

Institute of Medicine (IOM) regarding hearing aids and personal sound amplification products (PSAP). In order to allow FDA and other interested parties to consider the PCAST recommendations and information presented and discussed during the recent public IOM meetings on this issue, FDA is reopening the comment period. This will further allow FDA to ensure consistent interpretation, consistent application of relevant regulatory requirements, and adequate protection of the public health.

FDA is reopening the comment period for 120 days. The Agency believes that a 120-day extension allows adequate time for interested parties to submit comments without significantly delaying finalizing the draft guidance on these important issues.

II. Other Issues for Consideration

FDA is soliciting comments on the availability, accessibility, and use of hearing aids and PSAPs for consumers with hearing impairment. Further, FDA requests interested parties to comment on the key issues and recommendations identified in the PCAST reporting, including: (1) The degree to which current FDA regulatory requirements may be acting as a barrier to hearing aid accessibility, affordability, and use of hearing aids; (2) the appropriateness of creating a "basic" category of hearing aids for consumers with "bilateral, gradual onset, mild-to-moderate age-related hearing loss" with appropriate labeling for over-the-counter sale; and (3) whether the benefits of expanded, over-the-counter access to hearing aids in this age-related hearing loss population outweigh the risks of forgoing the condition for sale (that the consumer may waive) that requires a medical evaluation to rule out treatable, potentially progressive causes of hearing loss.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please

use the document number 1832 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485, and the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120.

Dated: December 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–00066 Filed 1–6–16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Certain Intermodal Containers

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 certain intermodal containers. Based upon the facts presented, CBP has concluded that the country of origin of the intermodal containers is the country of origin of the imported panels for purposes of U.S. Government procurement.

DATES: The final determination was issued on December 23, 2015. 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 February 8, 2016.

FOR FURTHER INFORMATION CONTACT:

Teresa M. Frazier, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade (202) 325–0139.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on December 23, 2015, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart

B), CBP issued a final determination concerning the country of origin of certain intermodal containers, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H267876, was issued 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 the processing in the United States does not result in a substantial transformation. Therefore, the country of origin of the intermodal containers is the country of origin of the imported panels for purposes of U.S. Government procurement for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination 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: December 23, 2015.

Myles B. Harmon,

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

H267876

OT:RR:CTF:VS H267876 TMF

CATEGORY: Country of Origin

Michael G. McManus
Duane Morris LLP
505 9th Street, N. W., Suite 1000
Washington, DC 20004–2166

Re: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. 2511); Substantial Transformation; Intermodal Shipping Containers

Dear Mr. McManus:

This is in response to your correspondence of July 29, 2015, supplemented by your letter of September 30, 2015, requesting a final determination on behalf of Sea Box, Inc. ("Sea Box"), pursuant to subpart B of part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 CFR 177.21 *et seq.*). Under pertinent regulations, which implement Title II 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 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 Sea Box shipping containers. We note that Sea Box, Inc. is a

party-at-interest within the meaning of 19 CFR 177.22(d)(1) and is entitled to request this final determination. A meeting was held November 4, 2015.

FACTS:

You state that the subject containers are made in various sizes: 20 foot long; Bicon; Tricon and Quadcon. The 20' shipping container is considered to be a standard unit in the shipping industry.

1. Twenty Foot Shipping Containers

You state that a 20 foot ISO¹-compliant container has the following external measurements:

19' 10.5" in length with a tolerance of +0, - 1/4 of an inch; 8.0' in width with a tolerance of +0, - 3/16 of an inch; 8.0' in height with a tolerance of +0, - 3/16 of an inch. The internal dimensions are: 19' 4 11/64" (L); 7' 8 17/32" (W); 7' 4 3/16" (H). The 20 foot container is comprised of corrugated steel sides and roofing which gives it a favorable strength to weight ratio; two sets of forklift "pockets" that permit forklifts to lift and move laden or unladen containers; wooden flooring tested to withstand 16,000 lbs. per square foot (144 square inches); 24 top and bottom wall tie down steel lashing rings each having a capacity of 4,000 lbs.; and two vents. The twenty foot containers weigh 5,000 lbs. each and can accommodate a payload of 47,910 lbs.

2. Bicons

You state that a Bicon is a shipping container that is approximately half the size of a 20 foot container and manufactured to precise dimensions such that when two are linked together by connecting couplers, they form a 20 foot equivalent unit ("TEU") and may be transported as if the combination were a single 20 foot container. The ISO-compliant Bicon container has the following external dimensions: 9' 9 3/4" in length with a tolerance of +0, - 3/16 of an inch; 8.0' in width with a tolerance of +0, - 3/16 of an inch; 8.0' in height with a tolerance of +0, - 3/16 of an inch. The internal dimensions are: 9' 3 1/2" (L); 7' 8 17/32" (W); 7' 4 3/16" (H). You state that the Bicon has similar features to the 20 foot unit, except that the Bicon only has one set of forklift "pockets" and uses several tie down steel lashings. You state that the Bicon has a weight of 2,900 lbs. and can accommodate a payload of 23,555 lbs., and has a storage capacity of 527 cubic feet.

3. Tricons

You state that a Tricon is approximately one-third the size of a 20 foot container and that it is manufactured to precise dimensions such that when three Tricons are linked together by connecting couplers, a TEU is formed and may be transported as if the combination was a single 20 foot container. The ISO-compliant Tricon container has the following external dimensions: 6' 5 9/16" in length with a tolerance of +0, - 3/16 of an inch; 8.0' in width with a tolerance of +0, - 3/16 of an inch; 8.0' in height with a tolerance of +0, - 3/16 of an inch. The

internal dimensions are: 6' 3 25/64" (L); 7' 7 22/32" (W); 7' 5 9/64" (H). You state that the Tricon has similar features to the 20 foot unit and the Bicon, except that instead of a wooden flooring, the Tricon has heavy duty steel flooring. You state the Tricon has a weight of 2,600 lbs. each laden and may accommodate a payload of 13,300 lbs., and has a storage capacity of 356 cubic feet.

4. Quadcons

You state that a Quadcon is approximately one-fourth the size of a twenty foot container and that it is manufactured to precise dimension such that when four Quadcons are linked together by connecting couplers, a TEU is formed and may be transported as if the combination were a single 20 foot container. The ISO-compliant Quadcon container has the following external dimensions: 4' 9 7/16" in length with a tolerance of +0, - 3/16 of an inch; 8.0' in width with a tolerance of +0, - 3/16 of an inch; 8.0' in height with a tolerance of +0, - 3/16 of an inch. The internal dimensions are: 4' 7 3/4" (L); 7' 6 9/16" (W); 7' 5" (H). You state that the Quadcon has similar features to the Tricon, except that it also has swing doors on both sides for convenient access. You state the Quadcon has a weight of 2,300 lbs. each unladen and may accommodate a payload of 8,900 lbs., and has a storage capacity of 260 cubic feet.

Manufacturing Process

In your submission, you described Sea Box's manufacturing facilities to include a separate, free-standing, testing center with equipment capable of testing containers for ISO compliance to 1.8 times the maximum required load (which is equivalent to 846,720 lbs.). You advise that the manufacturing process requires the manipulation of large components to form a structurally sound container to its precise size in accordance with ISO specifications, allowing containers to be capable of transport by rail, truck and ship with uniform fitting on preexisting truck and rail support structures. You provided a list of the 43 components of the containers. We note that that the front wall panel, side wall panel, right-hand door, right-hand door gasket, left-hand door gasket, roof panel, floor panel, lashing rings, front corner post tie downs, and corner blocks, all originate from one foreign country. Connecting couplers, hand assembly restraint bar, tie-back, rivets nuts and bolts, hinges, amongst other components, originate from the U.S. You indicate that by using grinders and/or cutting wheels, the components are ground to bare steel where welding is required. Specifically, the floor sections, wall section, front and rear-end sections, and roof section are ground to bare steel where welding is required. Next, the components are loaded into the Jig and once the dimensional tolerances are verified and adjusted, the components are tacked and stitch-welded together, vertical seams are welded, and all outside components are fully welded. If required, roof corner plates and floor gussets are welded, and door tieback hooks are welded. Next, pilot holes are drilled into the floor and steel cross-members and doors are secured. The container is then moved to the blast booth for painting with

primer and a top coat. You indicate that the particular steel that is used in the roof and sides is not available in the U.S.

You state that the containers must be capable of being stacked up to nine units high, with the base of a stack strong enough to support 470,400 static lbs. above a container (8 containers x 58,800 lbs. per container). You also state the container must be able to support a dynamic load taking into account a vessel's motion in conformity with the American Bureau of Shipping (ABS). You also advise that the containers must be CSC² certified at a CSC certified, manufacturer's facility that is preapproved by the U.S. Coast Guard.

ISSUE:

Whether the intermodal containers are considered to be products of the United States for U.S. Government procurement purposes.

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 a product of a designated country for the purpose of granting waivers of certain "Buy American" restrictions on U.S. Government procurement.

In rendering final determinations for purposes of U.S. Government procurement, CBP applies the provisions of Subpart B of Part 177 consistent with the Federal Procurement Regulations. *See* 19 CFR 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the Trade Agreements Act. *See* 48 CFR 25.403(c)(1). The Federal Acquisition Regulations define "U.S.-made end product" as "an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with name, character, or use distinct from that of the article or articles from which it was transformed." *See* 48 C.F.R. 25.003.

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 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,

¹International Organization for Standardization set standard sizes and manufacturing specifications for all containers.

²International Container Safety Convention concerning testing, inspection, approval and maintenance of shipping containers.

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.

Substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. See *United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940). 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. See *Belcrest Linens v. United States*, 6 Ct. Int'l Trade 204, 573 F. Supp. 1149 (1983), *aff'd*, 741 F.2d 1368 (Fed. Cir. 1984).

In *Uniroyal, Inc. v. United States*, the Court of International Trade held that no substantial transformation occurred because the attachment of a footwear upper from Indonesia to its outsole in the United States was a minor manufacturing or combining process which left the identity of the upper intact. *Uniroyal, Inc. v. United States*, 3 CIT 220, 224, 542 F. Supp. 1026, 1029 (1982), *aff'd*, 702 F.2d 1022 (Fed. Cir. 1983). The court found that the upper was readily recognizable as a distinct item apart from the outsole to which it was attached, it did not lose its identity in the manufacture of the finished shoe in the United States, and the upper did not undergo a physical change or a change in use. Also, under *Uniroyal*, the change in name from "upper" to "shoe" was not significant. The court concluded that the upper was the essence of the completed shoe, and was not substantially transformed.

In *National Hand Tool Corp. v. United States*, 16 CIT 308 (1992), *aff'd*, 989 F.2d 1201 (Fed. Cir. 1993), the court considered sockets and flex handles which were either cold formed or hot forged into their final shape prior to importation, speeder handles which were reshaped by a power press after importation, and the grip of flex handles which were knurled in the U.S. The imported articles were heat treated, cleaned by sandblasting, tumbling, and/or chemical vibration before being electroplated. In certain instances, various components were assembled together which the court stated required some skill and dexterity. The court determined that the imported articles were not substantially transformed and that they remained products of Taiwan. In making its determination, the court focused on the fact that the components had been cold formed or hot forged "into their final shape before importation", and that "the form of the components remained the same" after the assembly and heat treatment processes performed in the U.S.

It is your position that the country of origin of the intermodal containers is the U.S. because your client's operations are "plainly complex and meaningful" in that every component loses its identity and becomes an integral part of the shipping container. You state that this process is more complex than processes found to effect a substantial transformation in certain past rulings, and you cite to Headquarters Ruling Letters (HQ) H248850, dated November 7, 2014; H259326, dated April 13, 2015; H192144, dated October 22, 2014; and H251592, dated June 24, 2014. You also state that the large scale industrial process that is employed to manipulate components weighing hundreds to thousands of pounds to manufacture a shipping container to narrow tolerances is surely a "complex operation requiring skilled workers." You also advise that this "large scale industrial" manufacturing process requires skilled labor, special equipment, facilities, labor resources and in-process quality assurance techniques and precision subject to ISO specifications and rigorous CSC certification. You argue that the strict dimensional tolerances that are required for safety and to assure compliance with ISO and CSC standards for use in international commerce makes the process precise, expensive, complex and meaningful. We reviewed your submission and note that although the large scale assembly requires skilled labor for safety and compliance with certain ISO and CSC certification requirements, this does not result in a substantial transformation of the non-U.S. components. Rather, the container assembly is distinguishable from the aforementioned cases where CBP found substantial transformation.

In H259326, the exoskeleton assistive walking device assembly consisted of hundreds of parts sourced from U.S. manufacturers, with the exception of three parts, all of which were assembled in the U.S. In H259326, CBP found the inclusion of the two of the three non-U.S. parts (a heat diffuser/shield, foot straps/binding) would be permanently attached to the finished devices such that they would "lose their separate identities and be subsumed into the finished exoskeleton," thereby resulting in a substantial transformation when used in the manufacturer of the finished exoskeleton. However, in this case, the foreign-origin front, side and roof and floor panels are not subsumed into a complex device.

Further, there is not complex assembly of the container like in H248850, dated November 7, 2014, in which CBP found a substantial transformation involving U.S. patented operations which consisted of bending of the HEX; brazing of various connections; and installing a control box which contained U.S. developed software. With the intermodal containers, although skilled workers are required to ensure safety and accuracy in accordance with ISO and CSC requirements, the grinding, welding and assembly processes essentially do not change the predetermined use of the panels, all of which originate from one foreign country. In regard to H251592, CBP determined that certain AIO cartridges assembled with toner powder from Japan, a cleaning unit from

Thailand, and a development unit from China, were substantially transformed because the toner powder was found to be the most critical element of the AIO cartridge. As in *Uniroyal*, the essential character of the container is imparted by the foreign-origin roof, side and bottom panels, which, like *National Handtool*, are already formed in the final shape prior to importation. In H192144, CBP found imported coated, optical lenses underwent a double substantial transformation in a beneficiary country to meet the 35 percent value-content GSP requirement, which is not at issue here. Therefore, we do not find a substantial transformation in the manufacture of the subject intermodal containers.

HOLDING:

Based upon the specific facts of this case, we find that the imported panels are not substantially transformed as a result of the described operations performed in the United States. The country of origin of the intermodal containers for purposes of U.S. Government procurement is imparted by the roof, side and floor panels, which are of non-U.S. origin.

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 of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Myles B. Harmon, Acting Executive Director
Regulations & Rulings Office of
International Trade

[FR Doc. 2015-33244 Filed 1-6-16; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2015-0069]

Meeting: Homeland Security Advisory Council

AGENCY: The Office of Public Engagement, DHS.

ACTION: Notice of partially closed Federal Advisory Committee meeting.

SUMMARY: The Homeland Security Advisory Council ("Council") will meet in person on January 21, 2016. Members of the public may participate in person. The meeting will be partially closed to the public.

DATES: The Council will meet Thursday, January 21, 2016, from 10:10 a.m. to 4:35 p.m. EST. The meeting will be open to the public from 1:30 p.m. to 3:00 p.m. EST. Please note the meeting