanners. Specialized fixtures, tooling, and other equipment are used throughout assembly to align, test, and calibrate the scanners as they are built. After assembly, the scanners are programmed with firmware developed in the United States, which constitutes the intelligence of the scanners. During such assembly and programming operations, the individual components and subassemblies of foreign-origin are subsumed into a new and distinct article of commerce that has a new name, character, and use. Therefore, we find that the country of origin of the Kodak i600 scanners for purposes of U.S. Government procurement is the United States.

Holding: Based upon the specific facts of this case, we find that the individual components and subassemblies imported into the United States are substantially transformed when assembled in the manner set forth above to form Kodak i600 desktop scanners. Therefore, the country of origin of the Kodak i600 line of desktop scanners for purposes of U.S. Government procurement is the United States.

Notice of this final determination will be given in the **Federal Register** as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Any party-at-interest may, within 30 days after publication of the **Federal Register** notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Michael T. Schmitz,
Assistant Commissioner, Office of
Regulations and Rulings.

[FR Doc. 05-18359 Filed 9-14-05; 8:45 am]

BILLING CODE 9110-06-P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Notice of Cancellation of Customs Broker License Due to Death of the License Holder

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

ACTION: General notice.

SUMMARY: Notice is hereby given that, pursuant to Title 19 of the Code of Federal Regulations § 111.51(a), the following individual Customs broker licenses and any and all permits have been cancelled due to the death of the broker:

| Name | License No. | Port name |
|----------------------|-------------|--------------|
| Thomas A. Borgia ... | 10419 | Miami. |
| Karl A. Becnel | 09684 | New Orleans. |

Dated: September 8, 2005.

Jayson P. Ahern,
Assistant Commissioner, Office of Field Operations.

[FR Doc. 05-18360 Filed 9-14-05; 8:45 am]

BILLING CODE 9110-06-P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Notice of Cancellation of Customs Broker Permit

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

ACTION: General notice.

SUMMARY: Pursuant to section 641 of the Tariff Act of 1930, as amended, (19 U.S.C. 1641) and the Customs Regulations (19 CFR 111.51), the following Customs broker permits are cancelled without prejudice.

| Name | Permit | Issuing port |
|---------------------------------------|--------|--------------|
| General Brokerage Services, Inc. | H34 | Miami. |