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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 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:

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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, 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

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 the fungal infection coccidioidomycosis meets the statutory criteria for addition to this tropical disease list. As discussed below, the Agency has determined that coccidioidomycosis does not meet the statutory criteria for designation as a PRV-eligible ''tropical disease'' under section 524 of the FD&C Act because of the potential market for preventive measures such as vaccines. Thus, FDA will not add it to the list of tropical diseases whose applications may be eligible for a priority review voucher at this time.

II. Decision Not To Designate Coccidioidomycosis

FDA has considered all disease suggestions 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, under the docket review process explained on the Agency's web page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.* Based on an assessment of currently available information, and using the criteria from its August 2015 final order, FDA has determined that coccidioidomycosis does not currently fulfill the criteria for addition to the list of diseases eligible for the tropical disease PRV program under section 524 of the FD&C Act and is not designating it as an addition to the list at this time.

A. Coccidioidomycosis

Coccidioidomycosis, also known as ''Valley fever,'' is a systemic fungal infection caused by inhalation of *Coccidioides* spp. spores. Major areas of endemicity include substantial parts of the southwestern United States. The fungus occurs in the environment, especially in certain soil types in hot, dry climates, and inhalation may occur after environmental disturbance such as soil disruption and wind. The species most commonly associated with disease are *C. immitis,* which is endemic to parts of California, and *C. posadasii,* which is found in Arizona, Utah, Texas, regions of Mexico, and Central and South America (Ref. 1). Most reported cases occur in individuals who live in or have traveled to endemic areas. From 1990 to 2011, the incidence of reported coccidioidomycosis in the United States increased greater than 8-fold in areas of endemicity (Ref. 2).

Manifestations of infection with *Coccidioides* spp. can range from subclinical (estimated at one-half to two-thirds of infections), that might not be detected unless the person is included in a skin test survey or serologic screening, to acute self-limited respiratory illness that may be difficult to distinguish from other acute respiratory infections, to severe disease with chronic or life-threatening complications (Ref. 3). Acute respiratory coccidioidomycosis has a 1- to 3-week incubation period and most commonly presents as a self-limited illness with fever, muscle pain, cough, rash, weight loss, and malaise (Ref. 4). In areas where the illness is highly endemic, upwards of 30 percent of community-acquired pneumonia cases may be caused by *Coccidioides* spp. (Ref. 5). Five to ten percent of affected patients develop severe or chronic lung disease such as cavitary pneumonia, nodules, and bronchiectasis, and in approximately one percent of patients, infection disseminates to the central nervous system, skin, joints, or bone. Individuals older than 65 years, smokers, and those with diabetes are at increased risk of pulmonary complications of coccidioidomycosis, while those with depressed cellular immune function (Refs. 6 and 7), pregnant women (Ref. 8), or persons of African or Asian descent have an elevated risk of disseminated disease (Ref. 9). Coccidioidal meningitis cannot be reliably cured with current antifungal therapy and has a mortality rate of approximately 30 percent (Ref. 10). Although the public health burden attributable to coccidioidomycosis in the United States is primarily due to morbidity, an estimated 200 coccidioidomycosis-associated deaths occur each year (Ref. 11).

Treatment recommendations depend upon the severity, location, and dissemination of the disease as well as the underlying immune status of the patient (Ref. 12). A 2016 publication of professional society guidelines recommends against antifungal therapy in patients with newly diagnosed, uncomplicated coccidioidal pneumonia, with mild or resolved symptoms, and without immunosuppressive conditions, advising that such patients receive supportive measures such as physical therapy and close monitoring. In individuals with severe disease or disseminated disease, these guidelines advise antifungal therapy for a minimum of 3 to 6 months with an azole (fluconazole or itraconazole), intravenous amphotericin B, or both. Patients with immunocompromise or other underlying conditions may require therapy for 12 months or longer. In individuals with meningitis due to *Coccidioides* spp., these guidelines recommend treatment for life (Ref. 13).

There are two FDA-approved treatments for coccidioidomycosis: Amphotericin B deoxycholate, available in brand or generic form, and ketoconazole. In 2013, FDA warned that ketoconazole should not be used as a first-line therapy for any fungal infection as it can cause severe liver injury, adrenal insufficiency, and harmful drug interactions, and should be prescribed only for endemic mycoses, such as coccidioidomycosis, when alternative antifungal therapies are not available or tolerated (Ref. 14). With respect to preventative products, no vaccines have yet been developed that protect persons from developing infection or progressing from infection to disease due to *C. immitis,* but potential for development of such vaccines has been a topic of interest in some expert discussions as outlined in the next section.

1. Significant Market in Developed Nations

In the August 2015 final order, FDA interpreted the statutory criterion ''no significant market'' to refer to the market for drugs for the treatment or prevention of infectious diseases. The August 2015 final order states, ''[b]ecause 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.'' In other words, if there is a significant market for either the treatment or prevention of the infectious disease, the criterion that there be ''no significant market'' in developed nations is not met.

The relative importance of prevention markets may vary in part according to whether most cases of a particular disease in developed countries are attributable to exposure in those same

countries (or would be in the absence of a preventive product such as vaccine) or to movement between countries of persons exposed elsewhere, because preventive measures may be more widely important if exposure could be local and unavoidable than if the potential for exposure is restricted to a small group of travelers. For example, in the August 24, 2018, final order adding four diseases to the PRV-eligible list (83 FR 42904), chikungunya and Lassa fever were noted as being principally imported diseases in their limited occurrence in developed countries (as also noted for Chagas disease and neurocysticercosis in the August 2015 final order), rabies prophylaxis was analyzed and estimated at below 0.1 percent per year in the United States, and cryptococcal meningitis was noted as not having prophylaxis recommendations at present even in highly immunocompromised patients. Conversely, in the August 24, 2018, document (83 FR 42896), a significant market for prevention was noted as the reason for not adding pneumocystis pneumonia to the PRV-eligible list.

In the current analysis, FDA has found that a sizeable direct market may exist for products to prevent coccidioidomycosis (*e.g.,* vaccines) in developed nations, depending upon the specific attributes of the product and the recommended population. For this reason, the statutory criterion that there be ''no significant market for prevention or treatment'' of coccidioidomycosis is not met. (21 U.S.C. 360n(a)(3)(S)).

The United States is a high-income economy according to the World Bank list of high-income countries and therefore is considered a developed country for purposes of this order (Ref. 15). The true incidence of coccidioidomycosis in the United States is difficult to establish because reporting is not required in all States, case definitions may vary, and many cases are misdiagnosed or lack confirmatory testing (Refs. 11 and 16). However, up to 150,000 new infections caused by *Coccidioides* spp. are estimated to occur annually in the United States (Ref. 3).

The incidence of reported coccidioidomycosis in the United States has increased in Arizona, California, Nevada, New Mexico, and Utah, from 5.3 per 100,000 population in 1998 to 42.6 per 100,000 in 2011 (Ref. 2). While approximately 96 percent of infections reported in 2017 in the United States occurred in Arizona and California (Ref. 11), coccidioidomycosis is increasingly being recognized outside these regions (Refs. 17 and 18). Proposed reasons for the rise in cases and geographic expansion include changes to the local environment due to climate variation and soil disruption, greater exposure of higher risk individuals, including the immunocompromised, and increased numbers of susceptible individuals living in or traveling to endemic regions (Refs. 9 and 19).

A recent *Morbidity and Mortality Weekly Report* (MMWR) surveillance summary noted fluctuating total numbers of reported U.S. cases in recent years (22,634 in 2011, 8,232 in 2014, 14,364 in 2017), all substantially higher than numbers reported annually in the United States from 1998 to 2000. The MMWR surveillance summary addressed potential factors contributing to such fluctuations, including environmental, population, and reporting changes; noted ''Preliminary modeling estimates of the actual number of cases suggest that the number of symptomatic cases nationwide could be 6 to 14 times higher than the number reported to public health authorities''; and recommended ''[h]ealth care providers should consider a diagnosis of coccidioidomycosis in patients who live or work in or have traveled to areas with known geographic risk for *Coccidioides* and be aware that those areas might be broader than previously recognized'' (Ref. 11).

In the August 2015 final order, FDA 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. For purposes of determining a reasonable indicator for the number of cases of coccidioidomycosis that might be considered for treatment in a given year annual incidence (new cases appearing during a given year) was used by FDA. Based on the 2010 U.S. census population of 308.7 million, and using an estimate of 150,000 total cases per year, the calculated annual incidence rate in the United States would be approximately 0.048 percent (Refs. 4 and 20). These estimates suggest the annual number of persons potentially considered for treatment for coccidioidomycosis in the United States is currently below 0.1 percent of the population. However, these estimates should be considered with due regard to their inherent uncertainty and also in the context of potential development of products for prevention of infection or prevention of disease due to *Coccidioides* spp.

Because of the ongoing environmental exposures and risk factors for severe disease when infection occurs, the market for prevention products such as vaccines could differ substantially from that for treatment of clinically manifest illness. Data to support a market estimate are limited, and discussions of potential vaccine cost-effectiveness have used widely different assumptions regarding annual target population size, from 90,000 (based on targeting birth cohorts in highly endemic regions within California and Arizona) (Ref. 21), to ''many millions'' in a worldwide estimate (Ref. 22).

An annual target population size estimate of 1,035,300 for a coccidioidomycosis vaccine for use in the United States was presented in an Institute of Medicine (IOM) committee report on ''Vaccines for the 21st Century'' commissioned by the National Institutes of Health (NIH), which utilized a quantitative model to provide decision makers with a tool to aid in prioritizing vaccine development (Ref. 23). The committee determined an estimate of annual target population for a coccidioidomycosis vaccine based upon targeting birth cohorts in five States where infections are ''most prominent'' plus persons who migrate into that area. This methodology was used because persons who move into the endemic part of the United States and were not previously vaccinated could be at risk from environmental exposure in the endemic area after their move. The committee report estimates that 90 percent of newborns and 10 percent of persons moving into the targeted areas would receive the vaccine.

Given the purpose of the IOM committee report, the methodology used, and the experts and stakeholders consulted in its development, FDA considers it a reasonable estimate of a potential target population for a licensed coccidioidomycosis vaccine. We acknowledge that there are limitations to any hypothetical estimate of a recommended population for a licensed coccidioidomycosis vaccine, and the true population would depend upon multiple factors that include, but are not limited to: The incidence and/or prevalence of disease, the extent of exposure risks that may not be readily avoidable by means other than vaccination, and the indication, safety profile, efficacy, and durability of the immune response associated with a specific product. However, the IOM analysis predicts a sizeable direct market for products to prevent the disease, and no strong evidence has been found that the potential market has become smaller since the time of the committee report.

A few efforts have been initiated to help facilitate development of products targeting coccidioidomycosis. At present, FDA is aware of funding for

coccidioidomycosis drug development by U.S. government sources, including grants reported as being awarded by FDA and the NIH (Refs. 25 and 26). FDA's Office of Orphan Product Development has accorded orphan product designation to several drugs intended to treat coccidioidomycosis (Ref. 27). FDA added *Coccidioides* species to the ''list of ''qualifying pathogens'' that have the potential to pose a serious threat to human health'' under the Generating Antibiotic Incentives Now title of the Food and Drug Administration Safety and Innovation Act, noting ''[i]t is estimated that up to 60 percent of people living in the endemic areas of southwestern United States have been exposed to the fungus'' (June 5, 2014, 79 FR 32464). *C. immitis* and *C. posadasii* were previously on the HHS list of Select Agents and Toxins but were removed in 2012 based on availability of treatment and a lowered assessment of impact on human health (Ref. 28). Further, *Coccidioides* species are not listed as a high priority threat in the 2017–2018 Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan (Ref. 29).

In summary, based on the analyses outlined above focusing on the estimated vaccination rates of infants born in endemic areas and persons who may be exposed by moving into those areas, FDA has found a significant potential direct market for products for prevention of coccidioidomycosis.

2. Coccidioides spp. Disproportionately Affects Poor and Marginalized Populations

Illnesses caused by *Coccidioides* spp. cause significant morbidity with a disproportionate impact on poor and marginalized populations. In addition to the well-known endemic regions of the United States, cases and outbreaks of coccidioidomycosis have been reported in Mexico, Guatemala, Honduras, Nicaragua, Colombia, Venezuela, Argentina, Brazil, Paraguay, and Bolivia (Ref. 30). With the exception of the United States and Argentina, none of these countries is on the World Bank list of high-income economies, which in the August 2015 final order FDA determined would be used as evidence that the country should be considered a ''developed nation'' for tropical disease determination (Ref. 15). While coccidioidal skin test antigens do not distinguish subclinical infection from symptomatic disease, and recent data from skin test surveys are sparse (Ref. 31), available information indicates that coccidioidomycosis may be as prevalent in parts of Latin America as in parts of the United States (Refs. 30 and 32). Coccidioidin skin test surveys in Mexico some decades ago were reported as demonstrating positivity ranging from 10 percent in Tijuana, to 40 percent in Torreon, to as high as 93 percent in 12 communities in Coahuila (Ref. 30). In Brazil, by one estimate, 7.12 of 1,000 hospital admissions were due to coccidioidomycosis (Ref. 33). Treatment options are more limited in Latin America than in the United States, as lipid formulations of amphotericin have restricted availability due to the high cost (Ref. 34).

In the United States, several racial and ethnic minority groups have been reported to have increased risk of severe disease; genetic, socioeconomic, occupational, and geographic factors have been suggested as potentially contributory factors. Analyses of hospitalizations from 2000 to 2011 and deaths from 2000 to 2013 in California have reported higher rates in African-Americans, Hispanics, and older persons compared to the general population (Refs. 35 and 36). Among immunocompromised or immunosuppressed populations, persons with HIV infection were reported to be strikingly vulnerable during the early years of the HIV pandemic. While effective antiretroviral therapy has decreased the disease burden in individuals with HIV, affected patients lacking access to treatment, or with poorly-controlled disease, are at higher risk for severe or disseminated disease (Ref. 37).

While adults over the age of 60 have the highest incidence of coccidioidomycosis (Ref. 38), children under the age of 17 and their caretakers bear a substantial burden of the disease in endemic regions, experiencing delays in diagnosis, prolonged symptoms, hospitalizations, and missed school and work (Ref. 39). In California, for example, during a period when reported cases and hospitalizations in the general population increased 4.5-fold and 2.7-fold, respectively, cases and hospitalizations in children increased almost 6-fold (Ref. 40).

Prison inmates in endemic regions are at particularly high risk of symptomatic disease. One study in California found that the risk of primary disease was highest in prisoners over the age of 40 and in non-white ethnic groups (Ref. 41). A significant increase in coccidioidomycosis that was observed in two California prisons led to a court ruling excluding inmates from incarceration at those locations if they were in risk groups identified by the American Thoracic Society for high risk of severe coccidioidomycosis (Ref. 42).

Coccidioidomycosis is not currently designated by WHO as a Neglected Tropical Disease and no data were found on Disability-Adjusted Life Years distinguishing the burden attributable to coccidioidomycoses in developing versus developed countries. However, patients with coccidioidomycosis often experience prolonged symptoms, delays in diagnosis, and unnecessary antibacterial therapy (Ref. 43). Due to greater barriers to medical care for diagnosis and treatment, poor and marginalized patents in both developing and developed countries experience a significant burden of disease. Resolution of symptoms may take months, thus resulting in significant impairment of activities of daily living and loss of productivity (Ref. 44).

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

B. FDA Determination

Given the factors described above, FDA has determined that coccidioidomycoses meets the statutory criteria of ''disproportionately affects poor and marginalized populations,'' but it does not meet the criteria of ''no significant market in developed nations'' due to the potentially significant direct market for products to prevent the disease. Therefore, FDA declines to designate coccidioidomycosis 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

FDA's current determination regarding coccidioidomycoses does not prevent 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 (*) have been placed on display at the Dockets Management Staff (see **ADDRESSES**). They may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and 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 but is not responsible for any subsequent changes to the websites after this document publishes in the **Federal Register**.

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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 No. FDA–1997–D–0444]

Special Considerations, Incentives, and Programs To Support the Approval of New Animal Drugs for Minor Uses and for Minor Species; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of draft guidance for industry (GFI) #61 entitled ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' This draft guidance is intended to assist those interested in pursuing FDA approval of new animal drugs intended for minor uses in major species or for use in minor species (MUMS drugs). It outlines the basic statutory and regulatory requirements and special considerations for these approvals, and describes the incentives available to encourage the development of MUMS drugs.

DATES: Submit either electronic or written comments on the draft guidance by November 12, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–1997–D–0444 for ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' 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