DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3614]

Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available as Over-the-Counter; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a final guidance for industry (GFI) #263 entitled ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to Be Available as Over-the-Counter.'' This guidance document provides information to sponsors of medically important antimicrobial new animal drug products who are interested in changing the approved marketing status of these products from over-the-counter (OTC) to by veterinary prescription (Rx) consistent with FDA's recommendation that the use of such drugs in animals be limited to uses that include veterinary oversight to mitigate development of antimicrobial resistance. It also establishes timelines for stakeholders wishing to comply voluntarily with this guidance.

DATES: The announcement of the guidance is published in the **Federal Register** on June 11, 2021.

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–2019–D–3614 for ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to Be Available as Over-the-Counter.'' 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 (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 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: John M. Mussman, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0589, email: *john.mussman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 25, 2019 (84 FR 50456), FDA published a notice of availability of a draft guidance entitled ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to Be Available Over-the-Counter'' giving interested persons until December 24, 2019, to comment on the draft guidance. FDA received comments on the draft guidance, which were considered as the guidance was finalized. Some comments addressed the process outlined in the draft guidance, specifically the proposed timeframe for sponsors to facilitate voluntary changes to the approved conditions of use of these drugs to prescription marketing status. Further, FDA notes that, in general, many of the comments received did not address the

specific process outlined in the draft guidance, but rather addressed support for, or concerns with, the underlying policy of judicious use of medically important antimicrobials in animals, specifically the principle of limiting medically important antimicrobial drugs to uses in animals that include veterinary oversight or consultation. As described in FDA GFI #209, ''The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals'' (77 FR 22328, April 13, 2012), the development of resistance to this important class of drugs, and the resulting loss of their effectiveness as antimicrobial therapies, poses a serious public health threat. Developing strategies to reduce antimicrobial resistance is critically important for protecting both public and animal health. This guidance is an extension of FDA's ongoing efforts to promote the appropriate or judicious use of medically important antimicrobial drugs in animals.

This guidance provides information to sponsors of new animal drug products containing antimicrobials of human medical importance who are interested in changing the approved marketing status of these products from OTC to Rx with specific recommendations on submission of revised labeling. Such changes are consistent with FDA's recommendation that the use of such antimicrobial drugs in animals include veterinary oversight in order to mitigate development of antimicrobial resistance and thereby preserve the effectiveness of these drugs for use as therapies to treat infections in humans and animals. The guidance also identifies timelines for stakeholders wishing to comply voluntarily with this guidance; these timelines remain as outlined in the draft guidance. In the final guidance, editorial changes were made to improve clarity.

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 recommendations for drug sponsors for voluntarily bringing under veterinary oversight all medically important antimicrobial drugs approved for use in animals that continue to be available as OTC products. 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. 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; the collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: June 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12297 Filed 6–10–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–E–2079]

Determination of Regulatory Review Period for Purposes of Patent Extension; BRAVECTO; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or Agency) published a notice in the **Federal Register** of February 12, 2018. After review of a timely request for reconsideration by the applicant of the determination of the regulatory review period of the animal drug, BRAVECTO, in that notice, FDA has determined that a revision of the **SUPPLEMENTARY INFORMATION** section is warranted. This document presents the revised regulatory review period.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 12, 2018 (83 FR 6033), in FR Doc. 2018–02761, in the first column, the first two paragraphs under the section ''II. Determination of Regulatory Review Period,'' the following correction is made on page 6034:

FDA has determined that the applicable regulatory review period for BRAVECTO is 1,054 days. Of this time, 1,016 days occurred during the testing phase of the regulatory review period, while 38 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) became effective:* June 28, 2011. The applicant claims February 19, 2010, as the date the investigational new animal drug application (INAD) became effective. However, after consideration of additional information presented by the applicant in response to the **Federal Register** notice (83 FR 6033), FDA has determined that the start of the testing phase was June 28, 2011, which was the date the first major health or environmental effects test began.

Dated: June 3, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12284 Filed 6–10–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1261]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Study of Disclosures to Healthcare Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by July 12, 2021.