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Reporting and Mitigating Animal Drug Shortages

Guidance for Industry

This version of the guidance replaces the version made available May 2020. The recommendations remain the same.

Submit comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2020-D-1140.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville MD 20855, and may be viewed on the Internet at https://www.fda.gov/animal-veterinary, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or http://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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Contains Nonbinding Recommendations

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

FDA is issuing this guidance to provide recommendations on the information sponsors should submit to the Center for Veterinary Medicine (CVM) to report and mitigate animal drug shortages. For purposes of this guidance, an animal drug shortage includes an actual or potential shortage, including a disruption or anticipated disruption in the supply chain for the drug product or any component of the drug product (including the active pharmaceutical ingredient (API), drug substance intermediates, inactive ingredients, or components of containers and closures) for the U.S. market.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

FDA closely monitors the animal drug supply chain for supply disruptions or shortages in the United States. Based on the Agency's experience with implementation and comments received, FDA is revising the guidance (originally titled, "Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency" (May 2020)) to clarify that the recommendations continue to reflect the Agency's current thinking and to assist sponsors in providing FDA timely, informative notifications about changes in the production of animal drugs that will, in turn, help the Agency in its efforts to prevent or mitigate shortages of these products. Accordingly, this version replaces the May 2020 version of the guidance.

III. Discussion

This guidance provides recommendations on the voluntary information for sponsors to submit to the Center for Veterinary Medicine (CVM) to report and mitigate animal drug shortages of certain drugs. This guidance applies to the voluntary reporting of information related to all animal drug shortages, regardless of the drug's status as a medically necessary veterinary product (MNVP).[1]

[1] A Medically Necessary Veterinary Product (MNVP) is a product that: (1) is used to treat or prevent a serious animal disease or condition or is needed to ensure the availability of safe food products of animal origin, and (2) no other available source of that product or adequate alternative drug substitute exists. Owner inconvenience and non-therapeutic uses are inappropriate reasons for classifying a product as an MNVP. See CVM Program Policy and Procedures Manual

A. Why should animal drug shortages be reported to FDA?

Although reporting animal drug shortages to FDA is voluntary, receiving information about shortages allows FDA to work with sponsors in a timely fashion and take steps, where possible, to help avoid or mitigate a shortage.

B. Who should report animal drug shortages to FDA?

Given that animal drug sponsors are most familiar with the supply chain affecting the manufacture, distribution, and sale of their animal drug products, FDA believes that animal drug sponsors are in the best position to analyze shortage situations related to their specific products. Information that is submitted to FDA will not be disclosed except in accordance with applicable disclosure law, which includes restrictions on the release of confidential commercial information and trade secrets. If FDA determines that a product is in shortage, the Agency intends to work with manufacturers to confirm the accuracy and appropriateness of information regarding the shortage before posting publicly on FDA's website.

C. How and when should an animal drug shortage be reported?

Sponsors should submit relevant information via email to AnimalDrugShortages@fda.hhs.gov as soon as they become aware of a potential or actual animal drug shortage.

D. What information should be included in the report?

- Information regarding the root cause of shortage, e.g., delay in API delivery, shortage of inactive ingredients or components of containers and closures, delayed inspection, manufacturing issues.
- Timing of shortage, e.g., when inventories are expected to be depleted, when finished product will be unavailable for the U.S. market.
- Planned resolution for avoiding or mitigating a shortage, e.g., identification of an alternate manufacturing site for finished products, API, or other components of the supply chain.
- Any other information that may be relevant to the shortage.

E. What information should a sponsor provide to support a CMC supplement or a CMC technical section for an alternate manufacturer or a new manufacturing facility proposed to prevent or mitigate a shortage?

The situation may arise where, in order to prevent or mitigate a drug shortage, an animal drug sponsor may need to utilize an alternate manufacturer or a new manufacturing facility for their drug product. These types of changes must be the subject of an approved supplemental application (21 CFR 514.8(b)(2)). In order to avoid approval delays for chemistry, manufacturing, and controls (CMC) supplements or delays in completing CMC technical sections due to Good Manufacturing Practice (GMP) status or anticipated difficulty obtaining

1240.4170 CVM Medically Necessary Veterinary Drug Product Shortage Management (https://www.fda.gov/media/70186/download).

pre-approval inspection coverage resulting from travel restrictions, sponsors are encouraged to submit information such as:

- recent foreign regulatory GMP inspection reports (translated to English) for the alternate or new manufacturing facility
- alternative interim proposals including but not limited to:
  - enhanced sampling/testing strategies,
  - additional facility manufacturing information,
  - other regulatory commitments

This information, if provided, may be considered as part of CVM's overall evaluation related to a reported shortage in order to support continuity in manufacturing and an adequate supply of animal drug products. For CVM to consider information from foreign regulatory authorities to support the approval of an application or supplement, the information must be submitted with an English translation (as described in 21 CFR 514.1(a)).

F. What information should a sponsor provide to support the acceptability of other types of manufacturing changes to prevent or mitigate a product shortage?

CVM will address these types of changes on a case-by-case basis. In general, the sponsor should provide any available information to ensure the safety, effectiveness, and quality of the animal drug.

G. What are examples of steps FDA may take to prevent or mitigate a shortage?

- CVM will work closely with the sponsor to assess the root cause of a shortage and determine possible actions that could help prevent or mitigate the shortage.
- CVM may advise sponsors on the best filing strategy for a regulatory submission intended to alleviate the shortage (e.g., submitting information as a Changes Being Effected supplement versus a Prior Approval Supplement) and the specific information that should be submitted to CVM. (See 21 CFR 514.8)
- For an animal drug product in shortage that is determined to be an MNVP, CVM intends to prioritize and expedite the review of any submissions needed to prevent or mitigate the shortage.

IV. References

Animal Drug Shortages webpage: https://www.fda.gov/animal-veterinary/product-safety-information/animal-drug-shortage-information.