

Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Mental Health and Substance Use, SAMHSA; and SAMHSA's Center Directors concerning matters relating to the activities carried out by and through the Centers and the policies respecting such activities.

Under Section 501 of the Public Health Service Act, the ACWS is statutorily mandated to advise the SAMHSA Assistant Secretary for Mental Health and Substance Use and the Associate Administrator for Women's Services on appropriate activities to be undertaken by SAMHSA and its Centers with respect to women's substance abuse and mental health services.

Pursuant to Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of September 23, 2004, SAMHSA established the TTAC for working with Federally-recognized Tribes to enhance the government-to-government relationship, and honor Federal trust responsibilities and obligations to Tribes and American Indian and Alaska Natives. The SAMHSA TTAC serves as an advisory body to SAMHSA.

The meeting will include remarks from the Assistant Secretary for Mental Health and Substance Use; SAMHSA's priorities and updates by the Centers and Office Directors; a presentation on the Report to Congress on the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC); a presentation on SAMHSA's role in recent behavioral health responses to disasters; and a council discussion.

The meeting is open to the public and will be held at the Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857. Attendance by the public will be limited to space available. Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person by February 8, 2018. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations are encouraged to notify the contact by February 8, 2018. Five minutes will be allotted for each presentation.

The meeting may be accessed via telephone and web conferencing will be available. To attend on site: Obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: <http://nac.samhsa.gov/Registration/>

*meetingsRegistration.aspx*, or communicate with SAMHSA's Committee Management Officer, CDR Carlos Castillo (see contact information below).

Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council's website at <http://www.samhsa.gov/about-us/advisory-councils/> or by contacting CDR Castillo. Substantive program information may be obtained after the meeting by accessing the SAMHSA Council's website, <http://nac.samhsa.gov/>, or by contacting CDR Castillo.

#### *Council Names:*

Substance Abuse and Mental Health Services Administration National Advisory Council  
Center for Mental Health Services National Advisory Council  
Center for Substance Abuse Prevention National Advisory Council  
Center for Substance Abuse Treatment National Advisory Council  
Advisory Committee for Women's Services Tribal Technical Advisory Committee

*Date/Time/Type:* February 15, 2018, 9:00 a.m. to 4:25 p.m. EDT, Open.

*Place:* Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

*Contact:* CDR Carlos Castillo, Committee Management Officer and Designated Federal Official, SAMHSA National Advisory Council, Room 18E77A, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276-2787, Email: [carlos.castillo@samhsa.hhs.gov](mailto:carlos.castillo@samhsa.hhs.gov).

**Carlos Castillo,**

*Committee Management Officer, SAMHSA.*

[FR Doc. 2018-02172 Filed 2-2-18; 8:45 am]

**BILLING CODE 4162-20-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Substance Abuse and Mental Health Services Administration**

#### **Notice of Meeting**

Pursuant to Public Law 92-463, notice is hereby given of the meeting on February 16, 2018, of the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Advisory Council (SAMHSA NAC).

The SAMHSA NAC was established to advise the Secretary, Department of Health and Human Services (HHS), and the Assistant Secretary for Mental Health and Substance Use, SAMHSA, to

improve the provision of treatments and related services to individuals with respect to substance use and to improve prevention services, promote mental health, and protect legal rights of individuals with mental illness and individuals who are substance users.

The meeting will include remarks from the Assistant Secretary for Mental Health and Substance Use; updates from the Department of Health and Human Services' Operating Divisions; updates from the ex-officio members, and a council discussion.

The meeting is open to the public and will be held at the Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857. Attendance by the public will be limited to space available. Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person by February 8, 2018. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact person by February 8, 2017. Five minutes will be allotted for each presentation.

The meeting may be accessed via telephone. To attend on site: obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: <http://nac.samhsa.gov/Registration/meetingsRegistration.aspx>, or communicate with SAMHSA's Committee Management Officer, CDR Carlos Castillo (see contact information below).

Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council's website at <http://www.samhsa.gov/about-us/advisory-councils/> or by contacting CDR Castillo. Substantive program information may be obtained after the meeting by accessing the SAMHSA Council's website, <http://nac.samhsa.gov/>, or by contacting CDR Castillo.

*Council Name:* Substance Abuse and Mental Health Services Administration National Advisory Council.

*Date/Time/Type:* February 16, 2018, 9:00 a.m. to 3:45 p.m. EDT, Open.

*Place:* Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

*Contact:* CDR Carlos Castillo, Committee Management Officer and Designated Federal Official, SAMHSA National Advisory Council, Room

18E77A, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276-2787, Email: [carlos.castillo@samhsa.hhs.gov](mailto:carlos.castillo@samhsa.hhs.gov).

**Carlos Castillo,**

*Committee Management Officer, SAMHSA.*

[FR Doc. 2018-02173 Filed 2-2-18; 8:45 am]

**BILLING CODE 4162-20-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Notice of Issuance of Final Determinations Concerning Certain Pharmaceutical Products

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

**ACTION:** Notice of final determinations.

**SUMMARY:** This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued 11 final determinations concerning the country of origin of certain pharmaceutical products. Based upon the facts presented, CBP has concluded that the country of origin of the Rosuvastatin Calcium Tablets, Levofloxacin Tablets, Levetiracetam Tablets, Metoprolol Tartrate Tablets, Gabapentin Capsules, Carvedilol Tablets, Paroxetine Hydrochloride Tablets, Entecavir Tablets, Montelukast Sodium Tablets, Simvastatin Tablets, Donepezil Hydrochloride Tablets is India for purposes of U.S. Government procurement.

**DATES:** These final determinations were issued on January 30, 2018. Copies of the final determinations are attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of these final determinations within March 7, 2018.

**FOR FURTHER INFORMATION CONTACT:** Elif Eroglu, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, (202) 325-0277.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on January 30, 2018 CBP issued 11 final determinations concerning the country of origin of certain pharmaceutical products, which may be offered to the U.S. Government under an undesignated government procurement contract pursuant to subpart B of part 177, CBP Regulations (19 CFR part 177, subpart B). These final

determinations (H289700, H289701, H289702, H289704, H289706, H289710, H289711, H289712, H289713, H289714, and H289715), were 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 determinations, CBP concluded that the processing in the United States does not result in a substantial transformation. Therefore, the country of origin for purposes of U.S. Government procurement of the pharmaceutical products is India, the country where the active pharmaceutical ingredient was produced.

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: January 30, 2018.

**Alice A. Kipel,**

*Executive Director, Regulations and Rulings, Office of Trade.*

**HQ H289700**

**January 30, 2018**

**OT:RR:CTF:** VS H289700 EE

**CATEGORY:** Origin

Stephen E. Ruscus  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Rosuvastatin Calcium tablets  
Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017, requesting a final determination on behalf of Acetris Health, (“Acetris”) <sup>1</sup>, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. 177.21 *et seq.*). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Rosuvastatin Calcium

<sup>1</sup> Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

tablets. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

#### FACTS:

The merchandise at issue are Rosuvastatin Calcium tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Rosuvastatin Calcium tablets, members of a family of statin drugs prescribed for the reduction of cholesterol and triglyceride levels and prevention of heart attacks and strokes.

You state that Acetris procures the Rosuvastatin Calcium tablets from Aurolife Pharma LLC (“Aurolife”), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Rosuvastatin Calcium tablets supplied to Acetris in a U.S. Food & Drug Administration (“FDA”) approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient (“API”) of the Rosuvastatin Calcium tablets is Rosuvastatin Calcium, which Aurolife sources from company X in India.

You state that the Rosuvastatin Calcium tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with several inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Rosuvastatin employs processes that convert these ingredients into finished, medically effective dosage tablets (5 mg, 10 mg, 20 mg, and 40 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Rosuvastatin Calcium tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows: