TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
314.107(e)—notification of court actions or written consent to approval	54	1.98	107	0.5 (30 minutes)	53.5
Subparts G, H, and I					
314.420—Drug Master Files—original Form FDA 3938	491	2.05	1,005	61	61,305
DMF Amendments—Technical	1,335	18.71	24,979	8	199,832
DMF Amendments—REMS	2	1	2	8	16
DM Amendments—administrative	1,024	9.67	6,851	6	41,106
DMFs—Annual reports	1,836	6.04	11,097	4	44,388
314.550—Promotional material and subpart H applications [2]	69	5.84	403	120	48,360
CPA Requests for NDA/Biologics License Application Products	1	1	1	5	5
Total					3,476,650

[1] Total burden hours have been rounded.
[2] We have included burden attendant to subpart H applications activity in our estimate of burden associated with § 314.50.

Our estimated burden for the information collection reflects an overall decrease of 642,293.5 hours. The reporting period for this information collection renewal includes the 3 years of the COVID–19 pandemic. We attribute this adjustment to a decrease in the number of submissions received during the public health emergency. We anticipate that the numbers of submissions to FDA will return to pre-pandemic levels as economic activity recovers. We also attribute a portion of the burden adjustment to improved operational efficiencies with regard to Agency data systems and digital submission processes.

Dated: February 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04715 Filed 3–5–24; 8:45 am]

BILLING CODE 4164–01–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 or the Agency) 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) 205677–004, submitted by Vanda Pharmaceuticals, Inc. (Vanda), for HETLIOZ (tasimelteon) capsules, 20 milligrams (mg), for the treatment of jet lag disorder. The decision, which also refuses approval of sNDA 205677–004, is available in the docket identified by the number in the heading of this document.

DATES: The decision was published in the docket on March 1, 2024.

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 October 16, 2018, Vanda submitted the supplemental NDA (sNDA) that is the subject at issue here: sNDA 205677–004 for HETLIOZ (tasimelteon) capsules, 20 mg, proposing to add a new indication for the treatment of jet lag disorder. 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 July 1, 2022, Vanda requested an opportunity for a hearing under 21 CFR 314.110(b)(3) on whether there are grounds under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) for denying approval of sNDA 205677–004 for the treatment of jet lag disorder. On August 29, 2022, CDER notified Vanda by registered mail, providing it with a notice of opportunity for a hearing (NOOH) on a proposal to refuse to approve sNDA 205677–004. The NOOH was subsequently published in the **Federal Register** of October 11, 2022 (87 FR 61337).

On November 10, 2022, Vanda filed a notice of participation and requested a hearing and, on December 12, 2022, submitted information, data, and analyses in support of that request. On June 12, 2023, CDER submitted a proposed order denying Vanda's request for a hearing and refusing to approve the sNDA. On August 11, 2023, Vanda responded to CDER's proposed order. On September 8, 2023, CDER submitted a reply, which included a revised proposed order.

After considering the parties' submissions, on March 1, 2024, FDA issued a decision denying Vanda's request for a hearing on CDER's proposal to refuse approval and refusing to approve sNDA 205677–004.

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 205677–004) are available at *https://www.regulations.gov* under the docket number found in brackets in the heading of this document.

Dated: March 1, 2024.

Namandjé N. Bumpus,

Principal Deputy Commissioner.

[FR Doc. 2024–04735 Filed 3–5–24; 8:45 am]

BILLING CODE 4164–01–P