DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by September 14, 2020.

ADDRESSES: Submit electronic comments on the collection of information to Leslie Green *Leslie.Green@acl.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Leslie Green, Administration for Community Living, *leslie.green@acl.hhs.gov,* 202–868–9384.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. A Collection of information includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

ACL is responsible for administering the Title VI Program Performance Report. The purpose of this data collection is to fulfill the annual programmatic reporting required by the Title VI Part A/B and C grants to American Indians, Alaskan Native and Native Hawaiian Programs to provide nutrition, supportive services and caregiver services to elders and their caregivers.

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: There are 282 respondents taking 3.49 hours each to complete the response.

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Title VI PPR	282	1	3.49	984
Total				984

Dated: July 8, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–15278 Filed 7–14–20; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2223]

Clinical Investigations for Prostate Tissue Ablation Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance entitled ''Clinical Investigations for Prostate Tissue Ablation Devices.'' This guidance provides recommendations for clinical investigations for high intensity ultrasound systems for prostate tissue ablation and new types of prostatic tissue ablation devices.

DATES: The announcement of the guidance is published in the **Federal Register** on July 15, 2020.

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–2019–D–2223 for ''Clinical Investigations for Prostate Tissue Ablation Devices.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Clinical Investigations for Prostate Tissue Ablation Devices'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: John Baxley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2626, Silver Spring, MD 20993–0002, 301–796–6549.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides draft recommendations for: (1) Complying with the clinical testing special control under 21 CFR 876.4340(b)(8) for premarket notifications (510(k)s) for high intensity ultrasound systems for prostate tissue ablation and (2) collecting clinical data to support marketing submissions for new types of prostatic tissue ablation devices. High intensity ultrasound systems for prostate tissue ablation transmit high intensity therapeutic ultrasound energy into the prostate to thermally ablate a defined, targeted volume of tissue. Other prostate ablation devices achieve the same clinical effect of ablating targeted tissue volumes using different sources of energy.

The scope of this guidance is limited to the clinical investigations of prostate tissue ablation systems to support marketing authorization for a general indication for ablation of prostatic tissue. This guidance does not address the clinical investigations of devices that are intended to treat specific prostatic diseases (*e.g.,* prostate cancer or benign prostatic hyperplasia). Additionally, this document does not address recommendations for non-clinical testing of prostate tissue ablation systems.

A notice of availability for the draft guidance appeared in the **Federal Register** of June 26, 2019 (84 FR 30125). FDA considered comments received and revised the guidance as appropriate in response to the comments, including minor edits to clarify and better explain FDA's recommendations for the clinical study design. 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 clinical investigations for prostate tissue ablation devices. 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Clinical Investigations for Prostate Tissue Ablation Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16011 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions	0910–0756
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910–0755
56	Institutional Review Boards	0910–0130

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15263 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0567]

Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes the Food and Drug Administration (FDA or Agency) to award priority review vouchers (PRVs) to tropical disease product applicants when the applications meet certain criteria. The FD&C Act lists the diseases that are considered tropical diseases for purposes of obtaining PRVs and provides for Agency expansion of that list to include other diseases that satisfy the definition of ''tropical diseases'' as set forth in the FD&C Act. The Agency has determined that brucellosis satisfies this definition and is therefore adding it to the list of designated tropical diseases whose product applications may result in the award of PRVs. Sponsors submitting certain drug or biological product applications for the prevention or treatment of brucellosis may be eligible to receive a PRV if such applications are approved by FDA.

DATES: This order is issued on July 15, 2020.

ADDRESSES: Submit electronic comments on additional diseases suggested for designation to *https://www.regulations.gov.* Submit written comments on additional diseases suggested for designation to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1300, *Katherine.Schumann@fda.hhs.gov;* or Stephen Ripley, 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:

Table of Contents

I. Background: Priority Review Voucher Program

Section 524 of the FD&C Act (21 U.S.C. 360n), which was added by section 1102 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), uses a PRV incentive to encourage the development of new drugs for prevention and treatment of certain diseases that, in the aggregate, affect millions of people throughout the world. To be eligible to receive a tropical disease PRV, a drug must be for a ''tropical disease'' as listed under section 524(a)(3) of the FD&C Act. This list can be expanded by the Agency under section 524(a)(3)(S) of the FD&C Act, which authorizes FDA to designate by order ''[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations'' as an addition to the tropical disease list. Further information about the tropical disease PRV program can be found in the guidance for industry ''Tropical Disease Priority Review Vouchers,'' available at *https://www.fda.gov/media/72569/download.*

On August 20, 2015, FDA published a final order (80 FR 50559) (August 2015 final order) designating Chagas disease and neurocysticercosis as additions to the list of tropical diseases eligible for PRV consideration. This final order also set forth FDA's interpretation of the statutory criteria for tropical disease designation and expands the list of tropical diseases under section 524(a)(3)(S) of the FD&C Act. Additions by order to the statutory list of tropical diseases published in the **Federal Register** can be accessed at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.*

In this document, FDA has applied its August 2015 criteria as set forth in the final order for analyzing whether the zoonotic infection brucellosis meets the statutory criteria for addition to the tropical disease list.

II. Disease Being Designated

FDA has considered all diseases submitted to the public docket (FDA–2008–N–0567) between October 1, 2018, and June 30, 2019, as potential additions to the list of tropical diseases under section 524 of the FD&C Act, pursuant to the docket review process explained on the Agency's website at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.* Based on an assessment using the criteria from its August 2015 final order, FDA has determined that brucellosis will be designated as an addition to the list of ''tropical diseases'' under section 524 of the FD&C Act.

Brucellosis is one of the most common zoonotic infections, meaning it is transmissible from animals to humans. The species most commonly associated with human disease are *B. abortus, B. melitensis, B. suis,* and, rarely, *B. canis.* Brucellosis occurs in greater than 500,000 individuals worldwide annually through contact with fluids or inhalation of aerosols from infected wild or domestic animals (including sheep, cattle, goats, pigs and other animals) or ingestion of food products derived from infected animals, such as undercooked meat or unpasteurized milk and cheese (Refs. 1 and 2). Brucellosis can cause significant morbidity in both humans and animals. FDA's rationale for adding this disease to the list is discussed in the analyses that follow.

Efforts to control infections caused by *Brucella* spp. in livestock in high-income countries have led to a notable drop in human infections but brucellosis continues to cause a significant burden of disease in developing countries (Ref. 3). Severity of disease can vary widely, from asymptomatic disease to moderate illness with acute fever, malaise, and weight loss, to more severe illnesses including meningitis, endocarditis, osteomyelitis, and pneumonitis (Refs. 4 and 5). With appropriate therapy, brucellosis rarely causes death. Chronic infections with *Brucella* spp. cause granulomatous disease that can affect any organ, leading to chronic debilitating symptoms including arthritis, uveitis, and neuropsychiatric abnormalities (Ref. 6). In pregnant women, *Brucella* spp. infections are associated with a high risk of spontaneous abortion, miscarriage, and fetal death (Ref. 1). The incubation