with a history of jet lag disorder. The other studies were conducted in healthy individuals with no evidence of experiencing jet lag disorder. Dr. Dunn evaluated Study 2102 and the other study submitted by Vanda as supportive evidence, Study VP–VEC–162–2101, and concluded that they were small phase 2 studies with design and methodological limitations. He also noted that jet lag disorder presents a series of complaints and symptoms beyond sleep disturbances and daytime sleepiness, and the sleep disturbances of jet lag disorder typically persist over several days. Because Studies 3101 and 3107 lacked robust assessment of important additional endpoints that might have been able to address these characteristics of jet lag disorder, Dr. Dunn concluded the data submitted do not support a finding of substantial evidence of effectiveness of tasimelteon for treatment of jet lag disorder. He also denied Vanda's requests: (1) for the Division to consider a narrower indication for treatment of insomnia and daytime sleepiness in jet lag disorder, because that request was raised after the complete response letter and therefore was outside the scope of the dispute resolution process and (2) for FDA to convene an Advisory Committee to answer the question of whether the supplement had provided substantial evidence of effectiveness, because he found no scientific questions that would have been appropriate for consideration by an Advisory Committee.

Vanda submitted another FDRR on September 2, 2020, for review of the Office of Neuroscience denial. Dr. Mary Thanh Hai, then-Acting Deputy Director of the Office of New Drugs (OND), denied the second FDRR on behalf of OND by correspondence dated October 21, 2020, based on her determination that the application did not provide substantial evidence of effectiveness for tasimelteon for treatment of jet lag disorder. Dr. Thanh Hai noted that the regulatory history of this development program revealed very clear advice from FDA on the study population and recommended endpoints for clinical trials to support a marketing application for the treatment of jet lag disorder. She also agreed with Dr. Dunn's denial of Vanda's requests regarding a narrower indication and convening an Advisory Committee.

On July 1, 2022, Vanda submitted a request for an opportunity for a hearing under § 314.110(b)(3) on whether there are grounds under section 505(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(d)) for denying approval of sNDA 205677–004.

II. Notice of Opportunity for a Hearing

For the reasons stated above and as explained in further detail in the August 16, 2019, complete response letter and the August 4, 2020, and October 21, 2020, FDRR denials, notice is given to Vanda and all other interested persons that the Center Director proposes to issue an order refusing to approve sNDA 205677–004 on the grounds that the application fails to meet the criteria for approval under section 505(d) of the FD&C Act because there is a lack of substantial evidence that the drug is effective for treatment of jet lag disorder (section 505(d)(5) of the FD&C Act).[4]

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 205677–004. 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 205677–004 based on the multiple deficiencies summarized above, any hearing request from Vanda must address all of 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 205677–004.

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 (§ 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 (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.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Sateia, M., ''Jet Lag Disorder,'' *International Classification of Sleep Disorders,* 3rd ed., Illinois: American Academy of Sleep Medicine, pp. 220–224, 2014.

* 2. FDA Guidance for Industry and Review Staff, ''Formal Dispute Resolution: Sponsor Appeals Above the Division Level,'' November 2017, (available at *https://www.fda.gov/media/126910/download*), accessed August 30, 2022.

Dated: October 4, 2022.

Jacqueline Corrigan-Curay,

Principal Deputy Center Director, Center for Drug Evaluation and Research.

[FR Doc. 2022–21932 Filed 10–7–22; 8:45 am]

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[4] Section 505(d)(5) of the FD&C Act provides that FDA shall refuse to approve an NDA supplement if ''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[.]'' For the reasons explained in this notice, CDER has concluded that the data and information submitted in the supplement do not show that the drug is effective for the proposed conditions of use.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will convene the 75th full council meeting virtually on Monday, October 17, 2022 from approximately 12:00–2:00 p.m. (ET). The meeting will be open to the public and there will be a public comment session; pre-registration is required to provide public comment. To pre-register to provide public comment, please send an email to *PACHA@hhs.gov* and include your name, organization, and title by close of business Monday, October 10, 2022. There is also an option to submit written statement by emailing *PACHA@hhs.gov* by close of business Monday, October 24, 2022. The meeting agenda will be posted on the PACHA page on *HIV.gov* at *https://www.hiv.gov/federal-response/pacha/about-pacha* prior to the meeting.

DATES: The meeting will be held on Monday, Monday, October 17, 2022 from approximately 12:00–2:00 p.m. (ET).

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Senior Management Analyst, at *PACHA@hhs.gov* or *Caroline.Talev@hhs.gov* or 202–795–7622. Additional information can be obtained by accessing the Council's page on the *HIV.gov* site at *www.hiv.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 14048, dated September 30, 2021. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective HIV diagnosis, treatment, prevention, and quality care services. The functions of the Council are solely advisory in nature.

The Council consists of not more than 35 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, population health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. PACHA selections also include persons with lived HIV experience and racial/ethnic and sexual and gender minority persons disproportionately affected by HIV. Council members are appointed by the Secretary.

B. Kaye Hayes,

Deputy Assistant Secretary for Infectious Disease, Director, Office of Infectious Disease and HIV/AIDS Policy, Executive Director, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2022–22013 Filed 10–7–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0020]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before December 12, 2022.

ADDRESSES: Submit your comments to *sagal.musa@hhs.gov* or by calling (202) 205–2634.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040–0020–60D and project title for reference, to Sagal Musa, email: *sagal.musa@hhs.gov,* or call (202) 205–2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: SF–424 Mandatory Form.

Type of Collection: Renewal.

OMB No.: 4040–0020.

Abstract: The Standard 424 Mandatory form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Agencies may use SF–424 Mandatory Form for grant programs not required to collect all the data that is required on the SF–424 core data set and form.

Type of respondent: The SF–424 Mandatory form is used by organizations to apply for Federal financial assistance in the form of grants. This form is submitted to the Federal grant-making agencies for evaluation and review. This IC expires on January 31, 2023. *Grants.gov* seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
SF424 Mandatory Form	Grant Applicants	5761	1	1	5761
Total		5761	1	1	5761