Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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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:

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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

period is highly variable, usually 1 to 4 weeks, but may be as long as 6 months.

The treatment regimens for adults with uncomplicated brucellosis have changed little in 30 years. There are currently three FDA approved treatments for brucellosis: Doxycycline, streptomycin, and tetracycline (Refs. 7, 8, and 25). Prolonged treatment (greater than 6 weeks) with two or more antimicrobials are generally required, and relapses occur in 5 to 15 percent of patients (Refs. 9 and 10). While an effective vaccine exists for brucellosis in livestock (Ref. 11), there are no vaccines licensed in the United States for human use.

A. No Significant Market in Developed Nations

No significant direct market exists for the prevention or treatment of brucellosis in developed nations. In high-income countries, the direct market for products to prevent brucellosis in humans is small due to the success of strategies to decrease human exposure through control efforts in livestock and food. The incidence in the United States is 0.4 cases per million with approximately 100 cases of brucellosis in humans reported annually (Ref. 12). Three-quarters of these cases are due to *B. melitensis* or *B. abortus* associated with ingestion of unpasteurized dairy products from countries where the disease remains endemic (Ref. 1). Brucellosis has been significantly reduced or eliminated in Northern Europe. For example, in Germany, 22 to 47 annual cases were reported between 2010 and 2015, with most cases occurring following travel or consumption of contaminated imported products (Ref. 13).

Brucellosis is considered endemic in some Mediterranean countries that are designated as high income by the World Bank; presence on the World Bank's list, FDA determined in the August 2015 final order, will be used as evidence that such a country should be considered a ''developed nation'' for tropical disease determination (Ref. 14). These high-income countries include Greece (20.9 cases per million of population per year), Spain (15.1), and Portugal (13.9). However, the annual incidence of brucellosis in these countries is considerably lower than in Turkey (262.2) and the Republic of North Macedonia (148), which are not on the World Bank list of high-income economies (Ref. 15). Saudi Arabia, classified by the Word Bank as high-income, has a reported annual incidence of brucellosis of 214.4 per million of population (Ref. 15). Within Latin America, Mexico is a prominent reservoir of human brucellosis, with an annual incidence of 28.7 cases per million of population, while Panama and Argentina, both on the World Bank list of high-income countries, have a lower rate of disease at 10.1 and 8.4 cases per million of population per year, respectively (Ref. 15).

The characteristics of specific diseases under consideration may affect the measures of occurrence used to estimate the likely market for interventions. As described in the August 2015 final order, FDA has used a disease prevalence rate of 0.1 percent of the population in developed countries for aiding in the determination of whether a ''significant market'' may exist for treatment of a disease. In this order, incidence rather than prevalence was considered to provide a better estimate of market size. Incidence measures new cases that are diagnosed in a population in a given time period. In an acute disease such as brucella, that can be resolved through treatment, incidence represents a reasonable indicator for the number of cases that would be treated in a given year and provides a better estimate of market size. As noted in the August 2015 final order, ''[t]he market for many FDA-approved products includes situations in which individuals (often reimbursed by their insurers) purchase the products for use by a specific patient. This reflects what we will refer to as the 'direct' market, and the direct market for a drug in a developed country can often by estimated by assessing the occurrence of a particular disease in that country.'' Even in countries designated by the World Bank as high-income where the disease is considered endemic, the incidence is well below 0.1 percent of the population; therefore, the direct market for products to prevent or treat brucellosis in humans would be small. These markets are unlikely to provide sufficient incentive to encourage development of products to treat or prevent brucellosis.

No significant indirect market exists for the treatment or prevention of brucellosis in developed nations. The U.S. Centers for Disease Control and Prevention (CDC) has designated *Brucella* spp. *B. suis, B. melitensis,* and *B. abortus* as select agents, a subset of biological agents and toxins that may pose a severe threat to public health, due to the ease of aerosolization, low infectious dose, and difficulty in diagnosis; and the CDC, U.S. Department of Agriculture, and U.S. Department of the Interior, have identified brucellosis as one of eight diseases of greatest national concern that should be addressed jointly by Federal zoonotic disease programs (Refs. 1 and 16). Despite these designations, at present FDA is unaware of any significant funding for drug development targeting treatment or prophylaxis of brucellosis by U.S. government sources. Further, *Brucella* spp. are not listed as a high priority threat in the 2017–2018 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (Ref. 17).

Given the above information, it is reasonable to conclude that no significant market exists in developed nations for the prevention or treatment of brucellosis in humans.

B. Disproportionately Affects Poor and Marginalized Populations

While brucellosis is not currently designated by the World Health Organization (WHO) as a neglected tropical disease, WHO has identified it as a neglected zoonotic disease (Ref. 18). Successful animal vaccination programs for brucellosis require sustained implementation over several years. Largely eliminated in developed nations, brucellosis disproportionally affects poor and marginalized populations in endemic countries where inadequate control measures maintain an ongoing reservoir of disease in animals. Brucellosis remains significant in many parts of the world, including some countries in the Mediterranean Basin, Africa, the Middle East, Asia, and Central and South America (Refs. 1 and 19). The reemergence of brucellosis in the Balkans and, more recently, some parts of the Middle East suggests that geopolitical factors could be important drivers of the disease (Refs. 20 and 21).

Illnesses caused by *Brucella* spp. result in significant morbidity with disproportionate impact on marginalized populations. Transmission of brucellosis to humans occurs most frequently in individuals who consume infected meat or unpasteurized dairy products, exposures that occur more commonly in resource-poor regions. Efforts to control *Brucella* spp. in humans in low-income countries using methods employed in high income nations, such as vaccination of livestock, have had limited success due to insufficient veterinary resources and high infection rates in wild animal populations (Ref. 22). In addition, routine pasteurization of dairy products tends to be less common in developing countries (Ref. 3).

Human infection with *Brucella* spp. results in significant losses in work days, lowering income and often the socioeconomic status of affected

individuals and their families (Ref. 3). A Disability-Adjusted Life Years (DALY) weighting for acute brucellosis is similar to an episode of malaria (Refs. 6 and 23). DALY burdens for brucellosis have not been calculated, however, in part due to the difficulty in obtaining accurate surveillance data in affected low-income countries (Ref. 22).

As mentioned above, prolonged treatment courses of greater than 6 weeks with two or more antimicrobials are generally required. These recommended treatment regimens pose special challenges for resource-poor countries (Ref. 24).

The above information demonstrates it is reasonable to conclude that brucellosis disproportionately affects poor and marginalized populations.

Given the factors described above, FDA has determined that brucellosis meets both the statutory criteria of ''no significant market in developed nations'' and ''disproportionately affects poor and marginalized populations.'' Therefore, FDA is designating brucellosis as an addition to the tropical disease list under section 524 of the FD&C Act.

III. Process for Requesting Additional Diseases To Be Added to the List

The purpose of this order is to add brucella to the list of tropical diseases that FDA has found to meet the criteria in section 524(a)(3)(S) of the FD&C Act. By expanding the list to include brucellosis with this order, FDA does not mean to preclude the addition of other diseases to this list in the future. Interested persons may submit requests for additional diseases to be added to the list to the public docket established by FDA for this purpose (see *https://www.regulations.gov,* Docket No. FDA–2008–N–0567). Such requests should be accompanied by information to document that the disease meets the criteria set forth in section 524(a)(3)(S) of the FD&C Act. FDA will periodically review these requests, and, when appropriate, expand the list. For further information, see FDA's Tropical Disease Priority Review Voucher Program web page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.*

IV. Paperwork Reduction Act

This final order reiterates the ''open'' status of the previously established public docket through which interested persons may submit requests for additional diseases to be added to the list of tropical diseases that FDA has found to meet the criteria in section 524(a)(3)(S) of the FD&C Act. Such a request for information is exempt from Office of Management and Budget review under 5 CFR 1320.3(h)(4) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Specifically, ''[f]acts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof'' are exempt, ''provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment.''

V. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–1066; FDA–2019–E–1067; and FDA–2019–E–1068]

Determination of Regulatory Review Period for Purposes of Patent Extension; ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 14, 2020. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 11, 2021. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 September 14, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 14, 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 Nos. FDA–2019–E–1066, FDA–2019–E–1067; and FDA–2019–E–1068 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM.'' 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. 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 § 10.20 (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://*