DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 317
[Docket No. FDA–2008–N–0567]

RIN 0910–AG37

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 order.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (the 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 to be tropical diseases for purposes of obtaining PRVs, and also 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. FDA has determined that Chagas disease and neurocysticercosis satisfy this definition, and therefore is adding them to the list of designated tropical diseases whose product applications may result in the award of PRVs. Sponsors submitting certain applications for the treatment of Chagas disease and neurocysticercosis may be eligible to receive a PRV if such applications are approved by FDA.

DATES: This order is effective August 20, 2015.

ADDRESS: Submit electronic comments on additional diseases suggested for designation to www.regulations.gov. Submit written comments on additional diseases suggested for designation to the Division of Dockets Management (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.


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I. Background: Priority Review Voucher Program

Much of the global burden of disease falls on populations who lack the resources to develop, encourage development of, or purchase disease prevention, detection, or treatment for which the approval of a tropical disease product is warranted. This order is a step toward ensuring that the United States is able to meet its obligations under section 524(a)(3) of the FD&C Act, and will further the Administration’s commitment to increase access to improved prevention, detection, or treatments for tropical diseases.

The order designates two tropical diseases, Chagas disease and neurocysticercosis, that satisfy the statutory criteria to be added to the list of tropical diseases. These diseases affect millions of people throughout the world. Specifically, section 524 of the FD&C Act defines the term “tropical disease product application” and sets forth criteria which, if met, enable those who submit an application for a tropical disease product to be eligible to receive a PRV upon approval of that tropical disease product application. To be eligible for a PRV, the tropical disease product application must meet all of the following criteria:

• The application must be a “human drug application,” as defined in section 351(1) of the FD&C Act (21 U.S.C. 379g(1)).
• The application must be for the “prevention or treatment of a tropical disease,” as defined by statute.
• The application must be deemed eligible for priority review by the Secretary of HHS.

The application must be approved after the date of enactment of FDAAA (i.e., September 27, 2007) for use in the prevention, detection, or treatment of a tropical disease.

Fälle der Deutschen Zentralstelle für Tuberkulose (DZT)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Fälle der Deutschen Zentralstelle für Tuberkulose (DZT)
Marginalized populations" as a disproportionately affects poor and developed nations and that which there is no significant market in "any other infectious disease for which there is no significant market in developed nations. . .designated by order of the Secretary as "tropical diseases" under section 524.

A. No Significant Market in Developed Nations

1. "Developed Nations"

In interpreting the term "developed nations," FDA acknowledges at the outset that the standards for determining a nation's level of development, as well as the threshold for a "developed" country, are the subject of debate. Some nations may score well in some markers of development (e.g., gross domestic product) and poorly in others (e.g., sanitation), leading to disagreements regarding which measures of development should serve as dominant indicators. After also examining the International Monetary Fund (IMF)'s list of advanced economies (Ref. 2) and the United Nations (U.N.)'s human development index (Ref. 3), the Agency is proposing to use a country's presence on the World Bank's list of "high income economies" (Ref. 4) as evidence that the country should be considered a "developed nation" for "tropical disease" determination purposes. Similarly, FDA will use a country's presence on the World Bank's list of "low income economies" (id.) as evidence that the country should not be considered a "developed nation" for purposes of "tropical disease" determination.

FDA recognizes that there is a correlation between economic strength (particularly purchasing power) and the market incentive for drug creation: People in high-income economies are more likely to be able to afford disease treatments and, thus, drug companies have an incentive to create products that will be in demand in those countries. The World Bank list of high-income economies is calculated based on gross national income per capita, and, importantly, it thus reflects wealth as a primary basis for categorization. FDA's recognition of the role of wealth is why we deemed the U.N. development index less helpful: It measures development across a broad array of categories (e.g., mean years of schooling) that, while informative, are less directly correlated with the drug development incentives reflected in the statutory scheme. Indeed, the U.N. itself has acknowledged that "[the human development index] was created to emphasize that people and their capabilities should be the ultimate criteria for assessing the development of a country, not economic growth alone" (Ref. 5). And although the IMF's list of "advanced economies" reflects purchasing power to some degree, the World Bank calculus is more transparent and predictable than the IMF's, and the U.S. government routinely uses the World Bank lists when determining a country's eligibility for Generalized System of Preferences benefits for trade in goods (Ref. 6).

2. "No Significant Market"

The list of tropical diseases in section 524(a)(3) of the FD&C Act includes "[a]ny other infectious disease for which there is no significant market in developed nations. . .designated by order of the Secretary." As an initial matter, the Agency notes that "infectious diseases," as such do not have markets—but drugs for the treatment or prevention of infectious diseases do. Because the statute offers vouchers for applications for drugs for either the treatment or prevention of infectious diseases, it is reasonable to assume that "no significant market" can refer to drugs for the treatment or prevention of infectious diseases. Thus, FDA will analyze the market for drugs for both the treatment and prevention of infectious diseases for a particular infectious disease. The threshold for what constitutes a "significant market" for drugs for the treatment or prevention of infectious diseases is difficult to quantify. Because of the challenges in providing a rigid definition of this term, FDA proposes that the following factors be considered in determining whether a "significant market" exists in developed countries.

a. Occurrence of the Disease in Developed Nations

As discussed previously, market forces are important drivers of drug development. The purpose of section 524 of the FD&C Act is to provide an incentive (through a PRV) for innovation where there otherwise would be an insufficient financial or market incentive to invest in developing drugs for tropical diseases. The 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 is different from what we will refer to as the "direct" market, and the direct market for a drug in a

- Malaria
- Blinding trachoma
- Buruli ulcer
- Cholera
- Dengue/Dengue haemorrhagic fever
- Dracunculiasis (guinea-worm disease)
- Fascioliasis
- Human African trypanosomiasis
- Leishmaniasis
- Leprosy
- Lymphatic filariasis
- Onchocerciasis
- Schistosomiasis
- Soil transmitted helminthiasis
- Yaws
- Filoviruses

In addition, section 524(a)(3)(R) of the FD&C Act authorizes the Secretary to expand by order the list of tropical diseases to include "[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations," and that is the purpose of this order.

II. Criteria for Expansion of the List of Tropical Diseases

On December 12, 2008, FDA convened a public hearing, at which the public provided suggestions regarding the following topics: (1) Criteria that should be used to determine the eligibility of an infectious disease for designation as a tropical disease, (2) the process that should be used to make tropical disease designations, and (3) recommendations for specific diseases that should be designated as tropical diseases. A number of participants in the public meeting commented that, given the lack of definitive data for some diseases, as well as the lack of consensus on how these criteria should be defined, FDA should use a flexible approach in determining whether specific diseases meet the criteria.

FDA agrees with the use of a flexible approach to tropical disease designation and is proposing that a scientifically informed, qualitative assessment of disease candidates is appropriate. FDA also is establishing a public docket that will continuously remain open to receive future suggestions for tropical disease designations under section 524 of the FD&C Act. The Agency proposes to review the contents of this public docket periodically and to take action to designate additional diseases when appropriate.

As stated previously, section 524(a)(3)(R) of the FD&C Act authorizes the Secretary 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

The "World Bank" is a term used to refer collectively to the International Development Association and the International Bank for Reconstruction and Development, which are two of the five organizations that comprise the World Bank Group.
developed country can often be estimated by assessing the occurrence of a particular disease in that country.2

If the prevalence of a disease in developed countries is less than 0.1 percent of the population of those countries, it is unlikely that ordinary market forces will offer a sufficient incentive to drive the development of new preventions or treatments. Thus, it is unlikely that there will be a “significant market” for the disease’s treatment in those countries. Accordingly, FDA has decided to use a disease prevalence rate of 0.1 percent of the population as a factor for aiding in the determination of whether a “significant market” may exist for a disease’s treatment.

b. The Existence of a Sizeable Indirect Market for the Tropical Disease Drug (e.g., Government, Including the Military) That Would Constitue a Financial Incentive for Drug Development

As discussed previously, the market for many FDA-approved products is the “direct” market, involving patients purchasing drugs for their own use. However, some drugs may have a sizeable “indirect” market composed of, for example, government entities or nongovernmental organizations that wish to purchase and distribute a drug for the treatment or prevention of an infectious disease, often for public health reasons, to a particular group of people. Indeed, for some diseases identified as high priorities for public health preparedness, governmental entities have initiated programs to provide support for product development and/or stockpiling (Ref. 7).3 In such cases, FDA would consider that market as a factor in determining whether a significant market for a drug for the treatment or prevention of an infectious diseases disease exists in developed nations.

3 For example, certain diseases have been prioritized for medical countermeasure development and investment (see Ref. 7) or are listed as priority pathogens by government entities such as the National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID), Center for Disease Control or Prevention, and military programs (Refs. 8, 9, and 10). These and other indications of potential priority designation that could affect governmental resource allocation may be taken into account in assessment of whether a market exists in developed countries.

B. Disproportionately Affects Poor and Marginalized Populations

As with the term “no significant market in developed nations,” FDA has elected to analyze multiple factors—none of which, alone, invariably will be outcome-determinative—in assessing whether a given disease meets the requirement of “disproportionately affects poor and marginalized populations” for classification as a “tropical disease” under section 524 of the FD&C Act. Those factors are the following:

1. The Proportion of Global Disability-Adjusted Life Years for the Disease That Is Attributable to Developing Countries

A disability-adjusted life year (DALY) measurement is not a direct measure of the prevalence of the disease; rather, it is a measure of the impact of that disease on a given population. “One DALY can be thought of as one lost year of ‘healthy’ life” (Ref. 11). An estimate of disease-related morbidity (a term which, as used in this order, refers to the state of being diseased (see Ref. 12)) and mortality in affected countries thus can be made by assessing available information about the DALY burden of a particular disease. “DALYs for a disease or health condition are calculated as the sum of the Years of Life Lost...due to premature mortality in the population and the Years Lost due to Disability...for people living with the health condition or its consequences” (Ref. 11). DALYs are an important measurement, enabling FDA to weigh “tropical disease” eligibility for those diseases that, although they may be present to some degree in developed countries (e.g., because of travel or immigration), cause much more harm to the public health of developing countries.

2. The Relative Burden of the Disease in the Most Impoverished Populations Within the Countries in Which It Is Found

If a disease’s prevalence is high in populations who cannot afford treatment and low in populations that can, there likely will be little market incentive for drug companies to create new treatments. In light of section 524 of the FD&C Act’s intent to create treatment development incentives, as well as its clear goal of improving the health of impoverished populations, FDA will consider the demographic distribution of a disease in determining whether it should be designated as a “tropical disease” for the purposes of section 524 of the FD&C Act.

3. The Relative Burden of the Disease in Infants, Children, or Other Marginalized Segments of the Population (e.g., Women, the Elderly) Within the Countries in Which It Is Found

One of the clear goals of section 524 of the FD&C Act is improving the health of marginalized populations, who generally suffer poorer health outcomes than their non-marginalized neighbors, even within the same country. To “marginalize” is to place (or keep) a person or population in a powerless or unimportant position (see, e.g., Ref. 13). Individuals or groups may be marginalized for any number of reasons, including, for example, gender, age, or extreme poverty. Marginalized populations generally lack a meaningful voice in societal decisionmaking, including decisions relating to the acquisition, distribution, and use of health resources. These populations, therefore, are less likely to have their health needs met and less likely to have the resources or political power needed to effect change in those aspects of health policy that most affect them—including incentivizing governments or private industry to offer disease treatments. Understanding the relative prevalence of a disease in these populations will help FDA determine whether treatment development for that disease would be spurred by the provision of section 524 of the FD&C Act’s PRV incentive.

4. Designation by the World Health Organization as a Neglected Tropical Disease

The World Health Organization (WHO), in its role as the directing and coordinating authority on international health within the U.N. system, has identified a list of diseases that it refers to as “neglected tropical diseases” (Ref. 14). According to the WHO, these diseases “are strongly associated with poverty” and tend to affect those with “little political voice”; rarely receive the attention of disease treatment innovators or the broader international community; and often flourish in tropical climates (id.). The WHO’s list includes 12 of the 17 enumerated diseases in section 524(a)(3) of the FD&C Act (see Ref. 15). Because the WHO’s list of “neglected tropical diseases” includes many of the types of diseases for which section 524 was designed to incentivize treatment development, FDA believes it is reasonable to consider WHO’s “neglected tropical disease” designations in determining whether a disease should be designated as a...
“tropical disease” for purposes of section 524 of the FD&C Act.

III. Diseases Being Designated

FDA has considered a number of diseases recommended in response to the Federal Register document announcing the December 12, 2008, public meeting (see 73 FR 66050, November 6, 2008), by meeting participants or others directing communications to FDA on the same topic. Based on an assessment using the criteria proposed previously, FDA has determined that the following diseases will be designated as “tropical diseases” under section 524 of the FD&C Act:

- Chagas disease.
- Neurocysticercosis.

FDA’s rationale for adding these diseases to the list is discussed in the analyses that follow.

A. Chagas Disease

Chagas disease, also known as American trypanosomiasis, is a vector-borne parasitic disease caused by the protozoan Trypanosoma cruzi (Ref. 16). After the initial infection, a 2-month “acute” phase occurs, during which there are some antiparasitic drugs that can be used for treatment in some patients (id.). Treatment efficacy generally decreases with length of infection, and if the disease is not cured during the initial “acute” infection phase, the chronic infection lingers over the next several years or decades, often causing organ and tissue damage (id.). For example, some Chagas disease sufferers who contract the disease during childhood die in early adulthood due to heart arrhythmias or other effects of organ damage. Efforts to reduce Chagas disease center around controlling the spread of the vector insects (e.g., through insecticide and roof repair) and protecting people from insect bites (e.g., through bed net use) (id.).

Chagas disease has a disproportionate effect on poor and marginalized populations. Developing countries in Central and South America suffer most of the global DALYs lost because of the disease (id.). Estimates vary, but approximately 8 million people are believed to be infected in Mexico, Central America, and South America (Ref. 17). Within Chagas-endemic countries, the disease often affects rural and/or poor populations who live in the mud huts that also are inhabited by the vector insects (Ref. 16). WHO has designated Chagas as a neglected tropical disease (Ref. 15). There is no significant market for Chagas disease treatment in developed nations. Based on estimates derived by applying published seroprevalence data to immigrant population estimates in the United States, it is estimated that there are just over 300,000 persons infected with T. cruzi in the United States (Refs. 17, 18, and 19). The number of persons with chronic cases for whom definitive recommendations for treatment would apply is likely less than 300,000. Transmission and acute cases of Chagas disease would be considered unlikely either in the United States or in other developed countries. The most common insect vector that transmits the parasite, the triatomine bug, is found mostly in Central and South America. The main risk of Chagas transmission to uninfected persons in developed countries is due to mother-to-child transmission, or blood transfusions or organ donations where the donor has lived in or visited Chagas-endemic countries—although there have been a few reports of vector-borne Chagas infecting people in the United States (Refs. 16 and 17).

There are no approved vaccines or other preventative therapies for the disease, either in the United States or elsewhere. The only drugs used to treat Chagas are benznidazole and nifurtimox, which are not approved in the United States for this use. In addition to the lack of a commercial market in developed countries (presumably because of the low prevalence of disease), there does not seem to be a sizeable indirect (e.g., government) market for Chagas treatments either—presumably because of the geographical limitations of the disease. As a general matter, Chagas-endemic countries are developing countries in Central and South America, and thus neither persons with Chagas disease nor their governments are likely to be in a position to provide a financial incentive for treatment development. Given the disease’s geographical limitations and its prevalence in non-touristed rural areas, it is unlikely that the travelers’ market would be a sufficient incentive to encourage treatment development for Chagas. Given the factors described in this document, FDA has determined that Chagas disease meets both statutory criteria of “no significant market in developed nations” and “disproportionately affects poor and marginalized populations.” Therefore, FDA is designating Chagas disease as a tropical disease under section 524 of the FD&C Act.

B. Neurocysticercosis

Cysticercosis is a disease caused by infection with Taenia solium, a tapeworm of the phylum Platyhelminthes, and is contracted when a person ingests the tapeworm eggs. After a person ingests the eggs, the tapeworm enters the larval stage and begins to infect the host’s tissues. The most severe form of the disease, called neurocysticercosis, occurs when larvae enter the central nervous system and establish cysts that can cause epilepsy (see, e.g., Ref. 20). Treatment guidelines from the American Academy of Neurology recommend treatment with anti-helmithic drugs like albendazole, with consideration for adjunctive corticosteroid therapy (Ref. 20).

Neurocysticercosis disproportionately affects poor and marginalized populations. Indeed, patients who have infection with T. solium generally have similar socioeconomic and demographic characteristics to those patients with soil transmitted helminthiasis, a disease already on the statutory list of “tropical diseases” in section 524 of the FD&C Act. As of the late 1990s, approximately 50 million people worldwide were estimated to harbor the tapeworm T. solium (Ref. 21), most of them living in poverty in the world’s poorest countries that lack effective systems for meat inspection and adequate sanitation (Refs. 22 and 23). Estimates of the number of people who have epilepsy caused by neurocysticercosis ranges from 450,000 to 1,350,000 in Central and South America and from 300,000 to 4,600,000 in sub-saharan Africa (Ref. 23). Neurocysticercosis is believed to contribute to high levels of human morbidity, notably epilepsy, though efforts are underway to adequately characterize an estimate of DALY for neurocysticercosis (Ref. 24). Notably, cysticercosis is included on WHO’s list of neglected tropical diseases (Ref. 15).

FDA also has determined that neurocysticercosis products have no significant market in developed nations. Although the disease does occur in the United States, estimates of annual incidence rates in the general U.S. population are low, at approximately 0.2 cases per 100,000 population. Incidence rates are much higher among Hispanics living in the United States, who most likely acquired the tapeworm in cysticercosis-endemic areas of Central and South America (Ref. 25), with estimates ranging between 3.1 and 5.8 cases per 100,000 Hispanic population (Ref. 26). FDA also is unaware of evidence suggesting any sizeable military, government, or other indirect market for neurocysticercosis products.

In view of the disease characteristics discussed previously, FDA considers the statutory criteria for addition of neurocysticercosis to the list of tropical
diseases in section 524 of the FD&C Act to be satisfied. This addition is effective upon the publication of this order.

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

The purpose of this order is to add diseases to the list of tropical diseases that FDA has found to meet the criteria in section 524(a)(3)(R) of the FD&C Act. By expanding the list with this order, FDA does not mean to preclude the future addition of other diseases to this list. To facilitate the consideration of future additions to the list, FDA is establishing a public docket (see http://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)(R) of the FD&C Act. FDA will periodically review these requests, and, when appropriate, expand the list.

V. Paperwork Reduction Act

This final order establishes a 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)(R) of the FD&C Act. This 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. 3501–3520). 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.”

VI. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at http://www.regulations.gov.

(FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)


A voucher holder to use the voucher assistance outside the jurisdiction of the PHA that initially issued the family its voucher. While portability offers an important mechanism to increase housing choice, this feature has not been maximized by PHAs and participating families because the current process for allowing a family to move from one jurisdiction to another is time consuming and burdensome. HUD recognizes that for the HCV program’s goals to support mobility and housing choice to be realized, the regulations governing the portability process must be clarified so that the burden on families and the PHA is reduced. This final rule completes the rulemaking process, which commenced in 2012, to revise the existing portability regulations to streamline the portability process and facilitate the ability of participating families to move to the jurisdiction of their choice.

C. Costs and Benefits

The changes made by this final rule are designed to minimize burden for PHAs and participating HCV families and thereby increase the ability of participating families to live in areas of their choice or relocate to a new area for employment opportunities or to gain access to preferred schools for their children. In addition, the improved portability process contributes to helping victims of domestic violence, dating violence, sexual assault, and stalking have access to the resources necessary to relocate to a safe, stable home away from an abuser. Further, moves to areas with relatively low concentrations of neighborhood poverty have shown to relay important benefits to housing choice voucher families, in particular mental and physical health for adults and long-term educational and earning gains for young children.

HUD recognizes that some policies may increase burden for some PHAs; however, the added clarity to the portability process afforded by this final rule is expected to improve the portability process and reduce the burden on families and PHAs.

The streamlining changes do not add any substantial cost to the HCV program.

II. Background—the March 28, 2012, Proposed Rule

On March 28, 2012, at 77 FR 18731, HUD published a rule in the Federal Register that proposed to amend HUD’s regulations governing portability in the HCV program. The HCV program is the Federal Government’s largest program for assisting very low-income families, the elderly, and persons with disabilities to afford decent, safe, and sanitary housing in the private market. The HCV program is authorized by section 8(o) of the United States Housing Act of 1937 (42 U.S.C. 1437f(o)) (1937 Act), and the HCV program regulations are found in 24 CFR part 982.

Housing choice vouchers are administered locally by PHAs. PHAs receive Federal funds from HUD to administer the HCV program. Under the HCV program, housing assistance is provided on behalf of the participating family who is responsible for finding a suitable housing unit of their choice where the owner agrees to rent under the program. The participant is free to choose any rental housing, including single family homes, townhouses, and apartments, that meets the requirements of the program and is not limited to units located in subsidized housing projects. Under certain circumstances, if authorized by the PHA, a family may use its voucher to purchase a modest home.

A housing subsidy is paid to the landlord directly by the PHA on behalf of the participating family. The family then pays the difference between the actual rent charged by the landlord and the amount subsidized by the program. The PHA determines the amount that the family will contribute toward rent, which is generally 30 percent of its adjusted annual income. A key feature