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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*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. 2020–15243 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–1984–N–0259 (formerly 84N–0167)]

Vasodilan Injection and Tablets Containing Isoxsuprine Hydrochloride; Final Decision on Proposal To Withdraw Approval of New Drug Application; Availability of Final Decision

AGENCY: Food and Drug Administration; Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing that the Initial Decision of the Administrative Law Judge (ALJ), that Vasodilan containing Isoxsuprine Hydrochloride had not been shown to be supported by substantial evidence consisting of adequate and well-controlled studies to be effective for treating symptoms relating to senile dementia of the Alzheimer type (SDAT) and multiple infarct dementia and peripheral vascular disease, is the final decision of the Commissioner of Food and Drugs (the Commissioner).

DATES: This notice is applicable July 15, 2020.

ADDRESSES: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION: Several parties to the hearing, including the new drug application (NDA) holder and identical, related, or similar (IRS) product manufacturers, filed exceptions to the ALJ's Initial Decision. FDA recently requested that the current owner of the NDA and successors-in-interest to IRS product manufacturers who submitted timely exceptions to the ALJ's Initial Decision affirm, within a specific timeframe, their interest in pursuing their appeals of the ALJ's Initial Decision. FDA did not receive any responses within the specified timeframe. Accordingly, FDA now deems those exceptions as withdrawn. Consequently, the proceeding is in the same procedural position as if no exceptions to the ALJ's Initial Decision had been filed. Therefore, the ALJ's Initial Decision has become the final decision of the Commissioner by operation of law.

I. Background

In 1962, the Federal Food, Drug, and Cosmetic Act (FD&C Act) was amended by the Drug Amendments Act of 1962, and these amendments provided that new drugs could no longer be approved unless both safety and efficacy had been established for them. As amended, the FD&C Act also required FDA to evaluate drugs approved as safe between 1938 and 1962 to determine whether such drugs were effective and to withdraw approval for any NDA where there was not substantial evidence of the drug's effectiveness. The person contesting the withdrawal of the approval had the burden of coming forward with evidence of effectiveness for the drug. FDA's review of these pre-1962 drugs is known as the Drug Efficacy Study Implementation program.

In a notice published in the **Federal Register** of July 11, 1972 (37 FR 13565, available at *https://www.govinfo.gov/content/pkg/FR-1972-07-11/pdf/FR-1972-07-11.pdf*), after receiving reports from the National Academy of Sciences/National Research Council, Drug Efficacy Study Group, FDA stated that Vasodilan Injection and Tablets containing Isoxsuprine Hydrochloride lacked substantial evidence of effectiveness for several indications. In a notice published in the **Federal Register** of May 25, 1979 (44 FR 30443, available at *https://www.govinfo.gov/content/pkg/FR-1979-05-25/pdf/FR-1979-05-25.pdf*), the Director of the Bureau of Drugs (now the Center for Drug Evaluation and Research), after reviewing all the data previously submitted, concluded that Vasodilan lacks substantial evidence of effectiveness for its labeled indications, and proposed to withdraw approval of the NDA and issued a notice of opportunity for hearing on a proposal to withdraw approval of Vasodilan.

Mead Johnson, the NDA holder of Vasodilan (NDA 11–832) submitted data intended to support the effectiveness of Vasodilan for other indications, including: (1) Relief of symptoms associated with SDAT and/or multiple infarct dementia; (2) relief of symptoms associated with peripheral vascular disease of arteriosclerosis obliterans, thromboangiitis obliterans, and Raynaund's disease; and (3) relief of symptoms of uterine motility, including premature labor, dysmenorrhea, and threatened abortion.

Mead Johnson and multiple IRS product manufacturers responded to the notice of opportunity for a hearing and submitted requests for a hearing. By notice published in the **Federal Register** on September 28, 1984 (49 FR 38363, available at *https://www.govinfo.gov/content/pkg/FR-1984-09-28/pdf/FR-1984-09-28.pdf*), the Commissioner granted a hearing; however, the Commissioner only granted a hearing concerning the use of Vasodilan in treating symptoms related to: (1) SDAT or multiple infarct dementia and (2) peripheral vascular disease. Although Mead Johnson requested a hearing on the issue of Vasodilan's effectiveness in relieving symptoms of uterine motility, including premature labor, dysmenorrhea, and threatened abortion, Mead Johnson later abandoned this indication and consented to withdrawal of Vasodilan's approval for it (see id.). Following the submission of written testimony and documentary evidence, an ALJ, Daniel J. Davidson, conducted a hearing and issued his Initial Decision on August 20, 1986. The ALJ found that the effectiveness of Vasodilan had not been shown to be supported by substantial evidence and, as a result, ordered that the approval of the NDA be withdrawn. Mead Johnson and certain IRS product manufacturers timely appealed the ALJ's Initial Decision by filing exceptions with the Commissioner under 21 CFR 12.125.

Separately, by notice published in the **Federal Register** of February 11, 2009 (74 FR 6896), FDA withdrew approval of Vasodilan. The current NDA holder and successor to Mead Johnson, Apothecon, c/o Bristol-Myers Squibb Co. (BMS), had requested that FDA withdraw approval of the application because the drug product was no longer marketed; additionally, BMS waived its opportunity for a hearing on the withdrawal.

On November 9, 2017, FDA sent letters to BMS and the successors-in-

interest to the IRS product manufacturers who submitted timely exceptions, to determine whether the companies remained interested in pursuing their appeals of the ALJ's Initial Decision. FDA informed the companies that, if they did not respond and affirm their desire to pursue their appeals by January 8, 2018, the Office of the Commissioner would conclude that the companies no longer wish to pursue the appeal of the ALJ's Initial Decision and will proceed as if the appeals have been withdrawn. The Office of the Commissioner did not receive a response from any of the companies by the given date; therefore, the Commissioner now deems the exceptions withdrawn.

II. Conclusion and Order

Given that the exceptions have been deemed withdrawn, this proceeding is now in the same procedural posture as if no exceptions had ever been filed. When parties do not file exceptions to the ALJ's Initial Decision, and the Commissioner does not file a notice of review, the ALJ's Initial Decision becomes the final decision of the Commissioner (see 21 CFR 12.120(e)). FDA will publish a notice in the **Federal Register** when an initial decision becomes the final decision of the Commissioner without appeal to or review by the Commissioner (see 21 CFR 12.120(f)).

Pursuant to the findings in the ALJ's Initial Decision, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)), there is a lack of substantial evidence that Vasodilan will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling for: (1) SDAT or multiple infarct dementia and (2) peripheral vascular disease. Distribution of products subject to the Initial Decision in interstate commerce without an approved application is prohibited and subject to regulatory action (see, *e.g.,* sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

The full text of the ALJ's Initial Decision may be seen at Dockets Management Staff (see **ADDRESSES**).

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15248 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0567]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final 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'' eligible for PRVs as set forth in the FD&C Act. The Agency has determined that two foodborne trematode infections, opisthorchiasis and paragonimiasis, satisfy this definition, and is therefore adding them 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 opisthorchiasis or paragonimiasis infections 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, including biological products, 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 prevention or treatment of 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 list of tropical diseases, approved drug applications for which may be eligible to receive a PRV. 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.*

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 sets forth FDA's interpretation of the statutory criteria for tropical disease designation and expands the list of tropical diseases under section 524(a)(3)(R) of the FD&C Act (redesignated as section 524(a)(3)(S) of the FD&C Act). Additions by order to the statutory list of PRV-eligible tropical diseases published in the **Federal Register** can be accessed at *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm534162.htm.*

In this document, FDA has applied its August 2015 final order criteria to analyze whether the foodborne