Dated: February 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04722 Filed 3–5–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Food and Drug Administration Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by April 5, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0001. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Applications for FDA Approval To Market a New Drug—21 CFR Part 314

OMB Control Number 0910–0001—Revision

This information collection supports implementation of statutory and regulatory authorities that govern new drugs. Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States unless an approval of an application filed with FDA under section 505(b) or (j) of the FD&C Act is effective with respect to such drug. We have issued regulations in part 314 (21 CFR part 314) that establish procedures and requirements for applications submitted in accordance with section 505 of the FD&C Act. The regulations in subpart A (§§ 314.1 through 314.3) set forth general provisions, while regulations in subparts B and C (§§ 314.50 through 314.99) set forth content and format requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) respectively. The regulations include requirements for the submission of specific data elements along with patent information, pediatric use information, supplements and amendments, proposed labeling, and specific postmarketing reports (PMRs). Respondents to the information collection are sponsors of these applications.

Regulations in subpart D (§§ 314.100 through 314.170) explain Agency actions on applications and set forth timeframes for FDA review. The information collection includes provisions established through our Agency user fee programs, most recently authorized under the FDA User Fee Reauthorization Act of 2022. These provisions pertain to performance goals, expedited programs, review transparency, communications with FDA, dispute resolution, drug safety enhancements, and the allocation of Agency resources to align with these program objectives as agreed to with our stakeholders and set forth in our ''User Fee Performance Goals for Fiscal Years 2023–2027'' Commitment Letters, which are available from our website at *https://www.fda.gov* along with more information about specific FDA user fee programs.

Included among the provisions in subpart G (§§ 314.410 through 314.445), § 314.420 covers information to include in drug master files (DMFs). To assist respondents to this information collection we have prepared templates, guidance, forms, and resources available from our website at *https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs.* We have developed Form FDA 3938 and accompanying instructions on submitting DMFs in accordance with the applicable regulations. We are revising Form FDA 3898 and the accompanying instructions to allow for multiple selections of submission types and to clarify the number of digits to be entered for the holder and establishment registration numbers.

In accordance with § 314.445, we also develop Agency guidance documents to assist respondents in complying with provisions in part 314. These guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115. To search available FDA guidance documents, visit our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Applications submitted in accordance with subpart H (§§ 314.500 through 314.560) pertain to accelerated approval of new drugs for serious or life-threatening illnesses.

Information collection and associated burden for the submissions in subpart I (§§ 314.600 through 314.650) pertain to approval of certain new drugs when human efficacy studies are not ethical or feasible. The regulations provide for the submission of specific data elements, animal studies of safety and efficacy to establish likely clinical benefit in humans and upon approval of the drug product, additional requirements and/or restrictions to ensure safe use of the product. Additional PMRs, safety reporting, and promotional material as well as requirements for withdrawal of these human drug applications, and FDA termination of requirements for these human drug applications are included in §§ 314.620 through 314.650. The estimated burden for these human drug applications is included in the reported submissions and burden under general human drug applications, § 314.50, and other specific regulations in the table for human drug application requirements in general.

Finally, we are also revising the collection to include the submission of information pursuant to the CREATES Act (enacted as part of the Further Consolidated Appropriations Act of 2020 (21 U.S.C. 355–1(1) and 355–2)). Under the CREATES Act, developers of potential drug and biological products are enabled to use the CREATES pathway to obtain samples of brand products that are needed to support their applications. Relevant products include those submitted in generic drug applications under section 505(j) of the FD&C Act and NDAs submitted under

section 505(b)(2) of the FD&C Act, and biosimilar products submitted under section 351(k) of the Public Health Service Act as amended by the Biologics Price Competition and Innovation Act of 2009. One of the requirements for using the CREATES pathway for products that are subject to a Risk Evaluation and Mitigation Strategy with elements to assure safe use is to obtain a Covered Product Authorization (CPA) from FDA (21 U.S.C. 355–2(b)(2)). Included in our estimated burden is effort we attribute to information collection activities associated with CPAs.

To assist respondents to the information collection we have developed the following forms:

- Form FDA 356h (and instructions): Application to Market a New or Abbreviated New Drug or Biologic for Human Use
- Form FDA 2252 (and instructions): Transmittal of Annual Reports for Drugs and Biologics for Human Use (§ 314.81)
- Form FDA 2253 (and instructions): Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use
- Forms FDA 3331/3331a (and instructions): Field Alert Reports
- Form FDA 3542 (and instructions): Patent Information Submitted Upon and After Approval of an NDA or Supplement
- FDA 3542a (and instructions): Patent Information Submitted with the Filing of an NDA, Amendment, or Supplement
- Revised Form FDA 3938 (and revised instruction): DMF submission
- Form FDA 3988 (and instruction): Transmittal of post marketing requirements (PMR)/postmarketing commitments (PMC) submissions for Drugs and Biologics
- Form FDA 3989 (and instruction): Transmittal of PMR/PMC Annual Status Report Information

Individuals requesting printed forms are instructed to contact the FDA Forms Manager by email at *formsmanager@OC.FDA.GOV*. Certain fees may be applicable.

Information collection pertaining to hearings and other administrative proceedings covered in 21 CFR subpart E are approved under OMB Control Number 0910–0191. Unless otherwise noted, information collection pertaining to postmarket safety reporting and associated recordkeeping is approved under OMB Control Numbers 0910–0230, and 0910–0291.

Respondents to the information collection are pharmaceutical industry entities who contribute to the preparation and marketing of pharmaceutical products regulated by the FDA.

In the **Federal Register** of September 28, 2023 (88 FR 66853), we published a notice inviting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Subpart B					
314.50(a)–(l)—Content and format of a 505(b)(1) or 505(b)(2) application ..	85	1.42	121	1,921	232,441
314.50(i)(1)—Patent certifications: Form FDA 3542	170	6.55	1,113	10	11,130
314.50(i)(1)—Patent certifications: Form FDA 3542a	1	1	1	15	15
314.50(i)(6) Amended patent certifications	73	4.33	316	2	632
314.52(a), (b), and (e)—NDAs—Notice of noninfringement of patent certification.	15	3	45	15	675
314.52(c)—Noninfringement of patent certification notice content	22	3	66	0.33 (20 minutes)	22
314.53(f)(1)—Correction of patent information errors by persons other than the NDA holder.	7	1.14	8	10	80
314.53(f)(2)—Correction of patent information errors by the NDA holder	8	1.13	9	1	9
314.60—Amendments to unapproved NDA, supplement or resubmission	269	7.22	1,942	80	155,360
314.60(f)—Patent certifications for unapproved applications	6	1	6	2	12
314.65—Withdrawal of unapproved applications	20	1.05	21	2	42
314.70 and 314.71—Supplements and other changes to approved application.	501	5.13	2,570	150	385,500
314.72—Changes of ownership of NDAs	73	1.67	122	2	244
314.81—Other PMR 314.81(b)(1) [3331 and 3331a field alert reports and follow-ups].	532	18.5	9,834	8	78,672
314.81(b)(2)—[Form FDA 2252]—Annual reports	692	4.46	3,090	40	123,600
314.81(b)(2)—[Form FDA 2253]—Promotional labeling	310	121	37,508	2	75,016
314.81(b)(2)(vii) Form FDA 3988—PMR/PMC	737	0.87	642	24	15,408
314.81(b)(2)(vii) Form FDA 3989—PMR/PMC Annual Status Report for Drugs and Biologics.	737	0.29	216	24	5,184
Subpart C					
314.93—Suitability Petitions	16	1.31	21	24	504
314.94(a) and (d)—ANDA content	213	4.02	857	480	411,360
314.94(a)(12)(viii) Amended patent certifications before approval of ANDA	153	1	153	2	306
314.95(c)—Noninfringement of patents (ANDAs)	209	3	627	16	10,032
314.96(a)(1)—Amendments to unapproved ANDAs	514	26.55	13,647	80	1,091,760
314.96(c) Amendment for pharmaceutical equivalent to a listed drug other than reference listed drug.	1	1	1	300	300
314.96(d)—Patent certification requirements	100	1	100	2	200
314.97—Supplements and other changes to ANDAs	343	17.57	6,027	80	482,160
314.97(b) Supplements to ANDA for pharmaceutical equivalent to a listed drug other than RLD.	1	1	1	300	300
314.99(a)—ANDA Applicants: Withdrawal of unapproved ANDAs	58	2.41	140	2	280
314.99(a)—ANDA Transfer of ownership	137	1.24	170	2	340
Subpart D					
314.101(a)—NDA or ANDA filing over protest	1	1	1	0.5 (30 minutes)	0.5

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]

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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