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Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency

Guidance for Industry

May 2020

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

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1140 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, the FDA webpage titled "Search for FDA Guidance Documents," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, and the Center for Veterinary Medicine webpage titled "Guidance for Industry," available at <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>. You may also send an e-mail request to AskCVM@fda.hhs.gov to receive a copy of the guidance. Please include the document number FDA-2020-D-1140 and complete title of the guidance in the request.

Questions

For questions about this document, contact AskCVM@fda.hhs.gov.

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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 plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

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 the duration of the public health emergency. 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.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, and renewed for 90 days on April 21, 2020, effective April 26, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020 (85 FR 16949), titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

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In general, FDA’s guidance documents, including this guidance, 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

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

FDA has been closely monitoring the animal drug supply chain for supply disruptions or shortages in the United States during the COVID-19 pandemic. FDA is issuing this guidance 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.

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 for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020 and renewed on April 21, 2020. 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).³

1. 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 communicate with sponsors in a timely fashion and take steps where possible to help avoid or mitigate a shortage.

¹ Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), renewed April 21, 2020, available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

³ 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 1240.4170 CVM Medically Necessary Veterinary Drug Product Shortage Management (<https://www.fda.gov/media/70186/download>).

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2. 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.

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

Sponsors should submit relevant information to AnimalDrugShortages@fda.hhs.gov as soon as they become aware of an animal drug shortage.

4. What information should be included in the report?

Information should include:

- 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.

5. What information should a sponsor provide to support the acceptability of 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 pre-approval inspection coverage resulting from FDA's current inspectional limitations due to COVID-19, 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:

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- o enhanced sampling/testing strategies,
- o additional facility manufacturing information,
- o 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)).

6. 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.

7. 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 Shortage webpage: <https://www.fda.gov/animal-veterinary/product-safety-information/animal-drug-shortage-information>.