

specific process outlined in the draft guidance, but rather addressed support for, or concerns with, the underlying policy of judicious use of medically important antimicrobials in animals, specifically the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timelines for stakeholders wishing to comply voluntarily with this guidance; these timelines remain as outlined in the draft guidance.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]

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## 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.