



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0892]

Prospective Grant of an Exclusive Patent License: Development, Production, and Commercialization of a Seasonal Influenza Vaccine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Sciogen Inc. located in San Jose, California.

DATES: Only written comments and/or complete applications for a license which are received by the FDA Technology Transfer Program within 15 days from the date of publication of this notice in the *Federal Register* will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, including inquiries concerning license applications, and comments and objections relating to the contemplated Exclusive Patent License should be directed to William Ronnenberg, Lead Patent Advisor, Technology Transfer Program, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; FDAINventionLicensing@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT: William Ronnenberg, Lead Patent Advisor, Technology Transfer Program, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; 240-402-4561, FDAINventionLicensing@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Patent No. 9,163,068 issued October 20, 2015, entitled, “Influenza Virus Recombinant Proteins” (FDA Ref. No. E-2010-004/US-03).

2. U.S. Patent No. 9,896,484 issued February 20, 2018, entitled, “Influenza Virus Recombinant Proteins” (FDA Ref. No. E-2010-004/US-04).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States.

The prospective exclusive license territory may be limited to the United States for certain of the rights, or worldwide, and the field of use may be limited to the following:

“The development, production, and commercialization of seasonal influenza vaccines.”

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 15 days from the date of this published notice, the Technology Transfer Program at FDA 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.

In response to this notice, the public may file comments or objections (See, ADDRESSES). Comments and objections, other than those in the form of a completed 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: April 21, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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4/27/2020]