

describing the nature of the request, and providing at least a 30-day public comment period. In accordance with § 488.1010(d), we have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of Community Health Accreditation Partner (CHAP) initial request for CMS's approval of its HIT accreditation program. This notice also solicits public comment on whether CHAP's requirements meet or exceed the Medicare conditions of participation for HIT services.

III. Evaluation of Deeming Authority Request

CHAP submitted all the necessary materials to enable us to make a determination concerning its request for initial approval of its HIT accreditation program. This application was determined to be complete on February 27, 2020. Under section 1834(u)(5) of the Act and § 488.1010 (Application and re-application procedures for national HIT AOs), our review and evaluation of CHAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of CHAP's standards for HIT as compared with CMS' HIT conditions for certification.
- CHAP's survey process to determine the following:
 - ++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.
 - ++ The comparability of CHAP's to CMS standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
 - ++ CHAP's processes and procedures for monitoring a HIT supplier found out of compliance with CHAP's program requirements.
 - ++ CHAP's capacity to report deficiencies to the surveyed supplier and respond to the suppliers' plan of correction in a timely manner.
 - ++ CHAP's capacity to provide CMS with electronic data and reports necessary for effective assessment and interpretation of the organization's survey process.
 - ++ The adequacy of CHAP's staff and other resources, and its financial viability.
 - ++ CHAP's capacity to adequately fund required surveys.
 - ++ CHAP's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ CHAP's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

- CHAP's agreement or policies for voluntary and involuntary termination of suppliers.
- CHAP agreement or policies for voluntary and involuntary termination of the HIT AO program.
- CHAP's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

IV. Collection of Information Requirements

This document does not impose information collection and requirements; that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 14, 2020.

Evell J. Barco Holland,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020-08796 Filed 4-24-20; 8:45 am]

BILLING CODE 4120-01-P

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.

[FR Doc. 2020-08879 Filed 4-24-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4824]

Office of Minority Health and Health Equity Strategic Priorities; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice, published in the **Federal Register** of January 3, 2020. In the notice, FDA opened a public docket to solicit input and comments from interested stakeholders, including racial and ethnic minority, underrepresented, and underserved populations on the Office of Minority Health and Health Equity Strategic Priorities (OMHHE).

FDA is reopening the comment period to update comments and to receive any new information.

DATES: FDA is reopening the comment period on the notice published January 3, 2020 (85 FR 316). Submit either electronic or written comments by June 26, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 26, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 26, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for

information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2019-N-4824 for “Office of Minority Health and Health Equity Strategic Priorities.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine Merenda, Food and Drug Administration, Office of Minority Health and Health Equity, 10903 New Hampshire Ave., Bldg. 32, Rm. 2382,