



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0173]

Practices to Prevent Unsafe Contamination of Animal Feed from Drug Carryover; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry #272 entitled “Practices to Prevent Unsafe Contamination of Animal Feed from Drug Carryover.” We are issuing this draft guidance to describe practices that medicated feed manufacturers can use to prevent unsafe contamination from drug carryover into a non-medicated animal feed or an animal feed containing a different approved new animal drug. Unsafe contamination of animal feed from drug carryover can pose a risk to human and animal health. When finalized, this guidance will replace Compliance Policy Guides (CPGs) Sec. 680.500 and 680.600.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any 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-2022-D-0173 for "Practices to Prevent Unsafe Contamination of Animal Feed from Drug Carryover."

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: Kevin Klommhaus, Center for Veterinary Medicine (HFV-236), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 515-318-8075.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #272 entitled “Practices to Prevent Unsafe Contamination of Animal Feed from Drug Carryover.” This draft guidance contains much of the information found in the CPGs Sec. 680.500 “Unsafe Contamination of Animal Feed from Drug Carryover” and 680.600 “Sequencing as a Means to Prevent Unsafe Drug Contamination in the Production, Storage, and Distribution of Feeds” but includes updates and additional information. We intend to withdraw the CPGs after this guidance is finalized. Drug carryover generally occurs when a drug used in the manufacture of a batch of medicated feed, for which the drug is approved, gets inadvertently included in a subsequent batch of: (1) a non-medicated feed, (2) a different medicated feed for which the drug is not approved (e.g., medicated feed for another species), or (3) a medicated feed that contains the same drug that can result in a higher drug level than is stated on the labeling. This carryover can occur for multiple reasons, including the use of the same equipment to manufacture both medicated and non-medicated feed, inadequate cleanout practices for manufacturing and distribution equipment between sequential batches, or human error.

We understand that an absolute avoidance of all batch-to-batch drug carryover may not be possible. However, measures can be implemented to avoid unsafe contamination of animal feed from drug carryover. In this draft guidance, unsafe contamination of an animal feed refers to a degree of contamination, by a drug approved for a medicated feed use, that poses an unacceptable risk to human or animal health. Human health may be at risk if humans consume a product derived from animals that have consumed animal feed contaminated from drug carryover and there is drug residue in the edible tissues of that animal (e.g., milk, meat, or eggs). Unsafe

contamination from drug carryover in animal feed can impact animal health when an animal consumes the contaminated feed, e.g., horses consuming feed contaminated with the drug monensin. Horses are sensitive to ionophore drugs like monensin, and ingestion can result in severe illness or death.

Our regulation “Current Good Manufacturing Practice for Medicated Feeds,” 21 CFR part 225, contains requirements for equipment cleanout procedures to avoid unsafe contamination of feeds with drugs (see 21 CFR 225.65 and 225.165). In this guidance, we provide information on some ways to comply with these requirements to help prevent unsafe contamination of animal feed from drug carryover.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on some practices that can be used in feed mills manufacturing medicated feed to prevent unsafe contamination of animal feed from drug carryover. 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

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: May 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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