received patent term restoration applications for KEBILIDI (U.S. Patent Nos. 10,898,585 and 11,865,188) from National Taiwan University, and the USPTO requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated September 23, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of KEBILIDI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for KEBILIDI is 1,612 days. Of this time, 1,368 days occurred during the testing phase of the regulatory review period, while 244 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* June 17, 2020. The applicant claims March 29, 2020, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 17, 2020, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* March 15, 2024. FDA has verified the applicant's claim that the biologics license application (BLA) for KEBILIDI (BLA 125722) was initially submitted on March 15, 2024.

3. *The date the application was approved:* November 13, 2024. FDA has verified the applicant's claim that BLA 125722 was approved on November 13, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 277 or 816 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–02976 Filed 2–12–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2925]

Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry (GFI) #273 entitled ''Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals.'' This guidance document provides recommendations on how sponsors may voluntarily establish defined durations of use for certain antimicrobial new animal drugs used in or on the medicated feed of food-producing animals that are currently approved with one or more indications that lack a defined duration of use. Establishing defined durations of use within the approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) is intended to mitigate development of antimicrobial resistance for these antimicrobial drugs, which are important to human medicine. It also proposes timelines for sponsors to voluntarily align their affected applications with this guidance.

DATES: The announcement of the guidance is published in the **Federal Register** on February 13, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency 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–2023–D–2925 for ''Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-

Producing Animals.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, U.S. Food and Drug Administration, Center for Veterinary Medicine, CPK1, 5001 Campus Drive, College Park, MD 20740–3835. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: *askCVM@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 26, 2023 (88 FR 66009), FDA published the notice of availability for a draft guidance entitled ''Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals'' giving interested persons until December 26, 2023, to comment on the draft guidance. In response to a request for an extension, the comment period was extended to January 5, 2024 (88 FR 82384, November 24, 2023).

FDA received 4,511 comments on the draft guidance from a variety of interested parties; 4,495 comments were campaign letters and from individuals, and 16 comments were from consumer advocacy groups, industry associations, pharmaceutical companies, academia, and veterinary organizations. The comments received from the campaign letters, consumer advocacy groups, and individuals primarily requested that FDA limit all durations of use to no more than 21 days and requested that drug sponsors provide data demonstrating that the established durations do not lead to increased antimicrobial resistance. The comments from industry associations, pharmaceutical companies, academia, and veterinary organizations expressed concerns regarding the timelines proposed in the draft guidance, sought assurance the antimicrobial resistance mitigation statements be clearly worded and consistently included on labeling, sought assurance that data and information used to justify newly-defined durations of use be of high quality and transparent, and expressed concerns that veterinarians may authorize the maximum labeled duration in practice if only a maximum duration is established. All comments were considered as the guidance was finalized.

Changes were made to the final guidance to (1) revise the anticipated submissions and overall project timelines, (2) clarify the discussion regarding mitigation statements with the inclusion of examples of such statements for illustrative purposes, (3) request that sponsors propose and justify a typical duration range, in addition to the maximum permitted duration, that encompasses durations that veterinarians would authorize in most circumstances, and (4) include criteria that should be followed to ensure that the justification of the typical duration range and maximum permitted duration is comprehensive, focused, balanced, and limits bias. The recommended directions for use statements in this guidance were revised accordingly and now describe the typical duration range as well as the maximum permitted duration. Other editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 23, 2023.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on defining durations of use for approved medically important antimicrobial drugs fed to food-producing animals. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be neither regulatory nor deregulatory.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032; the collections of information in section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov/.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–02934 Filed 2–12–26; 8:45 am]

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