TABLE 3—CDRH GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID–19) Public Health Emergency (Revised); Guidance for Industry and Food and Drug Administration Staff.	800, 801, and 809		0910–0485
	803		0910–0437
	806		0910–0359
	807, subpart E		0910–0120
	807, subparts A through D		0910–0625
	820		0910–0073
	830 and 801.20		0910–0720
		Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	0910–0595

IV. Withdrawn COVID–19-Related Guidance Documents

On June 30, 2021, FDA announced the revocation of the Emergency Use Authorizations (EUAs) for Decontamination and Bioburden Reduction Systems for Personal Protective Equipment. The full text of the revocations are available electronically at *https://www.regulations.gov* (Docket No. FDA–2021–N–0762) and *https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations.* With the revocation of these EUAs, on June 30, 2021, FDA also withdrew two related decontamination and bioburden reduction guidance documents (listed in table 4), as the documents no longer represent the Agency's current thinking.

TABLE 4—WITHDRAWN GUIDANCES RELATED TO THE COVID–19 PUBLIC HEALTH EMERGENCY

Docket No.	Center	Title of withdrawn guidance	Withdrawal date
FDA–2020–D–1138	CDRH	Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency; Guidance for Industry and Food and Drug Administration Staff.	June 30, 2021.
FDA–2020–D–1138	CDRH	Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators During the Coronavirus Disease (2019) Public Health Emergency.	June 30, 2021.

These withdrawn guidance documents are presented on FDA's website, for historical purposes only, at *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/withdrawn-guidance.*

V. Electronic Access

Persons with access to the internet may obtain COVID–19-related guidances at:

- FDA web page entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders;*
- FDA web page entitled ''Search for FDA Guidance Documents'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents;* or
- *https://www.regulations.gov.*

Dated: September 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21798 Filed 10–5–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1400]

Use of Real-World Data and Real-World Evidence To Support Effectiveness of New Animal Drugs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry (GFI) #266 entitled ''Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs.'' The guidance describes FDA's current thinking with respect to assisting sponsors in incorporating real-world data and real-world evidence (including ongoing surveillance activities, observational studies, and registry data) into proposed clinical investigation protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on October 6, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2020–D–1400 for ''Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs.'' Received comments 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, 240–402–7500.

- 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Storey, Center for Veterinary Medicine (HFV–131), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0578, *susan.storey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, the Agency has taken steps to leverage modern, rigorous analyses of real-world data to inform our work. The COVID–19 pandemic has brought an urgency to these efforts and the Agency has worked quickly to advance collaborations with public and private partners to collect and analyze a variety of real-world data sources. We recognize that real-world data sources have the potential to provide a wealth of rapid, actionable information to support and advance regulatory decision making for both human and animal drugs.

In the **Federal Register** of July 15, 2020 (85 FR 42880), FDA published the notice of availability for a draft guidance entitled ''Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs,'' giving interested persons until October 13, 2020, to comment on the draft guidance. This guidance describes how the Center for Veterinary Medicine (CVM) intends to evaluate real-world data (RWD) and real-world evidence (RWE) in submissions to CVM to demonstrate substantial evidence of effectiveness for new animal drug applications or a reasonable expectation of effectiveness for applications for conditional approval of a new animal drug. It also provides information about how sponsors may obtain feedback from CVM on technical issues related to the use of RWD and RWE before the submission of an application.

FDA received comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to this final guidance to improve clarity. For example, we added language to provide context to the use of RWD and RWE from retrospective studies in addition to RWD and RWE from prospective studies. We also revised the language of the guidance to clarify that the term ''animals'' can refer to an individual animal or a flock, tank, or group depending on the context in which RWD and RWE is collected. The guidance announced in this notice finalizes the draft guidance dated July 2020.

This level 1 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 ''Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections 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 for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in FDA's guidance entitled ''Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs''

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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 29, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21687 Filed 10–5–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Personalized Tumor Vaccine and Use Thereof for Cancer Immunotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the (U.S.) Patents and Patent Applications listed in the Supplementary Information section of this notice to NE1 Inc, located at 515 Madison Avenue, 8th Fl. Suite 8096, New York, NY 10022.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before October 21, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Dr. Berna Uygur, Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276–5530; Email: *berna.uygur@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

(United States Provisional) Patent Application No. 62/946,934, filed on December 11, 2019 and entitled ''Personalized Tumor Vaccine and Use Thereof for Cancer Immunotherapy'' [HHS Reference No. E–003–2020/0–US–01]. (PCT) Patent Application No. PCT/US2020/064412, filed on December 11, 2020 and entitled ''Personalized Tumor Vaccine and Use Thereof for Cancer Immunotherapy'' [HHS Reference No. E–003–2020/0–PCT–02].

The patent rights in this invention are co-owned by (a) the United States of America, as represented by the Secretary, Department of Health and Human Services, (b) University of South Bohemia, and (c) NE1 Inc. The prospective exclusive license territory may be worldwide, and the field of use may be limited to: Development, manufacture, and commercialization of the MBTA Therapy Products, as claimed in the Licensed Patent Rights, for the treatment of cancer in humans.

This technology discloses ''MBTA Therapy Product(s)'' which are vaccine products comprising irradiated tumor cells pulsed with phagocytic agonists (Mannan-BAM, a polysaccharide derivative of mannan), TLR (Toll-like receptor) ligands, and Anti-CD40-monoclonal antibody. The MBTA Therapy Products may be used as personalized tumor vaccines to treat cancer.

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 Cancer Institute 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: October 1, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021–21845 Filed 10–5–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Mechanism for Time-Sensitive Research Opportunities in Environmental Health Sciences.

Date: October 12, 2021.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27713 (Virtual Meeting).

Contact Person: Quentin Li, M.D., Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MSC K3–05, Research Triangle Park, NC 27709, 240–858–3914, *quentin.li@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: September 30, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21793 Filed 10–5–21; 8:45 am]

BILLING CODE 4140–01–P