the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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

FDA is announcing the availability of draft GFI #265 entitled ''Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs.'' Section 305 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (Pub. L. 115–234), among other things, directed FDA to hold a public meeting for interested parties to discuss innovative animal drug investigation designs and to issue guidance addressing the incorporation of the use of such elements of investigations as complex adaptive and other novel investigation designs, data from foreign countries, real-world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, and surrogate endpoints into clinical investigation protocols and applications to support the effectiveness of new animal drugs.

In the **Federal Register** of July 9, 2019 (84 FR 32749), FDA's Center for Veterinary Medicine (CVM) published a notice of a public meeting entitled ''Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs'' giving interested persons until August 17, 2019, to comment on the topics discussed at the public meeting and the questions published in the meeting notice (84 FR 32749 at 32750–32751).[1] On August 13, 2019, we published a notice announcing the extension of the comment period to September 16, 2019 (84 FR 40071). CVM received numerous comments on the topics discussed at the public meeting and the questions published in the meeting notice and those comments were considered as the draft GFI #265 entitled ''Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs'' was developed.

This draft guidance describes principles for designing, conducting, and reporting the results for investigations or studies, including data from foreign countries, in submissions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 describes how sponsors may obtain feedback from CVM regarding the incorporation of data from foreign countries into investigations and study protocols before the submission of an application. FDA is committed to supporting data that may be recognized globally in order to enhance animal drug development, facilitate the use of foreign data, and minimize the need to conduct duplicative studies.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent the current thinking of FDA regarding the use of data from foreign investigational studies to support the 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

FDA tentatively concludes that this draft 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 draft guidance refers to previously approved FDA collections of information found in FDA regulations for new animal drug applications submitted under sections 512(b) (21 U.S.C. 360b(b)) and 571 (21 U.S.C. 360ccc) of the FD&C Act. These collections of information are subject to review by the OMB under the PRAct. 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 draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: July 9, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–15242 Filed 7–14–20; 8:45 am]

**BILLING CODE 4164–01–P**

[1] *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/public-meeting-incorporating-alternative-approaches-clinical-investigations-new-animal-drugs.*

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–N–0567]**

### Notice of Decision Not To Designate Clonorchiasis as an Addition to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency), in response to suggestions submitted to the public docket FDA–2008–N–0567, between June 20, 2018, and November 21, 2018, has analyzed whether the foodborne trematode infection clonorchiasis meets the statutory criteria for designation as a ''tropical disease'' for the purposes of obtaining a priority review voucher (PRV) under the Federal Food, Drug, and Cosmetic Act (FD&C Act), namely whether it primarily affects poor and marginalized populations and whether there is ''no significant market'' for drugs that prevent or treat clonorchiasis in developed countries. The Agency has determined at this time that clonorchiasis does not meet the statutory criteria for addition to the tropical diseases list under the FD&C Act. Although clonorchiasis disproportionately affects poor and marginalized populations, it is an infectious disease for which there is a significant market in developed nations; therefore, FDA declines to add it to the list of tropical diseases.

**DATES:** 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., 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, including biological products, for prevention and treatment of certain diseases that, in the aggregate, affect millions of people throughout the world. Further information about the tropical disease PRV program can be found in the October 6, 2016 (81 FR 69537) guidance for industry ''Tropical Disease Priority Review Vouchers,'' available at *https://www.fda.gov/media/72569/download.* Additions to the statutory list of tropical diseases by an FDA final order 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.*

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 under section 524 of the FD&C Act. The August 2015 final order also set forth FDA's interpretation of the statutory criteria for designating additions to the section 524 list of tropical diseases and expands the list of tropical diseases under section 524(a)(3)(R) of the FD&C Act. That section, later redesignated as section 524(a)(3)(S) of the FD&C Act, 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 a tropical disease for which approved drug applications may be eligible for a PRV.

FDA has applied its criteria as set forth in the August 2015 final order to analyze whether clonorchiasis meets the statutory criteria for addition to the tropical diseases list. As discussed below, the Agency has determined that clonorchiasis does not meet the statutory criteria for designation as a PRV-eligible ''tropical disease'' under section 524 of the FD&C Act; thus, FDA will not add it to the list of tropical diseases whose applications may be eligible for a priority review voucher.

## II. Decision Not To Designate Clonorchiasis

FDA has considered all disease suggestions submitted to the public docket (FDA–2008–N–0567) between June 20, 2018, and November 21, 2018, as potential additions to the list of tropical diseases under section 524 of the FD&C Act, under the docket review process explained on the Agency's web page at *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm534162.htm.* Based on an assessment of currently available information, and using the criteria from its August 2015 final order, FDA has determined that clonorchiasis will not be designated as a ''tropical disease'' for purposes of the tropical disease PRV program under section 524 of the FD&C Act.

### *A. Clonorchiasis*

Clonorchiasis is caused by *Clonorchis sinensis,* trematodes (parasitic flatworms), also known as flukes, which are acquired by humans through the consumption of raw or undercooked fish (Ref. 1). The natural final hosts of *C. sinensis* are dogs and other fish-eating carnivores (Ref. 2). *C. sinensis* are reported in the Democratic People's Republic of Korea (North Korea), the Republic of Korea (South Korea), China, Taiwan, Vietnam, Japan, and the Russian Far East (Ref. 1).

The final location of adult *C. sinensis* is the smaller bile ducts of the liver (Ref. 2). The symptoms of clonorchiasis are related to inflammation and fibrosis of the tissues adjacent to bile ducts. While the majority of infected individuals are asymptomatic, patients may develop cholangitis, intrahepatic calculi, or cholangiohepatitis (Ref. 2). Chronic infection is also associated with the development of cholangiocarcinoma, a severe and fatal form of bile duct cancer, and *C. sinensis* is recognized by the International Agency for Research on Cancer (IARC) as Group 1, which means that the agent is classified as carcinogenic to humans (Refs. 3 and 4).

There is one FDA approved treatment for clonorchiasis, praziquantel, approved in 1982 and indicated for the treatment of infections due to all species of schistosoma and infections due to the liver flukes *C. sinensis* and *Opisthorchis viverrini* (Ref. 5).

### 1. Significant Market in Developed Nations

FDA was unable to make the determination that no significant market exists for the treatment or prevention of clonorchiasis in developed nations, as the most recent data shows significant prevalence of clonorchiasis in a developed nation. As stated above, clonorchiasis occurs as a result of infection by *C. sinensis,* which has been reported in North Korea, South Korea, China, Taiwan, Vietnam, Japan, and the Russian Far East. The limited range of *C. sinensis* means that individuals are infected only in those countries noted, and infections in other countries only occur from the movement of infected persons. North Korea, China, Vietnam, and the Russian Federation (Russia) are not on the World Bank's list of high-income countries (Ref. 6). However, South Korea, Japan, and Taiwan are high-income economies, based on World Bank's list of high-income countries, and therefore are considered developed countries for purposes of this order (Ref. 6).

In the developed countries where *C. sinensis* is found, clonorchiasis rates are typically low. *C. sinensis* was endemic in Japan throughout the 1950s; however, improved hygiene associated with modernization and industrialization has reduced its incidence in humans in the country to a negligible level (Ref. 7). Likewise, in Taiwan, *C. sinensis* has been nearly eliminated from all but a small number of poor rural areas (Refs. 8 and 9). However, as of 2008, South Korea had an estimated 1.4 million people infected with *C. sinensis.* Based on data from 1981, the egg-positive proportion of people living near 7 major rivers was 22 percent among 13,373 examined, varying from 0.6 percent to 45.5 percent (Ref. 10). The persistence of *C. sinensis* infection is thought to be primarily due to difficulties in changing the traditional habit of eating raw freshwater fish (Refs. 10 and 11). The 2017 South Korean population was 51.42 million, and using the most recent estimate of 1.4 million people infected with *C. sinensis,* the estimated prevalence of *C. sinensis* infection in South Korea is over 2 percent of the population (Ref. 12). This prevalence is higher than 0.1 percent of the population of South Korea. The 0.1 percent of the population was discussed in FDA's order of 2015 as a factor for aiding in the determination of whether a significant market may exist for a disease's treatment. FDA worked to find a more recent prevalence rate for clonorchiasis infections in South Korea but was unsuccessful. If more recent

prevalence information is publicly accessible, please provide this information to the Dockets Management Staff for Docket No. FDA–2008–N–0567 (see **ADDRESSES**) and the Agency will reevaluate our findings.

There is currently no estimate of the number of individuals with clonorchiasis in the United States. Of the infections that do occur in the United States, foodborne trematode infections occur predominantly in immigrants and travelers from endemic regions (Refs. 13 and 14). For example, in a retrospective study in one U.S. travel medicine clinic over 6 years, only 17 cases of *Opisthorchis spp.* and *Clonorchis spp.* were identified through the review of ova and parasite records (Ref. 15). All patients with identified cases were migrants from Laos, Cambodia, Thailand, Vietnam, the former Soviet Union, and Ecuador (Ref. 15).

There is evidence that U.S. military personnel were exposed to *Opisthorchis spp.* and *Clonorchis spp.* during their service in the Vietnam War (Ref. 16). In one study, there was evidence that veterans were likely previously infected, but patients in the study did not have evidence of ongoing infection given negative stool exams and negative imaging studies, and therefore would not have ongoing infections requiring treatment now (Ref. 16).

As illustrated above, clonorchiasis occurs rarely in most developed nations. However, in South Korea, the prevalence was 1.4 million people infected as of 2008, which may offer an incentive to drive development of new drug products to treat or prevent clonorchiasis.

2. Clonorchiasis Disproportionately Affects Poor and Marginalized Populations

Clonorchiasis disproportionately affects poor and marginalized populations around the world. As areas where clonorchiasis occurs develop economically, the epidemiology of clonorchiasis changes, and fewer cases of clonorchiasis occur. This is supported by data in Japan and Taiwan where incidences of clonorchiasis have fallen rapidly with improved hygiene as the countries have developed (Refs. 7 and 8).

Transmission of foodborne trematodes within countries is typically restricted to limited areas and reflects behavioral and ecological patterns that are related to socioeconomic status. This includes people's food habits, methods of food production and preparation, and the distribution of intermediate hosts. For example, food can be contaminated through unhygienic preparation and storage. Furthermore, the consumption of raw fish and crustaceans is a main risk factor for contracting these parasites. The parasite's life cycle is closely linked with water and sanitation. In populations without access to toilets, or without sewage system infrastructure, unprocessed human and animal fecal waste may be found near water or used as manure or fish feed. This can contaminate drinking water and aquatic vegetables, leading to a continuous cycle of infections.

Clonorchiasis is included in the World Health Organization (WHO) List of Neglected Tropical Diseases (Ref. 17). The WHO Foodborne Disease Burden Epidemiology Reference Group identified clonorchiasis as an important cause of disability, with an estimated annual incidence of over 31,620 infections and 5,770 deaths, resulting in global disability adjusted life years, which is calculated by adding the number of years of life lost to mortality and the number of years lived with disability due to morbidity due to the illness, of 522,863 (Ref. 18). Given the above information, it is reasonable to conclude that clonorchiasis disproportionately affects poor and marginalized populations.

*B. FDA Determination*

In sum, although clonorchiasis disproportionately affects poor and marginalized populations, it is an infectious disease that fails to meet the statutory criterion for ''no significant market in developed nations.'' FDA has determined that, at this time, the available information does not support a determination that clonorchiasis meets the statutory criteria in section 524 of the FD&C Act for addition to the list of tropical diseases.

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

FDA's current determination regarding clonorchiasis does not preclude interested persons from requesting its consideration in the future. To facilitate the consideration of future additions to the list, FDA established a public docket (see *https://www.regulations.gov,* Docket No. FDA–2008–N–0567) through which interested persons may submit requests for additional diseases to be added to the list. 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 notice 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 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 also are 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.

1. *U.S. Centers for Disease Control and Prevention, 2018, ''Parasites—Clonorchis: Epidemiology & Risk Factors,'' accessed October 24, 2019, *https://www.cdc.gov/parasites/clonorchis/epi.html.*
2. *WHO, 2018, ''Fact Sheet on Foodborne Trematodiases,'' accessed October 23, 2019, *https://www.who.int/news-room/fact-sheets/detail/foodborne-trematodiases.*
3. *WHO, IARC, 2019, ''IARC Monographs on the Identification of Carcinogenic Hazards to Humans, Agents Classified by the IARC Monographs,'' Vols. 1–125, accessed October 23, 2019, *https://monographs.iarc.fr/agents-classified-by-*

*the-iarc/.*
4. *WHO, IARC, 2012, ''IARC Monographs on the Evaluation of Carcinogenic Risks in Humans, Opisthorchis Viverrini and Clonorchis Sinensis,'' Vol. 100B, 341–370, accessed October 23, 2019, *https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100B-13.pdf.*
5. U.S. National Library of Medicine, 2015, ''Label: Biltricide-Praziquantel Tablet, Film Coated,'' *DailyMed.*
6. The World Bank, ''World Bank Country and Lending Groups,'' accessed December 12, 2018, *https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.*
7. Nakamura-Uchiyama, F., K. Hiromatsu, K. Ishiwata, et al., 2003, ''The Current Status of Parasitic Diseases in Japan,'' *Internal Medicine,* 42(3):222–236.
8. Lo, T.C., J.H. Chang, H.H. Lee, et al., 2013, ''Risk Factors for and Prevalence of Clonorchiasis in Miaoli County, Taiwan,'' *Southeast Asian Journal of Tropical Medicine and Public Health,* 44(6):950–958.
9. Yeh, T.C., P.R. Lin, E.R. Chen, et al., 2001, ''Current Status of Human Parasitic Infections in Taiwan,'' *Journal of Microbiology, Immunology, and Infection,* 34(3):155–160.
10. Seo, B.S., S.H. Lee, S.Y. Cho, et al., 1981, ''An Epidemiologic Study on Clonorchiasis and Metagonimiasis in Riverside Areas in Korea,'' *Kisaengchunghak Chapchi,* 19(2):137–150.
11. Shin, E.H., S.M. Guk, H.J. Kim, et al., 2008, ''Trends in Parasitic Diseases in the Republic of Korea,'' *Trends in Parasitology,* epub ahead of print February 5, 2008, doi: 10.1016/j.pt.2007.12.003.
12. Statistics Korea, 2018, ''2017 Population and Housing Census,'' accessed October 24, 2019, *http://kostat.go.kr/portal/eng/pressReleases/8/7/index.board.*
13. Furst, T., U. Duthaler, B. Sripa, et al., 2012, ''Trematode Infections: Liver and Lung Flukes,'' *Infectious Disease Clinics of North America,* 26(2):399–419.
14. Qian, M.-B., Y.-D. Chen, S. Liang, et al., 2012, ''The Global Epidemiology of Clonorchiasis and its Relation with Cholangiocarcinoma,'' *Infectious Diseases of Poverty,* epub ahead of print October 25, 2012, doi: 10.1186/2049–9957–1–4.
15. Stauffer, W.M., J.S. Sellman, and P.F. Walker, 2004, ''Biliary Liver Flukes (Opisthorchiasis and Clonorchiasis) in Immigrants in the United States: Often Subtle and Diagnosed Years After Arrival,'' *Journal of Travel Medicine,* 11(3):157–159.
16. Psevdos, G., F.M. Ford, and S.T. Hong, 2018, ''Screening US Vietnam Veterans for Liver Fluke Exposure 5 Decades After the End of the War,'' *Infectious Diseases in Clinical Practice,* epub ahead of print January 16, 2018, doi: 0.1097/IPC.0000000000000611.
17. *WHO, 2018, ''Neglected Tropical Diseases,'' accessed October 24, 2019, *https://www.who.int/neglected_diseases/diseases/en/.*
18. *WHO, Foodborne Disease Burden Epidemiology Reference Group, 2015, ''WHO Estimates of the Global Burden of Foodborne Diseases 2007–2015,'' accessed October 24, 2019, *https://www.who.int/foodsafety/publications/foodborne_disease/fergreport/en/.*

Dated: July 8, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–15253 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]**

### Notice of Decision Not To Designate Coccidioidomycosis as an Addition to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency), in response to suggestions submitted to the public docket number FDA–2008–N–0567 between October 1, 2018, and June 30, 2019, has analyzed whether coccidioidomycosis meets the statutory criteria for designation as a tropical disease for the purposes of obtaining a priority review voucher (PRV) under the Federal Food, Drug, and Cosmetic Act (FD&C Act), namely whether it primarily affects poor and marginalized populations, and whether there is ''no significant market'' for drugs that prevent or treat coccidioidomycosis infections in developed countries. The Agency has determined that coccidioidomycosis does not meet the statutory criteria for designation as a tropical disease eligible for PRV consideration because of the potential market for preventive products (such as vaccines), and therefore declines to designate it as an addition to the list of tropical disease PRV-eligible diseases at this time.

**DATES:** 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, including biological products, for prevention and treatment of certain diseases that, in the aggregate, affect millions of people throughout the world. 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.* Section 524(a)(3) of the FD&C Act includes a list of infectious diseases, applications for the prevention or treatment of which may be eligible to qualify for a PRV, and Congress has amended that list multiple times to add new diseases since section 524 was first enacted. Additions to the statutory list of PRV-eligible tropical diseases by an FDA final order 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.*

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 under section 524 of the FD&C Act. The August 2015 final order also set forth