i. Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

ii. Enhance the accuracy of the agency's estimates of the burden of the proposed collection of information.

iii. Enhance the quality, utility, and clarity of the information to be collected.

iv. Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic collection technologies or other forms of information technology.

II. Information Collection Request

Agency: Federal Mediation and Conciliation Service.

Title: Arbitrator's Personal Data Questionnaire (FMCS Form R–22).

OMB Number: 3076–0001.

Type of Request: Extension without change of a currently approved collection.

Affected Public: Private Sector to include businesses or other for-profits.

Frequency: Once a year.

Burden: The total annual burden estimate is that FMCS will receive approximately 50 responses per year, one response per year and updates as necessary. This form takes about 2 hours to complete.

Information Collection Requirement:

Purpose and Description of Data Collection: Title II of the Labor Management Relations Act of 1947, 29 U.S.C. 171(b), provides that ''the settlement of issues between employers and employees through collective bargaining may advance by making available full and adequate governmental facilities for conciliation, mediation, and voluntary arbitration . . .'' Pursuant to the statute and 29 CFR part 1404, FMCS has long maintained a roster of qualified, private sector labor arbitrators to hear disputes arising under collective bargaining agreements and provide fact finding and interest arbitration. The existing regulation establishes the policy and administrative responsibility for the FMCS roster, criteria, procedures for listing and removing arbitrators, and procedures for using arbitration services.

Use of Results: The FMCS uses the information received from arbitrator applicants to evaluate the credentials of the applicants and determine an arbitrator's suitability for inclusion on FMCS' roster of arbitrators.

III. The Official Record

The official records are electronic records.

Dated: March 4, 2025.

Alisa Zimmerman,

Deputy General Counsel.

[FR Doc. 2025–03699 Filed 3–6–25; 8:45 am]

BILLING CODE 6732–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2390]

Notice of the Denial of a Hearing Request Regarding a Proposal To Refuse To Approve a Supplemental New Drug Application for HETLIOZ (Tasimelteon)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the decision to deny a request for a hearing regarding the proposal of the Center for Drug Evaluation and Research (CDER) to refuse to approve the supplemental new drug application (sNDA) 205677–012, submitted by Vanda Pharmaceuticals, Inc. (Vanda), for HETLIOZ (tasimelteon) capsules, 20 milligrams (mg), for the treatment of insomnia characterized by difficulties with sleep initiation. The decision, which also refuses approval of sNDA 205677–012, is available in the docket identified by the number in the heading of this document.

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:

I. Background

On January 31, 2014, FDA approved new drug application (NDA) 205677 for HETLIOZ (tasimelteon) for treatment of non-24-hour sleep-wake disorder, a circadian-rhythm disorder that disproportionately afflicts individuals who are totally blind. On December 1, 2020, FDA approved NDA 214517 for HETLIOZ (tasimelteon) suspension for the treatment of nighttime sleep disturbances in pediatric patients with Smith-Magenis Syndrome, a rare genetic neurodevelopment disorder. On May 4, 2023, Vanda submitted the sNDA that is the subject at issue here: 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.

On March 4, 2024, CDER issued a complete response letter to Vanda 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 for the proposed indication—treatment of insomnia characterized by difficulties with sleep initiation, nor does the application demonstrate that the drug is safe for this use. 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 (NOOH). On June 6, 2024, CDER notified Vanda by electronic mail, providing it with a NOOH on a proposal to refuse to approve sNDA 205677–012. The NOOH was subsequently published in the **Federal Register** of June 7, 2024 (89 FR 48647) and described the grounds on which the application failed to meet the criteria for approval under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)).

On July 3, 2024, Vanda filed a notice of participation and requested a hearing, and, on August 6, 2024, Vanda submitted information, data, and analyses in support of that request. On October 31, 2024, CDER submitted a proposed order denying Vanda's request for a hearing and refusing to approve the sNDA. On December 31, 2024, Vanda submitted a response to CDER's proposed order.

After considering the parties' submissions, on February 28, 2025, FDA issued a decision denying Vanda's request for a hearing on CDER's proposal to refuse approval and refusing to approve sNDA 205677–012.

II. Electronic Access

Persons with access to the internet may obtain the final decision at *https://www.regulations.gov/docket/FDA-2022-N-2390*. The final decision and other documents pertaining to the refusal to approve HETLIOZ (sNDA 205677–012) are available at *https://www.regulations.gov* under the docket number found in brackets in the heading of this document.

Dated: March 4, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–03697 Filed 3–6–25; 8:45 am]

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