
SUPPLEMENTAL POLICIES

**CVM MEDICALLY NECESSARY VETERINARY DRUG PRODUCT
SHORTAGE MANAGEMENT**

I. Purpose

This guide establishes Center procedures for the evaluation of essential animal drug product shortage situations, so that appropriate actions may be taken promptly.¹

II. Definition

CVM Drug Shortage Coordinator - designated by the Center's Deputy Director to facilitate a determination by the appropriate Office Director(s) as to the medical necessity of the shortage product(s) as soon as practicable.

Medically Necessary Veterinary Product (MNVP): A product is considered to be an MNVP if it is used to treat or prevent a serious disease or condition, or needed to assure the availability of safe food products of animal origin and there is no other available source of that product or alternative drug that is judged by CVM's veterinary staff to be an adequate substitute. Inconvenience and non-therapeutic uses are insufficient basis to classify a product as an MNVP.

III. Background

It is Agency policy to attempt to prevent or alleviate shortages of MNVPs. An MNVP shortage may involve an actual or potential shortage of a drug product. The Agency may be alerted to shortage situations by external sources such as veterinarians, producer associations, animal health industry, the press and/or consumer groups, or through normal FDA surveillance and enforcement activities. FDA requests the reporting of shortage situations, including an assessment of the cause(s) and potential solutions.

¹This guide does not confer any rights or expectations on any person who may claim that the guidance was not followed or was implemented improperly.

Drug shortages may arise from varying causes, such as the unavailability of raw materials or packaging components, marketing decisions, and enforcement issues. Shortages can be broadly classified as compliance-related or alternatively, noncompliance-related.

The Agency response to a situation of a MNVP will be guided, in order of priority by protection of public health, animal health, and the environment.

IV. Responsibilities and Procedures

All drug shortage situations should be reported promptly to CVM. Information on shortage situations should be reported to CVM at the Office of Surveillance and Compliance (HFV-200). MNVP shortages involving FDA enforcement activities will be forwarded to the Division of Compliance (HFV-230), while all other shortage situations will be forwarded to the Division of Surveillance (HFV-210).

All reports will be reviewed by HFV-210 and HFV-230 to determine whether a real or potential shortage situation, in fact, exists. If a bona fide shortage situation is confirmed, the shortage issue will be brought to the attention of the CVM MNVP Shortage Coordinator for a determination as to the necessity of that product(s) as soon as practicable.

If a determination is made that a product for which a shortage exists is an MNVP, special actions to alleviate the shortage will be considered. Special actions may range from discussions with the industry, acceleration of NADA/ANADA review activities, and/or, in extraordinary circumstances, enforcement discretion.

A. Center for Veterinary Medicine

1. Office of the Director

The Deputy Director (or designee) serves as the CVM MNVP Shortage Coordinator.

Responsibilities include:

- a. Requesting the Offices of NADE and S&C to determine whether a product is an MNVP. If appropriate, convenes an ad hoc meeting with the appropriate Office Director(s) and Division personnel.
- b. When an essential animal drug shortage exists, coordinates an action plan to prevent or mitigate, whenever possible, a supply disruption.

Note: Enforcement discretion may be exercised where the shortage situation results from compliance issues. A decision to exercise such discretion as the option best meeting the public interest must be based on careful consideration of the impact of the violations on the quality of the product, the risks that would result from them, and any other factor that CVM deems relevant. The Office of Regulatory Affairs, and Office of Chief Counsel will participate in these discussions to describe the impact of the violations on the overall quality of the product.²

- c. Determining whether there are other sources, or alternate products, including alternate dosage forms, for the drug product(s) (the Field offices may be requested to assist in determining alternate sources and production capacity); and,
- d. Determining if human food safety concerns necessitate limiting the scope of the Center's response to an MNVP shortage, and what these limitations should be.
- e. Assuring that the Agency position is defensible and documented. This may require consultation and/or concurrence of the Director of CVM, OCC, or other Agency officials..

² A decision to exercise or refrain from exercising enforcement discretion is not subject to judicial review.

2. Division of Surveillance (HFV-210)

Monitors all reports or situations involving product shortages relating to non-compliance problems. Responsibilities include:

- a. Receiving reports of shortages from FDA units, industry, and health professionals, and others.
- b. Conducting an evaluation of the reported shortage, which includes:
 - (1) determining the cause of the reported shortage, e.g., production vs. distribution;
 - (2) contacting the person who reported the shortage to obtain additional information, including actions taken to obtain the drug;
 - (3) identifying proportional market share.
 - (4) consulting with the appropriate NADE review Division(s) as needed to verify an MNVP situation.
- c. Contacting the Division of Compliance, HFV-230 to determine whether the reported shortage is related to FDA compliance actions.
- d. Forwarding a confirmed drug shortage situation to the CVM Drug Shortage Coordinator to determine whether the product is an MNVP.
- e. Responding to Division of Compliance requests for market share information for use in resolving evaluations of situations involving compliance problems.
- f. Maintaining a database containing all essential animal drug product shortage reports.

3. Division of Compliance (HFV-230)

CVM's Division of Compliance monitors the resolution of all shortage situations involving compliance issues. Depending on these issues, HFV-230 will consult with appropriate NADE Divisions or HFV-210 for technical expertise in carrying out these duties. Responsibilities include:

- a. Receiving and monitoring reports of shortage situations involving compliance problems. Situations may result from voluntary actions by the manufacturer, e.g., recalls, cessation of distribution, or from contemplated/ongoing regulatory actions to correct violations.
- b. Screening the reports and forwarding to the MNVP Shortage Coordinator if a bona fide shortage situation exists. This may involve coordination with Division of Surveillance, NADE, and/or various headquarters and Field offices to obtain information that more fully characterizes the nature and scope of the situation.
- c. Participating in discussions to characterize the impact of the compliance issues on the overall quality of the product and to identify any precedent actions bearing upon the issue.

4. Office of NADE, Deputy for HFS and Consultative Services

- a. Participates in all MNVP activities arising from shortages of products approved for use in food-producing animals.
- b. Coordinates evaluation of all HFS issues arising from MNVP shortages and recommends appropriate limits to the Center's response to the Center MNVP Shortage Coordinator.

B. Office of Regulatory Affairs

1. The District will forward information on MNVP shortage situations issues directly to CVM. Shortages can be reported to the Division ADR Hot Line during after-

hour emergencies (301) 594-0797. HFV-210 will immediately advise the CVM Shortage Coordinator and HFV-230.

2. District recommendations for regulatory actions will identify potential shortage situations warranting consideration by CVM.
3. For MNVP, the District will work with CVM in determining the nature and scope of shortage situations.