However, section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national Accrediting Organization (AO) that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at §§ 488.4 and 488.5. The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

Community Health Accreditation Partner's (CHAP's) current term of approval for their hospice accreditation program expires February 24, 2025.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a national AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the CHAP request for continued approval of its hospice accreditation program. This notice also solicits public comment on whether the CHAP's requirements meet or exceed the Medicare conditions of participation (CoPs) for hospices.

III. Evaluation of Deeming Authority Request

CHAP submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its hospice accreditation program. This application was determined to be complete on April 20, 2024. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national AO) our review and evaluation of CHAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of CHAP's standards for hospices as compared with CMS' hospice CoPs.
- CHAP's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of CHAP's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ CHAP's processes and procedures for monitoring hospices, which are found out of compliance with CHAP's program requirements. These monitoring procedures are used only when CHAP identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the SA monitors corrections as specified at § 488.9.

++ CHAP's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ CHAP's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of CHAP's staff and other resources, and its financial viability.

++ CHAP's capacity to adequately fund required surveys.

++ CHAP's policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced.

++ CHAP's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ CHAP's agreement to provide CMS with a copy of the most current accreditation survey, together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document forpurposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–12495 Filed 6–6–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2390]

Proposal To Refuse To Approve a New Drug Application Supplement for HETLIOZ (Tasimelteon); Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Director of the Center for Drug Evaluation and Research (Center Director) at the Food and Drug Administration (FDA or Agency) is

proposing to refuse to approve a supplemental new drug application (sNDA) submitted by Vanda Pharmaceuticals, Inc. (Vanda), for HETLIOZ (tasimelteon) capsules, 20 milligrams (mg), in its present form. This notice summarizes the grounds for the Center Director's proposal and offers Vanda an opportunity to request a hearing on the matter.

DATES: Either electronic or written requests for a hearing must be submitted by July 8, 2024; submit data, information, and analyses in support of the hearing and any other comments by August 6, 2024.

ADDRESSES: You may submit hearing requests, documents in support of the hearing, and any other comments as follows. Please note that late, untimely filed requests and documents will not be considered. The *https://www.regulations.gov* electronic filing system will accept hearing requests until 11:59 p.m. Eastern Time at the end of July 8, 2024, and will accept documents in support of the hearing and any other comments until 11:59 p.m. Eastern Time at the end of August 6, 2024. Documents received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before these dates.

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–2022–N–2390 for ''Proposal To Refuse To Approve a New Drug Application Supplement for HETLIOZ (Tasimelteon); Opportunity for a Hearing.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Christopher Koepke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–651–7695, *Christopher.Koepke@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Proposal To Refuse To Approve sNDA 205677–012

FDA approved new drug application 205677 for HETLIOZ (tasimelteon) capsules for treatment of non-24-hour sleep-wake disorder on January 31, 2014, and for treatment of Smith-Magenis syndrome in patients 16 years of age and older on December 1, 2020. On May 4, 2023, Vanda submitted sNDA 205677–012 for HETLIOZ (tasimelteon) capsules, 20 mg, as an efficacy supplement proposing to add a new indication for the treatment of insomnia characterized by difficulties with sleep initiation.

To support an indication for the treatment of insomnia characterized by difficulties with sleep initiation, Vanda referred to three studies, Study 3101, Study 3104, and Study 3107, as primary support for demonstrating substantial evidence of effectiveness. The application proposes that Studies 3101, 3104, and 3107 together; Study 3104 alone; or Study 3104 with confirmatory evidence, provides substantial evidence of effectiveness for the proposed conditions of use.

On March 4, 2024, the Office of Neuroscience in the Center for Drug Evaluation and Research (CDER) issued a complete response letter to Vanda under § 314.110(a) (21 CFR 314.110(a)) stating that sNDA 205677–012 could not be approved in its present form because the application does not provide substantial evidence of effectiveness for tasimelteon and does not demonstrate that the drug is safe for the treatment of insomnia characterized by difficulties with sleep initiation. The complete response letter described the specific deficiencies that led to this determination and, where possible, recommended ways that Vanda might remedy these deficiencies. Those deficiencies are summarized below.

(1) Studies 3101 and 3107 are not adequate and well-controlled for

insomnia disorder because the design excluded subjects with insomnia disorder, and scientific evidence was not provided to demonstrate that changes in healthy volunteers without insomnia disorder would correspond to a similar degree of response in patients with insomnia disorder (see 21 CFR 314.126(b)(3)).

(2) The application does not include adequate subjective, patient-reported data to demonstrate clinical benefit associated with the polysomnogram findings in Study 3104. Only one subjective endpoint at an early timepoint was found to be nominally significant; no other secondary endpoints were nominally significant, and none were statistically significant. Endpoints derived from patient-reported outcome measures are necessary to demonstrate that the change in sleep latency measured by polysomnogram is perceptible to the patient and that the patient experiences a measurable subjective improvement in symptoms.

(3) The results of Studies 3101 and 3107 do not demonstrate statistically or nominally significant improvements on subjective sleep latency. Furthermore, they are not adequate to provide substantiation of the effect of a drug used for insomnia, which is a chronic indication, because they were single-dose studies in healthy subjects that excluded subjects with insomnia.

(4) The application does not provide longer-term efficacy data to demonstrate that this treatment would be effective for long-term use in this chronic condition.

(5) The application does not provide data to support effectiveness in patients 65 years of age and older with insomnia disorder, who are within the intended patient population according to the proposed conditions of use.

(6) The application does not provide long-term safety data in adults of all ages with insomnia disorder. In addition, the application provided insufficient data to support safety in patients 65 years and older with insomnia disorder.

(7) With respect to the proposals that Study 3104 alone, or with confirmatory evidence, is sufficient to demonstrate substantial evidence of effectiveness, the application does not establish either. Even if Study 3104 did not have the deficiencies described in the complete response letter and summarized above, and even if a single adequate and well-controlled study could be sufficient for the proposed conditions of use, Study 3104 lacks the features of a study that could alone provide substantial evidence of effectiveness. In addition, the confirmatory evidence proposed in the application (*i.e.,* to provide evidence of effectiveness for closely related approved indications, mechanistic data, or the effectiveness of members of the same pharmacological class as tasimelteon) would be insufficient.

These deficiencies preclude a finding that the application provides substantial evidence of effectiveness for tasimelteon or that the application demonstrates that tasimelteon is safe, for the treatment of insomnia characterized by difficulties with sleep initiation. The complete response letter stated that to address the deficiencies, Vanda would need to submit at least one positive, adequate, and well-controlled study that addresses the deficiencies described in the complete response letter.

The complete response letter stated that Vanda is required either to resubmit the application, fully addressing all deficiencies listed in the letter, or take other actions available under § 314.110 (*i.e.,* withdraw the application or request an opportunity for a hearing).

Following the complete response letter, in a letter dated April 11, 2024, Vanda indicated that it wished to receive approval of its application or a notice of opportunity for a hearing. For the reasons described above, FDA cannot approve the application in its current form; thus, we are issuing this notice of opportunity for a hearing.

II. Notice of Opportunity for a Hearing

For the reasons stated above and as explained in the March 4, 2024, complete response letter, notice is given to Vanda and all other interested persons that the Center Director proposes that FDA issue an order refusing to approve sNDA 205677–012 on the grounds that the application fails to meet the criteria for approval under section 505(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(d)) because there is a lack of substantial evidence that the drug is effective, and the drug has not been shown to be safe, for treatment of insomnia characterized by difficulties with sleep initiation (sections 505(d)(4) and 505(d)(5) of the FD&C Act).[1]

Vanda may request a hearing before the Commissioner of Food and Drugs (the Commissioner) on the Center Director's proposal to refuse to approve sNDA 205677–012. Pursuant to § 314.200(c)(1) (21 CFR 314.200(c)(1)), if Vanda decides to seek a hearing, it must file: (1) a written notice of participation and request for a hearing on or before 30 days after the notice is published in the **Federal Register** and (2) the studies, data, information, and analyses relied upon to justify a hearing, as specified in § 314.200, on or before 60 days after the date the notice is published in the **Federal Register**.

As stated in § 314.200(g), a request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing to resolve. We note in this regard that because CDER proposes to refuse to approve sNDA 205677–012 based on the multiple deficiencies summarized above, any hearing request from Vanda should address all those deficiencies. Failure to request a hearing within the time provided and in the manner required by § 314.200 constitutes a waiver of the opportunity to request a hearing. If a hearing request is not properly submitted, FDA will issue a notice refusing to approve sNDA 205677–012.

The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest (see § 314.200(g)(6)). If a hearing is granted, it will be conducted according to the procedures provided in 21 CFR parts 10 through 16 (see 21 CFR 314.201).

Paper submissions under this notice of opportunity for a hearing should be filed in one copy, except for those submitted as ''Confidential Submissions'' (see ''Written/Paper Submissions'' and ''Instructions'' in **ADDRESSES**). Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, submissions may be seen in the Dockets Management Staff Office between 9 a.m. and 4 p.m., Monday through Friday, and on the internet at *https://www.regulations.gov.* This notice is issued under section 505(c)(1)(B) of the FD&C Act and §§ 314.110(b)(3) and 314.200.

Dated: May 31, 2024.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 2024–12564 Filed 6–6–24; 8:45 am]

BILLING CODE 4164–01–P

[1] Section 505(d) of the FD&C Act provides that FDA shall refuse to approve an application if, among other reasons, ''upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions'' or ''there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof[.]'' (Sections 505(d)(4) and 505(d)(5) of the FD&C Act.)