hearing participant requesting approval of a drug application).

IV. Factual Issues for the Hearing

The central factual issue for the hearing is whether Vanda has provided substantial evidence that HETLIOZ (tasimelteon) is effective for treatment of jet lag disorder. As noted by CDER, the decision by the Court of Appeals for the D.C. Circuit included two key holdings that limit the factual scope of the hearing with respect to that central issue. First, the Court upheld FDA's previous conclusion that the question for any hearing on this matter would be whether there is substantial evidence of effectiveness for the indication in the sNDA's proposed labeling—as opposed to any narrower or modified indication that Vanda might now propose, such as treatment of insomnia related to jet lag disorder (*Vanda,* 150 F.4th at 578–79). Second, the Court held that FDA ''reasonably determined'' that approval of the proposed indication for HETLIOZ (tasimelteon)—treatment of jet lag disorder—requires establishing an effect on both sleep and next-day impairment (Id. at 577 (finding that Vanda has an ''obligation to prove [effectiveness regarding] the second symptom of jet lag, next-day impairment'' and that it is not adequate to ''show only that tasimelteon can remedy sleep-disturbance symptoms'')).

On May 15, 2026, pursuant to 21 CFR 12.85(a)(4), CDER submitted to the Dockets Management Staff, *inter alia,* a narrative position statement that, consistent with the deficiencies listed in the NOOH and the decision by the Court of Appeals for the D.C. Circuit, identifies eight specific issues for the hearing:

1. Whether Vanda failed to demonstrate that the primary endpoints in Studies 2102, 3101, and 3107 were appropriate to assess effectiveness of tasimelteon for the treatment of jet lag disorder.
2. Whether Vanda failed to demonstrate that the secondary endpoints in Studies 2102, 3101, and 3107 were appropriate to assess effectiveness of tasimelteon for the treatment of jet lag disorder.
3. Whether the sNDA provides sufficient evidence of an effect on symptoms that are integral to jet lag disorder, such that effectiveness could be established for the proposed indication—treatment of jet lag disorder.
4. Whether Vanda's analysis of the secondary endpoints in Studies 2102, 3101, and 3107 lacks the statistical rigor to reliably support conclusions about the effectiveness of tasimelteon for the treatment of jet lag disorder.
5. Whether the interpretability of Studies 3101 and 3107 is impaired by the failure to include sufficient data (*e.g.,* via collecting baseline polysomnograms or other methods) to determine whether subjects experienced a sleep disturbance after undergoing a phase advance in the laboratory setting.
6. Whether Vanda failed to provide adequate data to demonstrate effectiveness of the drug when administered according to the dosing and administration information in the proposed labeling.
7. Whether Vanda's assessment of next-day functioning was inadequate.
8. Whether Vanda's application lacks adequate data to characterize the use of tasimelteon to treat jet lag disorder associated with westward travel (CDER's Narrative Position Statement, 5–6).

The presiding officer may further revise the factual issues for the hearing under 21 CFR 12.35(b).

V. Parties to the Hearing

The parties to the hearing will be FDA's CDER and Vanda. Other interested persons shall be permitted to participate as nonparty participants as provided by 21 CFR 12.45 and 12.89.

VI. Disclosure of Information by CDER, Vanda, and Other Hearing Participants

In accordance with 21 CFR 12.85(a), CDER has filed with the Dockets Management Staff a narrative statement setting forth its position on the issues of the hearing and a summary of the types of evidence to be introduced in support of its position in the hearing, together with copies of data and information contained in the Center's files that relate to the issues to be resolved at the hearing. Hearing participants other than CDER, including Vanda, shall disclose data and information and submit their narrative statements pursuant to 21 CFR 12.85(b) to the Dockets Management Staff (see **ADDRESSES**) on or before August 3, 2026, or within another period of time set by the presiding officer. Interested persons may also examine the data on the drug subject to this hearing notice (with the exception of any data identified as confidential pursuant to the provisions of 21 CFR 10.20(j)) via *https://www.regulations.gov* or at the Dockets Management Staff, between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

VII. Prehearing Conference

The prehearing conference will be held on July 20, 2026, beginning at 10:00 a.m. Eastern Daylight Time, by videoconference with instructions to be provided. The hearing will be held on a date to be set at the prehearing conference. Written notices of participation shall be filed with the Dockets Management Staff no later than July 6, 2026. All participants are required both to attend the prehearing conference and to be prepared to comply with the provisions of 21 CFR 12.92.

VIII. Conclusion

In accordance with the foregoing, under section 505 the FD&C Act (21 U.S.C. 355) and under authority delegated to me, I order that a formal evidentiary public hearing be held on the issues set out in this notice. The hearing will be open to the public by visiting the HHS Live Streaming page at *www.hhs.gov/live.* A direct link for the hearing will be visible on the HHS Live Streaming page once a hearing date has been set by the presiding officer after the prehearing conference. Interested persons are encouraged to monitor the docket for any updated links for public access.

IX. References

1. U.S. Department of Health and Human Services, Departmental Appeals Board, Civil Remedies Division, Vanda Pharmaceuticals, Inc. Supplemental New Drug Application for Hetlioz (Tasimelteon), C–26–457, Case Development Order [Civil Remedies Division Procedures, March 28, 2016], June 3, 2026.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–11046 Filed 6–2–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2602]

Third Annual Animal Drug User Fee Educational Conference; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following educational conference (public meeting) entitled ''Third Annual Animal Drug User Fee Educational Conference.'' This is the third of five annual educational conferences FDA will host as described in the ''Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028.'' The purpose of this series of conferences is to provide educational sessions for stakeholders who are interested in the new animal drug approval process.

DATES: The third educational conference will be held on July 7, 2026, from 9 a.m. to 1 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration dates and information. You may submit comments at any time for this series of educational conferences. We request that you submit either electronic or written comments within 90 days after each annual educational conference to ensure that the Agency considers your comment on a topic discussed at that conference.

ADDRESSES: The third educational conference will be available in person and virtually. The in-person conference will be held at the Harvey W. Wiley Federal Building, 5001 Campus Drive, Room 1A–001, College Park, MD 20740. Routine security check procedures will be performed at the entrance to the building. Participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to *https://www.dhs.gov/real-id/real-id-faqs.* Persons interested in attending this educational conference must register at: *https://events.gcc.teams.microsoft.com/event/8a5f6cc5-9964-48f3-8ae6-b8041bdef77e@7d2fdb41-339c-4257-87f2-a665730b31fc.*

You may submit comments as follows.

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–2024–N–2602 for ''Third Annual Animal Drug User Fee Educational Conference.'' Received comments 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: Krystyna Reign, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240–402–0631, *adufa_v_edu_conference@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Animal Drug User Fee Act (Pub. L. 108–130) (ADUFA or the Act) was originally signed into law in 2003 and was subsequently reauthorized by Congress in 2008, 2013, 2018, and 2023. ADUFA authorizes FDA to collect fees for certain new animal drug applications, products, establishments, and sponsors. Resources generated under ADUFA supplement the Agency's funding to enhance the performance of the drug review process, ensuring that new animal drug products are safe and effective for animals, and that food derived from treated animals will be safe for consumption. FDA considers the timely review of the safety and effectiveness of new animal drug applications to be central to the Agency's mission to protect and promote human and animal health.

The Animal Drug User Fee Amendments of 2023 (ADUFA V), the most recent reauthorization of the Act, authorizes FDA to collect user fees through fiscal year 2028. ''The Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028'' (Performance Goals Letter) sets forth the Agency's performance goals for the period covered by ADUFA V. Among other goals, the document commits the Agency to hosting triannual meetings (three meetings per calendar year) with Animal Health Institute (AHI) members, one of which will consist of an educational conference of up to 8 hours for the animal drug industry. This notice announces the third of these annual Animal Drug User Fee Educational Conferences. These conferences are open to the public.

II. Topics for Discussion at the Educational Conference

As described in the Performance Goals Letter, FDA will plan a series of topics for the educational conferences during the 5 years of ADUFA V. While the agenda for each educational conference is determined by the Agency with input from AHI, all stakeholders

are welcome to submit comments to the docket requesting topics to be included for future educational conferences (see **ADDRESSES**).

This third conference will focus on the following topics:

(1) Overview of Available Regulatory Pathways
(2) Conditional Approval and Indexing for Minor Use/Minor Species (MUMS)
(3) Expanded Conditional Approval and Reasonable Expectation of Effectiveness
(4) Real World Example of Regulatory Flexibility During a Public Health Emergency
(5) Animal Biotechnology Products and the Veterinary Innovation Program (VIP)
(6) Protocol Quality and Best Practices

The conference will also contain a Q&A session during which FDA will address specific questions from the in-person and virtual audience as time allows. Questions and comments received during each annual conference and comments submitted to the docket will inform the conversation and topics considered in subsequent conferences.

III. Participating in the Educational Conference

Registration: This educational conference is open to the public and will be available virtually and in-person. When registering, please provide complete contact information for each attendee, including name, title, affiliation (if any), address, and email. Also, please self-identify as a member of one of the stakeholder categories: regulated industry, scientific or academic experts, veterinary professionals, consumer advocacy groups, press/media relations, FDA, other government/congress, or other.

Early registration is recommended for persons who wish to attend in person. Registrants will receive confirmation when their registration has been received, and they will be provided the webcast link. Persons interested in attending this conference virtually may register until the start time of the conference. Persons interested in attending this conference in person are encouraged to register online at *https://events.gcc.teams.microsoft.com/event/8a5f6cc5-9964-48f3-8ae6-b8041bdef77e@7d2fdb41-339c-4257-87f2-a665730b31fc* no later than June 25, 2026.

If you need special accommodations due to a disability, please contact Krystyna Reign (see **FOR FURTHER INFORMATION CONTACT**) no later than June 25, 2026.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–11101 Filed 6–2–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–1257]

Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft document entitled ''Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing.'' The draft guidance document provides sponsors engaged in the development of human gene therapy (GT) products incorporating ex-vivo and in vivo genome editing (GE) of human somatic cells (GE products) with FDA's recommendations on the type of prior knowledge that may be scientifically appropriate to leverage to advance product development.

DATES: Submit either electronic or written comments on the draft guidance by September 1, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2026–D–1257 for ''Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing; Draft Guidance for Industry.'' Received comments 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