

process that leaves the identity of the article intact. See *United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and *National Juice Products Ass'n 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 ("HQ") 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002.

For example, in HQ H267177, CBP held that Indian- and Chinese-origin Acyclovir was not substantially transformed in the United States when it was combined with excipients and processed into tablets. In that case, the Indian or Chinese Acyclovir was the only active pharmaceutical ingredient in the final product. Accordingly, we found that the processing performed in the United States did not result in a change in the medicinal use of the finished product. Furthermore, the Acyclovir maintained its chemical and physical characteristics and did not undergo a change in name, character, or use. Consistent with our previous rulings, we held that processing the Acyclovir into dosage form and packaging it for sale in the United States did not constitute a substantial transformation. Accordingly, the country of origin of the final product for purposes of U.S. Government procurement was either China or India, where the active ingredient was produced.

Similarly, in HQ H233356, CBP held that the processing and packaging of imported mefenamic acid into dosage form in the United States did not constitute substantial transformation. Based on previous CBP rulings, we found that the specific U.S. processing—which involved 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. Accordingly, we held that the country of origin of the final product was India, where the mefenamic acid was produced.

In HQ 561975, we also held that the processing of imported bulk Japanese-origin anesthetic drugs into dosage form in the United States did not constitute substantial transformation. Although the bulk form of the drug underwent testing operations, filtering, and packaging in the United States, these processes did not change the chemical or physical properties of the drug. Furthermore, there was no change in the product's name, which was referred to as sevoflurane in both its bulk and processed form. Additionally, because the imported bulk drug had a predetermined medicinal use as an anesthetic drug, the processing in the

United States did not result in a change in the product's use. The country of origin of the finished product was therefore Japan.

Here, as in the cases cited above, the processing of bulk imported pharmaceuticals into dosage form will not result in a substantial transformation. In this case, the processing begins with Taiwanese-origin bulk pravastatin sodium and, after this product is combined with inactive ingredients in India, results in pravastatin sodium tablets in individual doses of 10, 20, 40, or 80 milligrams. Because the product is referred to as "pravastatin sodium" both before and after the Indian processing, no change in name occurs in India. Furthermore, no change in character occurs in India because the pravastatin sodium maintains the same chemical and physical properties both before and after the Indian processing. Finally, because the imported, bulk-form pravastatin sodium had a predetermined medicinal use as an antilipimic agent that is used to reduce the risk of myocardial infarction, no change in use occurs after processing in India. Under these circumstances, and consistent with previous CBP rulings, we find that the country of origin of the final product is Taiwan, where the active ingredient was produced.

#### HOLDING:

The country of origin of the pravastatin sodium tablets for purposes of U.S. Government procurement is Taiwan.

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,

Alice A. Kipel,  
Executive Director,  
Regulations & Rulings,  
Office of Trade.

[FR Doc. 2017-18205 Filed 8-25-17; 8:45 am]

**BILLING CODE 9111-14-P**

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## INTER-AMERICAN FOUNDATION

### Sunshine Act Meetings

**TIME AND DATE:** September 6, 2017, 11:00 a.m.–12:00 p.m.

**PLACE:** Via tele-conference hosted at Inter-American Foundation, 1331 Pennsylvania Ave. Suite 1200, NW., Washington, DC 20004.

**STATUS:** Meeting of the Board of Directors, Open to the public.

**MATTERS TO BE CONSIDERED:** Next steps for updating advisory council membership.

The role of the Board in funding decisions.

**FOR DIAL-IN INFORMATION CONTACT:** Karen Vargas, Executive Assistant, (202) 524-8869.

**CONTACT PERSON FOR MORE INFORMATION:** Paul Zimmerman, General Counsel, (202) 683-7118.

**Paul Zimmerman,**  
General Counsel.

[FR Doc. 2017-18263 Filed 8-24-17; 4:15 pm]

**BILLING CODE 7025-01-P**

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-R8-ES-2017-N084; FF08EVEN00-FXFR1337088SSO0]

### Marine Mammal Protection Act; Stock Assessment Report for the Southern Sea Otter in California

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; response to comments.

**SUMMARY:** In accordance with the Marine Mammal Protection Act of 1972, as amended (MMPA), and its implementing regulations, we, the U.S. Fish and Wildlife Service (Service), announce that we have revised our stock assessment report (SAR) for the southern sea otter stock in the State of California, including incorporation of public comments. We now make our final revised SAR available to the public.

**ADDRESSES:** *Document Availability:* You may obtain a copy of the SAR from our Web site at <https://www.fws.gov/ventura/endangered/species/info/ssa.html>. Alternatively, you may contact the Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003; telephone: 805-644-1766.

**FOR FURTHER INFORMATION CONTACT:** For information on the methods, data, and results of the stock assessment, contact Lilian Carswell by telephone (805-677-3325) or by email ([Lilian\\_Carswell@fws.gov](mailto:Lilian_Carswell@fws.gov)). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800-877-8339.

**SUPPLEMENTARY INFORMATION:** We are announcing the availability of the final revised SAR for the southern sea otter (*Enhydra lutris nereis*) stock in the State of California.

### Background

Under the MMPA (16 U.S.C. 1361 *et seq.*) and its implementing regulations