

*Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. See e.g., Headquarters Ruling Letter ("HQ") 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; and, HQ 735146, dated November 15, 1993.

For instance, in HQ 561975, the anesthetic drug sevoflurane imported into the U.S. in bulk form and processed into dosage form by extensive testing operations, followed by filtering and packaging into bottles, was found not to have undergone a substantial transformation in the U.S. There was no change in name (the product was identified as sevoflurane in both its bulk and processed form). The sevoflurane retained its chemical and physical properties after the U.S. processing. Lastly, because the imported bulk sevoflurane had a predetermined medicinal use as an inhalable anesthetic drug, the processing in the United States resulted in no change in the product's use.

Likewise, in HQ 561544, the testing, filtering and sterile packaging of Geneticin Sulfate bulk powder, to create Geneticin Selective Antibiotic, was not found to have substantially transformed the antibiotic substance because the processing only involved the removal of impurities from the bulk chemical and the placement of the chemical into smaller packaging.

In HQ 735146, 100 percent pure acetaminophen imported from China was blended with excipients in the United States, granulated and sold to pharmaceutical companies to process into tablets for retail sale under private labels. It was found that the process in the United States did not substantially transform the imported product because the product was referred to as acetaminophen before importation and after U.S. processing, its use was for medicinal purposes and continued to be so used after U.S. processing, and the granulating process minimally affected the chemical and physical properties of the acetaminophen.

In HQ H233356 dated December 26, 2012, mefenamic acid imported from

India was blended with excipients and packaged into dosage form in the United States. Based on prior rulings, we found that the specific processing consisting of blending the active ingredients with inactive ingredients in a tumbler and then encapsulating and packaging the product did not substantially transform the mefenamic acid because its chemical character remained the same. As such, we found that the country of origin of the Ponstel (mefenamic acid) capsules was India, where the mefenamic acid was manufactured.

In this case, the processing performed in the U.S. does not result in a change in the medicinal use of the finished product and the active ingredient. The Acyclovir retains its chemical and physical properties and is merely put into a dosage form and is packaged for sale. The active ingredient does not undergo a change in name, character or use. Therefore, in accordance with our prior rulings, we find that no substantial transformation occurs in U.S., and for purposes of government procurement, the Acyclovir tablets would be considered a product where the active ingredient was produced, which would be China and India.

#### **HOLDING:**

Based upon the facts in this case, we find that the imported Acyclovir is not substantially transformed in U.S. Accordingly, the country of origin for government procurement purposes of the Acyclovir tablets is China and India, where the active ingredient is produced.

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  
Office of Regulations and Rulings  
Office of International Trade*

[FR Doc. 2015-28827 Filed 11-12-15; 8:45 am]

**BILLING CODE P**

## **DEPARTMENT OF HOMELAND SECURITY**

### **U.S. Customs and Border Protection**

[1651-0124]

#### **Agency Information Collection Activities: Cargo Container and Road Vehicle Certification for Transport Under Customs Seal**

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

**ACTION:** 30-Day notice and request for comments; extension of an existing collection of information.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Cargo Container and Road Vehicle for Transport under Customs Seal. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

**DATES:** Written comments should be received on or before December 14, 2015 to be assured of consideration.

**ADDRESSES:** Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229-1177, at 202-325-0265.

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** (80 FR 48117) on August 11, 2015, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10. CBP invites the general public and other Federal

agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3507). The comments should address:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimates of the burden of the collection of information;

(c) ways to enhance the quality, utility, and clarity of the information to be collected;

(d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and

(e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

*Title:* Cargo Container and Road Vehicle for Transport under Customs Seal.

*OMB Number:* 1651-0124.

*Abstract:* The United States is a signatory to several international Customs conventions and is responsible for specifying the technical requirements that containers and road vehicles must meet to be acceptable for transport under Customs seal. Customs and Border Protection (CBP) has the responsibility of collecting information for the purpose of certifying containers and vehicles for international transport under Customs seal. A certification of compliance facilitates the movement of containers and road vehicles across international territories. The procedures for obtaining a certification of a container or vehicle are set forth in 19 CFR part 115.

*Action:* CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

*Type of Review:* Extension (without change).

*Affected Public:* Businesses.

*Estimated Number of Respondents:* 25.

*Estimated Number of Annual Responses per Respondent:* 120.

*Estimated Time per Response:* 3.5 hours.

*Estimated Total Annual Burden Hours:* 10,500.

Dated: November 4, 2015.

**Tracey Denning,**

*Agency Clearance Officer, U.S. Customs and Border Protection.*

[FR Doc. 2015-28828 Filed 11-12-15; 8:45 am]

**BILLING CODE 9111-14-P**

## DEPARTMENT OF HOMELAND SECURITY

### Agency Information Collection Activities: National Initiative for Cybersecurity Careers and Studies (NICCS) Cybersecurity Training and Education Catalog (Training/Workforce Development Catalog) Collection

**AGENCY:** Cybersecurity Education & Awareness Office (CE&A), DHS.

**ACTION:** 30-Day notice and request for comments; reinstatement with change, 1601-0016.

**SUMMARY:** The Department of Homeland Security, Cybersecurity Education & Awareness Office (CE&A), will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). DHS previously published this information collection request (ICR) in the **Federal Register** on Wednesday, September 2, 2015 at 80 FR 53180 for a 60-day public comment period. No comments were received by DHS. The purpose of this notice is to allow additional 30-days for public comments.

**DATES:** Comments are encouraged and will be accepted until January 12, 2016. This process is conducted in accordance with 5 CFR 1320.1.

**ADDRESSES:** Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to OMB Desk Officer, Department of Homeland Security and sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-5806.

**SUPPLEMENTARY INFORMATION:** Title II, Homeland Security Act, 6 U.S.C. 121(d)(1) To access, receive, and analyze laws enforcement information, intelligence information and other information from agencies of the Federal Government, State and local government agencies . . . and Private sector entities and to integrate such information in support of the mission responsibilities of the Department. The following authorities also permit DHS to collect information of the type contemplated: Federal Information

Security Management Act of 2002 (FISMA), 44 U.S.C. 3546; Homeland Security Presidential Directive (HSPD) 7, "Critical Infrastructure Identification, Prioritization, and Protection" (2003); and NSPD-54/HSPD-23, "Cybersecurity Policy" (2009).

In May 2009, the President ordered a Cyberspace Policy Review to develop a comprehensive approach to secure and defend America's infrastructure. The review built upon the Comprehensive National Cybersecurity Initiative (CNCI).

In response to increased cyber threats across the Nation, the National Initiative for Cybersecurity Education (NICE) expanded from a previous effort, the CNCI #8. NICE formed in March 2011, and is a nationally coordinated effort comprised of over 20 federal departments and agencies, and numerous partners in academia and industry. NICE focuses on cybersecurity awareness, education, training and professional development. NICE seeks to encourage and build cybersecurity awareness and competency across the Nation and to develop an agile, highly skilled cybersecurity workforce.

The NICCS Portal is a national online resource for cybersecurity awareness, education, talent management, and professional development and training. NICCS Portal is an implementation tool for NICE. Its mission is to provide comprehensive cybersecurity resources to the public.

To promote cybersecurity education, and to provide a comprehensive resource for the Nation, NICE developed the Cybersecurity Training and Education Catalog. The Cybersecurity Training and Education Catalog will be hosted on the NICCS Portal. Training Course and certification information will be included in the Training/Workforce Development Catalog. Note: Any information received from the public in support of the NICCS Portal and Cybersecurity Training and Education Catalog is completely voluntary. Organizations and individuals who do not provide information can still utilize the NICCS Portal and Cybersecurity Training and Education Catalog without restriction or penalty. An organization or individual who wants their information removed from the NICCS Portal and/or Cybersecurity Training and Education Catalog can email the NICCS Supervisory Office. There are no requirements for a provider to fill out a specific form for their information to be removed; standard email requests will be honored. Department of Homeland Security (DHS) Cybersecurity Education & Awareness Office (CE&A) intends for the collected information from the