Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management. Collecting voluntary customer feedback is the least burdensome, most effective way for the Agency to determine whether or not its public websites are useful to and used by its customers. Generic clearance is needed to ensure that the Agency can continuously improve its websites through regular surveys developed from these pre-defined questions. Surveying the Agency websites on a regular, ongoing basis will help ensure that users have an effective, efficient, and satisfying experience on any of the websites, maximizing the impact of the information and resulting in optimum benefit for the public. The surveys will ensure that this communication channel meets customer and partner priorities, builds the Agency's brands, and contributes to the Agency's health and human services impact goals. *Form Number:* CMS–10415 (OMB control number 0938–1185); *Frequency:* Occasionally; *Affected Public:* Individuals and Households; *Number of Respondents:* 2,000,000; *Number of Responses:* 2,000,000; *Total Annual Hours:* 50,000. (For policy questions regarding this collection contact Aaron Lartey at 410–786–7866.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Social Security Office (SSO) Report of State Buy-In Problem; *Use:* The statutory authority for the State Buy-in program is Section 1843 of the Social Security Act, amended through 1989. Under section 1843, a State can enter into an agreement to provide Medicare protection to individuals who are members of a Buyin coverage group, as specified in the State's Buy-in agreement. The Code of Federal Regulations at 42 CFR 407.40 provides for States to enroll in Medicare and pay the premiums for all eligible members covered under a Buyin coverage group. Individuals enrolled in Medicare through the Buy-in program must be eligible for Medicare and be an eligible member of a Buy-in coverage group. The day to day operations of the State Buy-in program is accomplished through an automated data exchange process. The automated data exchange process is used to exchange Medicare and Buy-in entitlement information between the Social Security District Offices, State Medicaid Agencies and the Centers for Medicare & Medicaid Services (CMS). When problems arise that cannot be resolved though the normal data exchange process, clerical actions are required. The CMS–1957, ''SSO Report of State Buy-In Problem'' is used to report Buy-in problems cases. The CMS–1957 is the only standardized form available for communications between the aforementioned agencies for the resolution of beneficiary complaints and inquiries regarding State Buy-in eligibility. *Form Number:* CMS–1957 (OMB control number 0938–0035); *Frequency:* Occasionally; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,400; *Number of Responses:* 1,400; *Total Annual Hours:* 467. (For policy questions regarding this collection contact Keith Johnson at 410–786–2262.)

Dated: September 12, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–20007 Filed 9–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2143]

Determination That Bacitracin for Injection, 10,000 Units/Vial and 50,000 Units/Vial, Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that bacitracin for injection, 10,000 units/vial and 50,000 units/vial, was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for bacitracin for injection.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, *Sungjoon.Chi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Bacitracin for injection, 10,000 units/vial and 50,000 units/vial, is the subject of ANDA 060733 (originally NDA 6–483), held by Pharmacia and Upjohn Company (a subsidiary of Pfizer Inc.), and was initially approved on July 29, 1948. Bacitracin for injection is an antibiotic for intramuscular administration, the use of which is limited to the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible

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