DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5976]

Use of Cannabis-Derived Products, Including Cannabidiol, in Veterinary Practice; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is soliciting comments from the public, particularly veterinarians, related to the use of cannabis-derived products (CDPs) in animals, with an emphasis on cannabidiol (CBD) products and general trends associated with those products, including information about: usage trends (*e.g.,* product selection, indications, etc.), quality standards, benefits of use, potential drug interactions, adverse events and safety problems, and toxicological concerns. This information will enhance the Center for Veterinary Medicine's (CVM's) knowledge of potential safety signals associated with these products, in addition to aiding our understanding of veterinarians' experiences related to the use of CDPs for their animal patients.

DATES: Either electronic or written comments on the request for information must be submitted by April 16, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 16, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–5976 for ''Use of Cannabis-Derived Products, including Cannabidiol, in Veterinary Practice; Request for Information.'' 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.'' We will review this copy, including the claimed confidential information, in our 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: Katherine Breed, Center for Veterinary Medicine, Food and Drug Administration, 12225 Wilkins Ave., Rockville, MD 20852, 301–796–9361, *Katherine.Breed@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The CDP marketplace has grown significantly in the past few years as the U.S. Government removed certain restrictions related to specific aspects of the Cannabis plant's use and distribution. The Agricultural Act of 2014 (also known as the 2014 Farm Bill (*https://www.congress.gov/bill/113th-congress/house-bill/2642*)) specifically defined ''industrial hemp'' as any part of the Cannabis sativa L. plant with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis, allowing its use in limited situations for research purposes only. The Agricultural Improvement Act of 2018 (also known as the 2018 Farm Bill (*https://www.congress.gov/bill/115th-congress/house-bill/2*)) further relaxed certain Federal restrictions on hemp, which resulted in allowing interstate commerce of hemp and removing hemp from the Controlled Substances Act statutory definition of marijuana, among other changes. The 2018 Farm Bill also explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds, including hemp, under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act (see 7 U.S.C. 1639r(c)).[1]

[1] See 86 FR 5596, *https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd* (see Question 2).

CVM is particularly interested in input from practicing veterinarians, whose expertise and experience can help inform FDA regarding the use and effect of CDPs in animals. FDA is gathering information relating to the use of CDPs in animals, with an emphasis on CBD products and other hemp-derived products and general trends associated with those products. For purposes of this request for information, ''cannabis'' refers to plants that can be further defined as either ''hemp'' or ''marijuana,'' depending on their delta-9 THC concentration. The focus of this request for information is hemp-derived products, and we use the term ''hemp'' to refer to the plant species Cannabis sativa L. and any part of that plant, including the seeds and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis. We are interested in information about the use of hemp-derived products (typically labeled as products containing CBD) and not marijuana-derived products.

Firms marketing CBD products for use in (non-human) animals often make claims regarding a wide variety of diseases or conditions. Some products are also purported to enhance general wellness and promote longevity. Products are marketed in many different formulations, such as tinctures/oils, treats/chews, pellets for large animals, capsules, and sometimes as food toppers or infused in foods such as peanut butter; topical products infused with CBD, such as balms and shampoos, are also available for pets. Products that are intended for use in the cure, mitigation, treatment, or prevention of diseases in animals are animal drugs.

Currently, no FDA-approved, conditionally approved, or indexed animal drugs contain CBD. However, with respect to human drugs, FDA has approved one cannabis-derived drug product: EPIDIOLEX (cannabidiol), and three synthetic cannabis-related drug products: MARINOL (dronabinol), SYNDROS (dronabinol), and CESAMET (nabilone). Under the Animal Medicinal Drug Use Clarification Act of 1994 and its implementing regulations at 21 CFR part 530, under certain conditions, veterinarians can lawfully prescribe approved human drugs for use in animals in an extralabel manner.

FDA has made the regulation of the CBD market a priority, including products marketed for animals. While there is some limited published information about use of CDPs in animals, significant data gaps exist surrounding many aspects of CBD and other CDPs in animals, and further research is necessary to assess the safety and effectiveness of these products. FDA is seeking a better understanding of what veterinarians are experiencing related to CDPs in their patients, such as: general patterns of use (*i.e.,* animal species, brands, formulations, doses, indications for use), quality standards, benefits of use, potential drug interactions, adverse events and safety problems, and toxicological concerns.

II. Questions for Consideration

We are particularly interested in input on the following questions regarding veterinarians' experiences related to CDPs in their patients (*Note:* You may submit your comment anonymously if you do not wish to provide your name along with your response. CVM will fully consider all comments. (*https://www.regulations.gov/faq*)):

1. Are you a veterinarian licensed to practice veterinary medicine in the United States? If so, in which State(s) do you hold an active license? Please indicate how many years of experience, as a practicing veterinarian, you have. Please indicate the type of community (*i.e.,* urban, suburban, or rural) that best describes where you work.

2. Are you in clinical practice, meaning, do you have physical contact with client-owned animals? If so, what species does your practice see (*e.g.,* food-producing species such as cattle, poultry, etc., and/or nonfood-producing species such as dogs, cats, etc.)?

3. Have clients asked you about using products derived from cannabis in their animals? If so, please describe approximately how often (weekly, monthly, quarterly, annually) your clients ask and describe for which animal species and for what indications your clients are using (or are interested in using) cannabis-derived products.

4. When clients ask about products derived from cannabis, do they generally distinguish between products derived from hemp versus those derived from marijuana (*i.e.,* do they ask about hemp products, marijuana products, or do they not specify)? What brands (if known) and formulations or types of products do clients ask about (*e.g.,* tinctures, treats, capsules, topical products, etc.)?

5. Have you prescribed or dispensed EPIDIOLEX, MARINOL, SYNDROS, or CESAMET for use in any of your patients? If so, which drug(s) for what species, and what was the reason or indication for which you prescribed or dispensed these drugs for animal patients?

6. Do you use or recommend hemp-derived cannabis products for your animal patients? If so, are you confident that the products you use or recommend are labeled accurately (*e.g.,* concentration, ingredients, etc.)? What factors influence your decision on which brand of hemp-derived cannabis product to use or recommend (*e.g.,* certificate of analysis, research, continuing education lectures, etc.)? What CBD:THC cannabinoid ratio in hemp-derived cannabis products do you use or recommend for your animal patients (if known)?

7. Describe your practices surrounding recommendations of hemp-derived cannabis products for your animal patients including: for what indications do you use or recommend hemp-derived cannabis products; for which species; and which dosage forms (*e.g.,* oral, topical, inhalation), dose, brand, and cannabinoid(s) do you prefer? What information sources do you use to make these treatment decisions (continuing education, specialist recommendations, industry recommendations, etc.)? Describe any benefits of use related to hemp-derived cannabis products in your patients.

8. Related to hemp-derived cannabis products only: Have clients reported to you, or have you observed, adverse effects following an animal being administered a hemp- derived cannabis product (*i.e.,* after a client intentionally administered a hemp-derived cannabis product, not accidental ingestion of adult recreational use products)? If so, please describe each event(s) including animal species, clinical signs and severity of the adverse event, product/dose/route of exposure (if known), whether veterinary intervention was needed, and whether the animal recovered, or the adverse event resulted in death. Did you report any adverse events to FDA?

9. Do you have questions or concerns about drug interactions between hemp-derived cannabis products and other medications? For purposes of this information request, we are interested in interactions with any product used for medical purposes, including FDA-approved drugs, United States Department of Agriculture-licensed biologics, and other products, such as veterinary nutraceuticals and veterinary phytotherapy (plant-derived) products. Are you concerned about, or have you seen potential drug interactions (*e.g.,* reduction in the effectiveness, safety margin, or both, of either the hemp-derived cannabis products or the other medications) between hemp-derived cannabis products and other medications?

10. If you do not use or recommend hemp-derived cannabis products for

your animal patients, what factors have influenced your decision (*e.g.,* legal issues surrounding cannabis, safety concerns, effectiveness concerns, product quality concerns, not found a need, etc.)? If you do not use or recommend hemp-derived cannabis products for your animal patients for reasons other than effectiveness concerns, are there any indications and species for which you believe they could be effective and why?

Dated: January 10, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00945 Filed 1–15–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5933]

Proposal to Refuse to Approve a New Drug Application for TRADIPITANT; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Director of the Center for Drug Evaluation and Research (Center Director) at the Food and Drug Administration (FDA or Agency) is proposing to refuse to approve a new drug application (NDA) submitted by Vanda Pharmaceuticals, Inc. (Vanda), for TRADIPITANT capsules, 85 milligrams (mg), in its present form. This notice summarizes the grounds for the Center Director's proposal and offers Vanda an opportunity to request a hearing on the matter.

DATES: Either electronic or written requests for a hearing must be submitted by February 18, 2025; submit data, information, and analyses in support of the hearing and any other comments by March 17, 2025.

ADDRESSES: You may submit hearing requests, documents in support of the hearing, and any other comments as follows. Please note that late, untimely filed requests and documents will not be considered. The *https://www.regulations.gov* electronic filing system will accept hearing requests until 11:59 p.m. Eastern Time at the end of February 18, 2025, and will accept documents in support of the hearing and any other comments until 11:59 p.m. Eastern Time at the end of March 17, 2025. Documents received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before these dates.

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'').

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- 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–5933 for ''Proposal To Refuse To Approve a New Drug Application for TRADIPITANT; Opportunity for a Hearing.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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: Tereza Hess, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 202–768–5659, *tereza.hess@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Proposal To Refuse To Approve NDA 218489

Vanda submitted NDA 218489 for TRADIPITANT capsules, 85 mg, on September 18, 2023, pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(1)). Vanda proposed that TRADIPITANT capsules be indicated for ''the treatment of [symptoms of] or [nausea in] in gastroparesis.''

To support a demonstration of substantial evidence of effectiveness, Vanda referred to two randomized, double-blind, placebo-controlled studies (Study 2301 and Study 3301, Group 1), and the following additional data submitted as confirmatory evidence: (1)