determining this patent's eligibility for patent term restoration. In a letter dated July 14, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of VERCISE DBS SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for VERCISE DBS SYSTEM is 393 days. Of this time, 0 days occurred during the testing phase of the regulatory review period, while 393 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* Not Applicable. The applicant claims no investigational device exemption for the regulatory review period.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* December 22, 2017. FDA has verified the applicant's claim that the premarket approval application (PMA) for VERCISE DBS SYSTEM (PMA P150031 Supplement 002 (S002)) was initially submitted December 22, 2017.

3. *The date the application was approved:* January 18, 2019. FDA has verified the applicant's claim that PMA P150031 S002 was approved on January 18, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 392 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16610 Filed 8–3–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1434]

Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry; Availability

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

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Waivers, Exceptions, and Exemptions from the Requirements of section 582 of the Federal Food, Drug, and Cosmetic Act.'' This guidance describes the process an authorized trading partner or other stakeholder should use to request a waiver, exception, or exemption from the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as well as the factors FDA intends to consider when evaluating such requests from an authorized trading partner or other stakeholder, and when determining FDA-initiated exceptions and exemptions. Additionally, this guidance describes the process the FDA intends to follow once every 2 years to review and make determinations on the appropriateness of renewing a previously approved waiver, exception, or exemption, where applicable. This guidance finalizes the draft guidance of the same title issued on May 9, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on August 4, 2023.

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–2018–D–1434 for ''Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry.'' 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. 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: Lysette Deshields, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov;* or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Waivers, Exceptions, and Exemptions from the Requirements of section 582 of the Federal Food, Drug, and Cosmetic Act.'' The Food Drug and Cosmetic Act, as amended by the Drug Supply Chain Security Act (DSCSA), outlines critical steps to enhance drug distribution security. These steps will ultimately allow tracing of certain human finished prescription drugs in an electronic, interoperable manner as they are distributed within the United States. Section 582 of the FD&C Act (21 U.S.C. 360eee–1), as amended by the DSCSA, applies to manufacturers, repackagers, wholesale distributors, and dispensers (collectively referred to as ''trading partners'') who engage in transactions of product, and outlines requirements related to product tracing, verification, product identification, and authorized trading partners.

Section 582(a)(3)(A) of the FD&C Act requires FDA to issue a guidance that: (1) establishes a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in section 582 of the FD&C Act, which the Secretary of HHS (Secretary) may grant if the Secretary determines that such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act; (2) establishes a process by which the Secretary determines exceptions, and a process through which a manufacturer or repackager may request such an exception, to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with section 582 of the FD&C Act; and (3) establishes a process by which the Secretary may determine other products or transactions that shall be exempt from the requirements of section 582 of the FD&C Act.

Additionally, section 582(a)(3)(B) of the FD&C Act requires the FDA to issue guidance that includes a process describing how the FDA intends to review and renew granted waivers, exceptions, and exemptions.

This guidance finalizes the draft guidance entitled ''Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act'' issued on May 9, 2018 (83 FR 21297). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft guidance to the final guidance include: (1) recommending that a requestor submit a request for a waiver, exception, or exemption to FDA electronically; (2) recommending additional information a requestor should provide to FDA in a request for waiver, exception, or exemption; (3) recommending that recipients of a waiver, exception, or exemption notify the Agency of any material change in circumstances that formed the basis for granting the initial request for regulatory relief as soon as possible; (4) recommending that recipients of a waiver, exception, or exemption notify affected entities that a product and/or transaction is subject to a waiver, exception, or exemption; (5) describing how an authorized trading partner and other stakeholder may submit a request to FDA to reconsider the scope of a waiver, exception, or exemption that has been granted; (6) describing how an authorized trading partner and other stakeholder may submit a request to FDA to reconsider and re-evaluate a denied waiver, exception, or exemption request; and (7) recommending that recipients of a waiver, exception, or exemption notify affected entities upon termination of a waiver, exception, or exemption. In addition, editorial changes were made to improve clarity.

This 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 ''Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic.'' 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 ''Waivers, Exceptions, and Exemptions from the Requirements of section 582 of the Federal Food, Drug, and Cosmetic Act'' have been approved under OMB control number 0910–0806.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16645 Filed 8–3–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Novel and Exceptional Technology and Research Advisory Committee.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*https://videocast.nih.gov/*).

Name of Committee: Novel and Exceptional Technology and Research Advisory Committee.

Date: August 29, 2023.

Time: 2:00 p.m. to 4:30 p.m.

Agenda: The Novel and Exceptional Technology and Research Advisory Committee meeting will include presentation, discussion, and possible finalization of the Draft Report of the Working Group on Data Science and Emerging Technology and will include discussion of next steps for the Committee.

Place: National Institutes of Health, 6705 Rockledge Drive, Suite 630, Bethesda, MD 20892 (Virtual Meeting Link will be available at *https://osp.od.nih.gov/policies/novel-and-exceptional-technology-and-research-advisory-committee-nextrac#tab4/*).

Contact Person: Jessica Tucker, Ph.D., Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 630, Bethesda, MD 20892, 301–496–9838, *SciencePolicy@od.nih.gov.*

Members of the public may request to make an oral public comment or may submit written public comments. To sign up to make an oral public comment, please submit your name, affiliation, and short description of the oral comment to the Contact Person listed on this notice at least two business days prior to the meeting date. Once all time slots are filled, only written comments will be accepted. Any interested person may file written comments by forwarding the statement to the Contact Person listed on this notice at least two business days prior to the meeting date. The statement should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person. Other than name and contact information, please do not include any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your comments. Please note that any comments NIH receives may be posted unredacted to the Office of Science Policy website.

Information is also available on the NIH Office of Science Policy website: *https://osp.od.nih.gov/policies/novel-and-exceptional-technology-and-research-advisory-committee-nextrac#tab4,* where an agenda, link to the webcast meeting, and any additional information for the meeting will be posted when available. Materials for this meeting will be posted prior to the meeting. Please check this website for updates.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: August 1, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16685 Filed 8–3–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Tribal Listening Session and Tribal Consultation; Notice of Meeting Change

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA).

ACTION: Notice of change to tribal consultation.

SUMMARY: Notice is given that the August 29, 2023, virtual meeting SAMHSA Tribal Consultation that was published in the **Federal Register** on July 11, 2023, (Document Number 2023–14638; pages 44134–4135), will now be a Tribal Listening Session. SAMHSA will host American Indian and Alaska Native (AI/AN) Federally Recognized Tribes for a virtual Tribal listening session on the BEHAVIORAL HEALTH AND SUBSTANCE USE DISORDER RESOURCES FOR NATIVE AMERICANS PROGRAM.

DATES: The virtual SAMHSA Tribal Listening Session will be held on August 29, 2023, from 4:00 p.m.–6:00 p.m. EDT. Registration is required at: *https://www.zoomgov.com/meeting/register/vJItfuitqDIvGJb-7z8G5vUTNjXjFDxOG8U.* Individuals must register to obtain the call-in number, access code, and/or web access link or request special accommodations for those with disabilities.

Instructions to access the Zoom virtual consultation will be provided in the above link following registration.

FOR FURTHER INFORMATION CONTACT: CAPT Karen Hearod, MSW, LCSW, Director, Office of Tribal Affairs and Policy, Substance Abuse and Mental Health Services Administration, Telephone: (202) 868–9931, Email: *otap@samhsa.hhs.gov.*

Dated: July 6, 2023.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2023–16666 Filed 8–3–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2023–0247]

Certificates of Alternative Compliance for the Eighth Coast Guard District

AGENCY: Coast Guard, DHS.