to the drug. However, in 1984, the Anti-Infective Drugs Advisory Committee concluded that intramuscular administration of bacitracin was not safe and effective. In addition, in April 2019, FDA's Antimicrobial Drugs Advisory Committee advised that the benefits of bacitracin for injection do not outweigh its risks for the drug's only approved indication.

Bacitracin for injection poses serious risks, including nephrotoxicity and anaphylactic reactions. Healthcare professionals generally no longer use bacitracin for injection to treat infants with pneumonia and empyema because other effective FDA-approved treatments are available that do not have these risks. Out of concern about these risks, on January 31, 2020, FDA requested that all application holders of bacitracin for injection voluntarily request withdrawal of approval of their applications under § 314.150(d) (21 CFR 314.150(d)). Two approved applications for bacitracin for injection had been withdrawn prior to January 31, 2020 (see 61 FR 40649, August 5, 1996, and 57 FR 6228, February 21, 1992) and therefore FDA did not need to request their withdrawal. In a letter dated February 7, 2020, Pfizer requested withdrawal of approval of ANDA 060733 (originally NDA 6–483) for bacitracin for injection under § 314.150(d) and waived its opportunity for a hearing. In separate letters dated February 5, 2020, Akorn Inc. and Mylan ASI LLC requested that FDA withdraw approval of ANDAs 206719 and 090211, respectively, under § 314.150(d) and waived their opportunity for a hearing. Additionally, in separate letters dated February 7, 2020, X–GEN Pharmaceuticals, Inc. and Fresenius Kabi USA, LLC requested that FDA withdraw approval of ANDAs 064153 and 065116, respectively, under § 314.150(d) and waived their opportunity for a hearing. In the **Federal Register** of March 12, 2021 (86 FR 14127), FDA announced that it was withdrawing approval of ANDAs 060733 (originally NDA 6–483), 206719, 090211, 064153, and 065116, and all amendments and supplements thereto, effective March 12, 2021.

In a letter dated June 14, 2021, the only remaining application holder, Xellia Pharmaceuticals USA, LLC, requested that FDA withdraw approval of ANDA 203177 under § 314.150(d) and waived its opportunity for a hearing. In the **Federal Register** of July 11, 2022 (87 FR 41135), FDA announced that it was withdrawing approval of ANDA 203177, and all supplements thereto, effective July 11, 2022. Accordingly, the Agency has withdrawn approval of all ANDAs for bacitracin for injection.

After reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that bacitracin for injection, 10,000 units/vial and 50,000 units/vial, was withdrawn for reasons of safety or effectiveness. We have reviewed our files for records concerning the withdrawal of bacitracin for injection from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. Based on a thorough evaluation of this information, including information presented to FDA's Antimicrobial Drugs Advisory Committee and the recommendations of that committee, and an evaluation of the latest version of the drug product's labeling, we have determined that bacitracin for injection, 10,000 units/vial and 50,000 units/vial, would not be considered safe and effective if it were introduced to the market today in the absence of new preclinical or clinical studies to address safety or effectiveness concerns identified during our review.

Accordingly, the Agency will remove bacitracin for injection, 10,000 units/vial and 50,000 units/vial, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Dated: September 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19995 Filed 9–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0176]

Defining Small Number of Animals for Minor Use Determination; Periodic Reassessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of its most recent periodic reassessment of the definition of ''small number of animals'' for minor use in major species (contained in our existing regulation for new animal drugs for minor use and minor species). We also are announcing that the small number of animals upper limit thresholds (small numbers) for horses and the food-producing major species (cattle, pigs, turkeys, and chickens) will remain the same. We are separately issuing a direct final rule and a companion proposed rule to revise (*i.e.,* increase) the small numbers for dogs and cats.

DATES: Submit either electronic or written comments on the notice at any time.

ADDRESSES: 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–2008–N–0176 for ''Defining Small Numbers of Animals for Minor Use Determination; Periodic Reassessment.'' 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: Margaret Oeller, Center for Veterinary Medicine (HVF–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0566, email: *margaret.oeller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Minor Use and Minor Species Animal Health Act of 2004 (Pub. L. 108–282) (the MUMS Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide incentives for the development of new animal drugs for use in minor animal species and for minor uses in major animal species. The MUMS Act defines ''minor use'' as the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually (see section 201(pp) of the FD&C Act (21 U.S.C. 321(pp)).

In the **Federal Register** of August 26, 2009 (74 FR 43043), we issued a final rule to define the term ''small number of animals'' by establishing for each major species of animal (horses, dogs, cats, cattle, pigs, turkeys, and chickens) an upper limit threshold (*i.e.,* small number) to provide a means of determining whether any particular intended use of a new animal drug in one of these species would qualify as a minor use under the MUMS Act. The small numbers for the seven major species of animals as established in the ''small number of animals'' definition at 21 CFR 516.3(b) are 50,000 horses, 70,000 dogs, 120,000 cats, 310,000 cattle, 1,450,000 pigs, 14,000,000 turkeys, and 72,000,000 chickens.

In our final rule, in response to comments, we agreed that periodic reassessment of the small numbers is appropriate and that such reassessments should occur approximately every 5 years. We conducted our first reassessment in 2013 and published the results in the **Federal Register** on May 19, 2014 (79 FR 28736). We concluded, based on that reassessment, that no changes to the definition of ''small number of animals'' were needed.

II. Current Reassessment

We conducted our second reassessment of the ''small number of animals'' definition in 2018–2019 (current reassessment), and the results of that reassessment are summarized in our memorandum ''2018–2019 Reassessment of Small Numbers of Animals for Minor Use Determination'' (Ref. 1). FDA developed different processes for establishing small numbers for the major species of companion animals and the major species of food-producing animals, and we continue to use those processes for our periodic reassessments of the small numbers. Both processes are described in detail in the preamble to the proposed rule that published in the **Federal Register** on March 18, 2008 (73 FR 14411) and in our memorandum for the current reassessment (Ref. 1).

Based on our current reassessment, there is not an adequate basis to propose revisions to the currently published small numbers for horses and the food-producing major species. The small numbers for horses and the four food-producing major species as established in the current ''small number of animals'' definition in § 516.3(b) are listed in table 1.

TABLE 1—CURRENT SMALL NUMBERS FOR HORSES AND THE FOOD-PRODUCING MAJOR SPECIES

[21 CFR 516.3(b)]

Species	Small No.
Horses	50,000
Cattle	310,000
Pigs	1,450,000
Turkeys	14,000,000
Chickens	72,000,000

In separate documents published elsewhere in this issue of the **Federal Register**, we are publishing a direct final rule to revise (*i.e.,* increase) the ''small numbers'' for dogs and cats, and a proposed rule as a companion to the direct final rule under FDA's usual procedures for notice and comment.

III. Paperwork Reduction Act of 1995

While this notice of reassessment of the small numbers 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 notice. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 516.20 have been approved under OMB control number 0910–0605.

IV. References

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.*

1. FDA Memorandum, ''2018–2019 Reassessment of Small Numbers of Animals for Minor Use Determination,'' 2021.

Dated: September 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19955 Filed 9–14–22; 8:45 am]

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