

inconsistent with the GRAS determination; and

—The basis for concluding, in light of the data and information submitted, that there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use.

○ For a GRAS determination through experience based on common use in food, such summary should include:

—A comprehensive discussion of, and citations to, generally available data and information that the notifier relies on to establish safety, including documented evidence of a substantial history of consumption of the substance by a significant number of animals. Where a substance is intended for use in the food of an animal used to produce human food, this should include a comprehensive discussion of, and citations to, generally accepted scientific data, information, methods, or principles about both safety to the target animal and human food safety. The scientific data, information, methods, or principles provided should be sufficient to show that the substance is generally recognized among qualified experts to be safe for animals consuming food containing the substance as well as to humans consuming food derived from such animals (i.e., under its intended conditions of use);

—A comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination;

—The basis for concluding, in light of the data and information submitted, that there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use.

IV. How FDA Will Administer Notices Under the Pilot Program

In general, the agency will administer the notices under the pilot program as described in proposed § 570.36(d) through (f) of the 1997 proposed rule, as follows:

1. Within 30 days of receipt of the notice, FDA intends to acknowledge receipt of the notice by informing the notifier in writing.

2. Under the 1997 proposed rule, FDA would respond to the notifier in writing within 90 days of receipt of the notice either that the notice provides a sufficient basis for the GRAS

determination or that FDA has identified questions as to whether the intended use of the substance is GRAS. Due to resource limitations in the animal food program, it is unlikely that CVM will be able to evaluate and respond to notices within the 90-day timeframe contained in the 1997 proposed rule. CVM will therefore respond to notifications of GRAS determinations in its pilot program as quickly as resources permit.

• Any GRAS determination claim submitted as part of the pilot program shall be immediately available for public disclosure on the date the notice is received. All remaining data and information in the notice shall be available for public disclosure, in accordance with 21 CFR part 20, on the date the notice is received.

• For each notice of GRAS determination submitted under the pilot program, the following information shall be readily accessible for public review and copying:

○ A copy of the submitted GRAS determination claim,

○ A copy of any letter issued by the agency, as described in paragraph 2 of this section.

○ A copy of any subsequent letter issued by the agency regarding such notice.

V. Paperwork Reduction Act of 1995

The collections of information in this notice are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), and have been previously approved by OMB. OMB originally approved Paperwork Reduction Act (PRA) burdens for GRAS notification under the 1997 proposed rule under OMB control number 0910–0342. The original OMB approval covered the collections of information in both proposed 21 CFR 170.36 and 570.36; however, only CFSAN operated a GRAS notification program for human food under the original OMB PRA approval. Extension of the original OMB PRA approval for GRAS notification was granted by OMB on August 24, 2009, under OMB control number 0910–0342.

As with the human food GRAS notification program administered by CFSAN, which has operated for several years, the animal food pilot program, which will be administered by CVM, will be based on the notification procedures announced in the 1997 proposed rule. The provisions for GRAS notification under proposed §§ 170.36 and 570.36 for human and animal food, respectively, are virtually identical and therefore the same number of hours per

response were estimated for reporting (150 hours) and recordkeeping (15 hours per record) burdens for both proposed sections under the original and extended OMB PRA approvals. Because CFSAN's GRAS program has successfully operated under these PRA estimates for several years, FDA believes these burden estimates remain accurate for CVM's GRAS pilot program.

FDA's estimate of the annual number of GRAS determination notices that will be received by CVM in the extended OMB PRA approval (5) was revised downward from the original PRA approval (10). This revision was based on the actual number of GRAS notices received by CFSAN from 1998 to 2008, which was lower than anticipated and caused CFSAN to also revise downward its estimate in the extended PRA approval. The revised estimate in the extended PRA approval reflects FDA's best judgment at this time as to the number of notices CVM will receive annually through this pilot program.

CVM believes that the PRA estimates in the extended PRA approval cover CVM's GRAS notice program.

Dated: May 26, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13464 Filed 6–3–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning a Lift Unit for an Overhead Patient Lift System

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

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of a lift unit for an overhead patient lift system. Based upon the facts presented, CBP has concluded in the final determination that Sweden is the country of origin of the lift unit for purposes of U.S. government procurement.

DATES: The final determination was issued on May 28, 2010. 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 July 6, 2010.

FOR FURTHER INFORMATION CONTACT:

Heather K. Pinnock, Valuation and Special Programs Branch; (202) 325-0034.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on 2010, 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 the lift unit which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, in HQ H100055, was issued at the request of Hill-Rom Company, Inc., 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). In the final determination, CBP concluded that, based upon the facts presented, the lift unit, assembled in Sweden from parts made in a non-TAA country and in Sweden, is substantially transformed in Sweden, such that Sweden is the country of origin of the finished article for purposes of U.S. government procurement.

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, CBP Regulations (19 CFR 177.30), provides 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: May 28, 2010.

Harold M. Singer,

Acting Executive Director, Regulations and Rulings, Office of International Trade.

Attachment

HQ H100055

May 28, 2010

OT:RR:CTF:VS H100055 HKP

CATEGORY: Marking

Karen A. McGee, Esq.

Linda M. Weinberg, Esq.

Barnes & Thornburg LLP

750 17th Street, N.W., Suite 900

Washington, DC 20006-4675

RE: Government Procurement; Country of Origin of a Lift Unit for an Overhead Patient Lift System; Substantial Transformation

Dear Ms. McGee and Weinberg: This is in response to your letter dated April 1, 2010, requesting a final determination on behalf of Hill-Rom Company, Inc., pursuant to subpart B of part 177 of the U.S. Customs and Border Protection Regulations (19 C.F.R. Part 177).

Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (TAA), as amended (19 U.S.C. 2511 et seq.),

CBP issues country of origin advisory rulings and final determinations as to 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.

This final determination concerns the country of origin of a lift unit for the Likorall Overhead Patient Lift System. We note that as a U.S. importer Hill-Rom is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

FACTS:

According to the information submitted, the Likorall Overhead Patient Lift System is a ceiling-mounted or free-standing patient lift system. The system is capable of lifting and transporting patients with limited mobility, weighing up to 550 pounds, from one part of a room to another or from one room to another. It can also be used for weighing and lifting in combination with a stretcher and for walking, standing, gait and balance training. The system is designed to lift and move patients safely while avoiding injuries to caregivers.

The merchandise at issue, the Likorall lift unit, is the motorized component of the Overhead Patient Lift System that extends and retracts the lift belt to which the patient-supporting sling is attached. The unit is manufactured in 3 basic models: (1) 242, which has a lifting capacity up to 440 pounds; (2) 243, which has a lifting capacity up to 507 pounds; and (3) 250, which has a lifting capacity up to 550 pounds. Models 243 and 250 come in an "ES" version, which is equipped with an infrared (IR) receiver for optional use with a remote control. Model 242 comes in the "S" version, which operates only with an attached hand control, as well as in the ES version. In addition, the 242 model has "R2R" versions, which feature a contact for a transfer motor so that the patient can be moved between two independent overhead rail systems in separate rooms, without the need for openings above doorways. The lift unit was designed, developed and engineered in Sweden. It incorporates approximately 100 components imported from non-TAA countries, except for the motor, which is imported from a TAA country and the IR remote control, which is made in Sweden.

At the manufacturing facility in Sweden, teams of employees assemble the lift unit in a four segment process and perform a 25-step final functional test under specified conditions. The segments are: Manufacturing the electrical motor, drum and motor package in a 17-step process; mounting batteries and installing the exterior covers of the drum/motor assembly in a 5-step process; connecting a printed circuit board assembly (PCBA) to the motor, housed drum and batteries in a 3-step process; and, assembling the emergency strap, cover and end caps in a 14-step process. The PCBA is assembled and programmed prior to importation into Sweden but is designed in Sweden and its software program is written in Sweden. During the final functional test the electronics of the lift unit are checked and

the maximum load is attached to check performance. At the conclusion of the test, the employee performing the test must complete a test protocol form, with the original being provided to the customer and a copy retained by the manufacturer in a test log that tracks units by serial number. The full manufacturing process takes approximately 45 minutes and the testing process takes approximately 15 minutes.

According to the information submitted, the employees manufacturing the lift unit have mechanical knowledge and skill related to their work gained from technical secondary education, product specific training, and certified final functional test training. The lift unit is also tested by an accredited testing institute and complies with the requirements of directives for medical-technical Class 1 products in the European Union (MDD 93/42/EEC).

Packaged for retail sale with the lift unit is a hand control, which is attached by cable to the overhead unit and is used to control power, lifting and lowering of the lift unit's belt, and the moving of the lift unit along the rails. The hand control plugs into a contact on one of the end plates and is physically and electrically connected to the overhead lift unit. It is made in a non-TAA country. An IR remote hand control (ES versions and 242 ESR2R), which can be used as an alternative to the attached hand control is also imported with the unit. The remote control and the PCB it incorporates are made in Sweden. A battery charger, into which the wired hand control is inserted to charge the batteries inside the lift unit, is also imported with the lift unit. The charger is made in the same non-TAA country as the hand control.

ISSUE:

What is the country of origin of the lift unit 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 as to 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 (Ct. Int'l Trade 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. Whether an operation is complex and meaningful depends on the nature of the operation, including the number of components assembled, number of different operations, time, skill level required, attention to detail, quality control, the value added to the article, and the overall employment generated by the manufacturing process.

In order to determine whether a substantial transformation occurs when components of various origins are assembled into completed products, CBP considers the totality of the circumstances and makes such determinations on a case-by-case basis. The country of origin of the item's components, extent of the processing that occurs within a country, and whether such processing renders a product with a new name, character, and use are primary considerations in such cases. Additionally, factors such as the resources expended on product design and development, the extent and nature of post-assembly inspection and testing procedures, and worker skill required during the actual manufacturing process will be considered when determining whether a substantial transformation has occurred. No one factor is determinative.

CBP has held in a number of cases that complex and meaningful assembly operations involving a large number of components result in a substantial transformation. In Headquarters Ruling Letter (HQ) H047362, dated March 26, 2009, CBP found that 61 components manufactured in China and assembled into ground fault circuit interrupters (GFCIs) in Mexico in a two-phase process by skilled workers using sophisticated equipment were substantially transformed in Mexico. In particular, we took into consideration that the first phase involved the assembly of a PCB in a 42-step technically complex process that took 12 minutes and that the completed PCB had all the major components necessary for the GFCI to fulfill its function. We also took into consideration that in the second phase the PCB would be assembled with 29 other components to form the GFCIs in a 43-step process taking approximately 10 minutes, after which the components would have lost their individual identities and become an integral part of the interrupters with a new name, character and use.

By contrast, assembly operations that are minimal or simple will generally not result in a substantial transformation. For example, in HQ 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.

In this case, approximately 100 components manufactured in non-TAA countries will be assembled in Sweden in four phases requiring specialized training. The manufacturing process has 39 steps and takes 45 minutes. After manufacturing, the unit is subjected to a 25-step testing process, which takes approximately 15 minutes. We find these manufacturing and testing operations in Sweden to be sufficiently complex and meaningful, in that individual components' names, uses and identities are lost and are transformed in Sweden into the lift unit. Therefore, the country of origin of the lift unit is Sweden.

You argue that of the lift unit, detachable hand control and battery charger being imported, the lift unit provides the essential character of the Litorall System. “The term ‘character’ is defined as ‘one of the essentials of structure, form, materials, or function that together make up and usually distinguish the individual.’” *Uniden America Corporation v. United States*, 120 F. Supp. 2d. 1091, 1096 (citations omitted) (Ct. Int'l Trade 2000), *citing National Hand Tool Corp. v. United States*, 16 Ct. Int'l Trade 308, 311 (1992). In *Uniden* (concerning whether the assembly of cordless telephones and the installation of their detachable A/C (alternating current) adapters constituted instances of substantial transformation), the Court of International Trade applied the “essence test” and found that “[t]he essence of the telephone is housed in the base and the handset. Consumers do not buy the article because of the specific function of the A/C adapter, but rather because of what the completed handset and base provide: communication over telephone wires.” *Id.* at 1096.

Further, you argue that the detachable hand control and battery charger are substantially transformed with the lift unit, in that they have a new character, use and name because they are attached to and form parts of the Litorall System. In support of this view, you cite *Uniden*, *supra*, in which the court also found that the detachable A/C adapters underwent a substantial

transformation pursuant to the Generalized System of Preferences (GSP) when installed into the cordless telephones. The court noted that the substantial transformation test is to be applied to the product as a whole and not to each of its detachable components. See *id.* Consequently, the court found that the A/C adapter, as part of the cordless phone, had a new character, use and name.

Based on the findings of the court in *Uniden*, we agree with your view that the detachable hand control and battery charger are substantially transformed when attached to the lift unit. Consequently, if they are imported from Sweden packaged together with the lift unit, their country of origin for purposes of U.S. government procurement will be Sweden.

HOLDING

Based on the facts of this case, we find that the manufacturing and testing operations performed in Sweden substantially transforms the non-TAA country components. Therefore, the country of origin of the lift unit is Sweden for purposes of U.S. government procurement. Moreover, because the lift unit conveys the essential character of the Litorall System and the detachable hand control and the battery charger are parts of that system, they are substantially transformed when attached to the lift unit. The country of origin of the hand control and battery charger for purposes of U.S. government procurement, when imported from Sweden packaged with the lift unit, is Sweden.

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. Pursuant to 19 CFR § 177.30, any party-at-interest may, within 30 days after publication in the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,
Harold M. Singer
Acting Executive Director
Regulations and Rulings
Office of International Trade

[FR Doc. 2010–13497 Filed 6–3–10; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5300–FA–25]

Announcement of Funding Awards for the Resident Opportunity and Self-Sufficiency (ROSS)—Service Coordinators Program for Fiscal Year 2009

AGENCY: Office of Public and Indian Housing, HUD.

ACTION: Announcement of funding awards.