documenting electronic data files and statistical analyses submitted to CVM to support new animal drug applications. These recommendations are intended to reduce the number of revisions that may be required for CVM to effectively review data submissions. They are also intended to simplify submission preparation for sponsors by providing a suggested documentation framework, including a sample structure on how to describe and organize the information regarding the electronic data files and statistical analysis programs.

This Level I guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Documenting Electronic Data Files and Statistical Analysis Programs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved collections of information. These collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: November 9, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25131 Filed 11–12–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1992]

Prospective Grant of an Exclusive Patent License: Field-Deployable Mass Spectrometer Diagnostic for SARS, SARS–CoV–2 and Other Viruses, Bacteria and Bacterial Serovar, and Drug Impurities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is contemplating the grant of an Exclusive Patent License to practice the invention embodied in the U.S. Patent listed in the Supplementary Information section of this notice to Advion, Inc. located in Ithaca, New York.

DATES: Only written comments and/or applications for a license which are received by the Food and Drug Administration's Technology Transfer Program on or before November 30, 2020 will be considered.

ADDRESSES: Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Ken Millburne, Food and Drug Administration Technology Transfer Program, Bldg. 1, Rm. 4213, Silver Spring, MD 20993, 240–478–1662; email: *Kenneth.millburne@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

FDA Reference No.: E–2011–021: ''Direct Impact Ionization (DII) Mass Spectrometry.''

I. U.S. Non-Provisional Application 13/271,182, filed October 11, 2011 (FDA Reference No.: E–2011–021/US–02).

II. U.S. Patent granted April 22, 2014: U.S. Patent 8,704,169 B2 (FDA Reference No. E–2011–021/U.S.–02)

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

The prospective exclusive license territory may be worldwide and in fields of use that may be limited to manufacture and commercialization of a field-deployable mass spectrometer diagnostic for the rapid detection of SARS, SARS–CoV–2 and other viruses, bacteria and bacterial serovar, and drug impurities.

Above listed patent covers inventions directed to a mass spectrometer for analyzing samples suspected of having microorganisms. It is also directed to methods for generating a mass spectrum profile of a sample.

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. The prospective exclusive license may be granted unless within 15 days from the date of this published notice, 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. 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: November 9, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25142 Filed 11–12–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Special Volunteer and Guest Researcher Assignment (Office of Intramural Research, Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, to provide opportunity for public comment on proposed data collection projects, the Office of Intramural Research (OIR), Office of the Director (OD), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection

plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Arlyn Garcia-Perez, Director of Policy and Analysis, Office of Intramural Research, Office of the Director, National Institutes of Health, 1 Center Drive MSC 0140, Building 1, Room 160, MSC–0140, Bethesda, Maryland, 20892 or call non-toll-free number (301) 496–1921 or (301) 496–1381 or Email your request, including your address to: *GarciaA@od.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Special Volunteer and Guest Researcher Assignment form—EXTENSION OMB # 0925–0177, exp., date February 28, 2021, Office of Intramural Research (OIR), Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Form Number: NIH–590 is a single form completed by an NIH official for each Guest Researcher or Special Volunteer prior to his/her arrival at NIH. The information on the form is necessary for the approving official to reach a decision on whether to allow a Guest Researcher to use NIH facilities, or whether to accept volunteer services offered by a Special Volunteer. If the original assignment is extended, another form notating the extension is completed to update the file. In addition, each Special Volunteer and Guest Researcher reads and signs an NIH Agreement.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 422.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual hour burden hours
Special Volunteer and Guest Researcher Assignment.	Special Volunteers and Guest researchers.	2,300	1	6/60	230
NIH Special Volunteer Agreement	Special Volunteers	2,100	1	5/60	175
NIH Guest Researcher Agreement ...	Guest Researchers	200	1	5/60	17
Totals	.....	2,300	4,600	.....	422

Dated: November 4, 2020.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2020–25091 Filed 11–12–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Dianca Finch, Ph.D., 240–669–5503; *dianca.finch@nih.gov.* Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows:

Identification of a New Human Monoclonal Antibody That More Potently Prevents Malaria Infection

Description of Technology:

Malaria is a major disease caused by a parasite transmitted through the bite of infected female mosquitoes. Globally, an estimated 214 million cases of malaria and 438,000 deaths from malaria occur annually, with chidren in African and South Asian regions being most vulnerable. Approximately 1,500–2,000 cases of malaria are reported in the United States each year, mostly in returning travelers from malaria-endemic countries. Among the international travelers, military personnel, diplomats, pregnant women, children and older individuals with weakened immune systems are more likely to be at risk of malaria infection and mortality.

Currently, there is no licensed vaccine against *Plasmodium falciparum,* the deadliest species of malaria parasites. Antibodies can prevent malaria infection by binding to sporozoites, the infectious form of *P. falciparum* that is transmitted to humans by the bites of infected mosquitoes. The major target of anti-sporozoite antibodies is the *P. falciparum* circumsporozoite protein (PfCSP), an abundant surface protein on sporozoites that is essential for infecting liver cells, which is the critical step for initiating a productive infection. PfCSP is comprised of an N-terminal domain, a central region and the C-terminal region.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID)