*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Sudha Veeraraghavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1504, *sudha.veeraraghavan@nih.gov*.

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Biophysics of Neural Systems Study Section.

*Date:* October 14–15, 2021.

*Time:* 10:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Geoffrey G. Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040–A, MSC 7850, Bethesda, MD 20892, 301–435–1235, *geoffreys@csr.nih.gov*.

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Human Studies of Diabetes and Obesity Study Section.

*Date:* October 14–15, 2021.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Hui Chen, MD, Scientific Review Officer, Center for Scientific Review National, Institutes of Health, 6701 Rockledge Drive, Room 6164, Bethesda, MD 20892, 301–435–1044, *chenhui@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 3, 2021.

**Tyeshia M. Roberson-Curtis,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2021–19534 Filed 9–9–21; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Prospective Grant of Exclusive Patent License: Chimeric Live-Attenuated Vaccine for West Nile Virus (WNV)

**AGENCY:** National Institutes of Health, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Commercialization Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Summary Information section of this notice to Blue Water Vaccines, Inc. (BWV), having a place of business in Cincinnati, Ohio, U.S.A.

**DATES:** Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office on or before September 27, 2021 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Commercialization Patent License should be directed to: Peter Soukas, Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, National Institutes of Health; Email: *ps193c@nih.gov;* Telephone: (301) 496–2644; Facsimile: (240) 627–3117.

**SUPPLEMENTARY INFORMATION:**

#### Intellectual Property

U.S. Provisional Patent Application Number 60/347,281, filed January 10, 2002, PCT Patent Application Number PCT/US2003/00594, filed January 9, 2003, U.S. Patent Application Number 10/871,775 filed June 18, 2004 (now U.S. Patent Number 8,778,671), U.S. Patent Application Number 14/305,572, filed June 16, 2014 (now U.S. Patent Number 10,058,602), U.S. Patent Application Number 16/025,624, filed July 2, 2018 (now U.S. Patent Number 10,456,461), U.S. Patent Application Number 16/596,175, filed October 8, 2019 (now U.S. Patent Number 10,869,920), U.S. Patent Application Number 16/952,864, filed November 19, 2020, Israeli Patent Application Number 162949, filed January 9, 2003 (now Israeli Patent Number 162949), Israeli Patent Application Number 209342, filed January 9, 2003 (now Israeli Patent Number 209342), Canadian Patent Application Number 2472468, filed January 9, 2003 (now Canadian Patent Number 2472468), Canadian Patent Application Number 2903126, filed August 27, 2015 (now Canadian Patent Number 2903126), Australian Patent Application Number 2003216046, filed January 9, 2003 (now Australian Patent Number 2003216046), Australian Patent Application Number 2008203442 filed July 31, 2008 (now Australian Patent Number 2008203442), Australian Patent Application Number 2011250694, filed November 10, 2011 (now Australian Patent Number 2011250694), Australian Patent Application Number 2017203108, filed May 10, 2017 (now Australian Patent Number 2017203018), Australian Patent Application Number 2019203166, filed May 6, 2019 (now Australian Patent Number 2019203166), Australian Patent Application Number 2021203089, filed May 17, 2021, Japanese Patent Application Number 2003–559545, filed January 9, 2003 (now Japanese Patent Number 4580650), European Patent Application Number 11000126.0, filed January 9, 2003 (now European Patent Number 2339011, validated in Belgium, Great Britain, the Netherlands, Norway, Germany, Denmark and France), entitled ''Construction of West Nile Virus and Dengue Virus Chimeras for use in a Live Virus Vaccine to Prevent Disease Cause by West Nile Virus,'' [HHS Reference No. E–357–2001–0,1]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive licensed territory may be worldwide, and the field of use may be limited to: ''Chimeric Live-Attenuated Vaccines for West Nile Virus (WNV) for use in animals or humans.''

West Nile virus (WNV) is a positive-strand RNA virus of the family Flaviviridae, part of the Japanese encephalitis virus serocomplex that includes important human pathogens such as Murray Valley encephalitis, Japanese encephalitis, and St. Louis encephalitis viruses. WNV has been present in Africa and Asia for decades and has usually been associated with mild illness that includes symptoms of low-grade fever, headache, rash, myalgia, and arthralgia. Recently, WNV has spread rapidly across the Western hemisphere and is now the major vector-borne cause of viral encephalitis in the United States. By 2010, 3 million adults were estimated to have been infected with WNV in the United States, with nearly 13,000 cases of neuroinvasive disease, almost half of which occurred in adults greater than 60 years of age. In this age group, WNV infection can cause hepatitis, meningitis, and encephalitis, leading to paralysis, coma, and death. In 2012, 286 people in the United States died of WNV, according to the U.S. Centers for Disease Control and Prevention (CDC). Preliminary data for 2013 indicate over 1,200 cases of neuroinvasive disease

and 114 deaths due to WNV. During 2009–2018, a total of 21,869 confirmed or probable cases of WNV disease, including 12,835 (59%) WNV neuroinvasive disease cases, were reported to CDC from all 50 states, the District of Columbia, and Puerto Rico.

WNV presents a significant public health threat. This epidemiological trend of WNV suggests that the United States can expect periodic WNV outbreaks, underscoring the need for a safe and effective vaccine to protect at-risk populations, especially older adults.

WNV is also a significant worldwide public health threat. Starting in the mid-1990s, the frequency, severity, and geographic range of WNV outbreaks increased. The virus can be found throughout Africa, regions of Europe and the Middle East, West Asia, Australia, Canada, Venezuela, and the United States. Outbreak areas are typically found along major bird migratory routes, with the largest outbreaks having occurred in Greece, Israel, Russia, Romania, and the United States. In the approximately eighty (80) years since its discovery, the virus has propagated to a vast region of the globe and is now considered the most important causative agent of viral encephalitis worldwide.

No vaccine exists today to prevent WNV in humans. The methods and compositions of this invention provide a means for prevention of WNV infection by immunization with live attenuated, immunogenic viral vaccines against WNV.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information, and any release of information in these license applications will be made only as required and upon a request under the *Freedom of Information Act,* 5 U.S.C. 552.

Dated: September 7, 2021.

**Surekha Vathyam,**

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

[FR Doc. 2021–19566 Filed 9–9–21; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

### Notice of Issuance of Final Determination Concerning Certain Calcitriol Soft-Shell Capsules

**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 Calcitriol soft-shell capsules. Based upon the facts presented, CBP has concluded in the final determination that the Calcitriol capsules would be products of a foreign country or instrumentality designated pursuant to CBP regulations for purposes of U.S. Government procurement.

**DATES:** The final determination was issued on August 27, 2021. 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 no later than October 12, 2021.

**FOR FURTHER INFORMATION CONTACT:** Albena Peters, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325–0321.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on August 27, 2021, CBP issued a final determination concerning the country of origin of Calcitriol capsules for purposes of Title III of the Trade Agreements Act of 1979. This final determination, HQ H319605, was issued at the request of the party-at-interest, 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 has concluded that, based upon the facts presented, the Calcitriol soft-shell capsules would be products of a foreign country or instrumentality designated pursuant to 19 U.S.C. 2511(b) 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: September 3, 2021.

**Alice A. Kipel,**

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

**HQ H319605**

**August 27, 2021**

**OT:RR:CTF:VS H319605 AP**

**CATEGORY: Origin**

Steven Lerner, Supply Chain Analyst, Sun Pharmaceutical Industries Ltd., 2 Independence Way, Princeton, NJ 08540

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. 2511); Subpart B, Part 177, CBP Regulations; Country of Origin of Calcitriol Capsules

Dear Mr. Lerner:

This is in response to your July 13, 2021 request, on behalf of Sun Pharmaceutical Industries Ltd. (''Sun Pharma''), for a final determination concerning the country of origin of Calcitriol soft-shell capsules. This request is being sought because the company wants to confirm eligibility of the merchandise for U.S. government procurement purposes under Title III of the Trade Agreements Act of 1979 (''TAA''), as amended (19 U.S.C. 2511 *et seq*.). Sun Pharma is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and 177.23(a).

**FACTS:**

Sun Pharma is among the largest specialty generic pharmaceutical companies in the world with more than 40 manufacturing facilities.[1] The company manufactures and imports Calcitriol [2] in the form of soft-shell capsules (0.25 mcg and 0.5 mcg). The

[1] *See* Sun Pharma, About Us, *https://sunpharma.com/about-us/* (last visited Aug. 2, 2021).

[2] The Calcitriol's National Drug Code Directory numbers are: 62756–967–83, 62756–967–88 and 62756–968–88.