

# Sec. 635.100 Large Volume Parenterals (LVPs) for Animal Use

## Compliance Policy Guide

### Guidance for FDA Staff

*This version of the Compliance Policy Guide replaces the version made available May 2015. The document has been revised to current CPG formatting standards and reflects minor editorial changes.*

*Additional copies are available from:*  
Policy and Regulations Staff (HFV-6)  
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Food and Drug Administration  
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Rockville MD 20855

<https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm>

Submit either electronic or written comments on this compliance policy guide 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 No. FDA-2018-N-2900.

For further information regarding this document, contact [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov).

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

**March 2019**

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*This compliance policy guide represents the current thinking of the Food and Drug Administration (FDA) 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 the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.*

#### **I. Introduction**

The purpose of this compliance policy guide (CPG) is to provide guidance for FDA staff on large volume parenterals (LVPs or large volume injections).

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

#### **II. Background**

For purposes of this document, large volume parenterals (LVPs or large volume injections) are aqueous solutions usually supplied in volumes of 100 ml to 5,000 ml. LVPs are typically used to provide fluid replacement therapy to animals. Routes of administration may include intravenous, intraperitoneal, or subcutaneous. Some examples of LVPs include solutions containing:

- Sodium bicarbonate
- Electrolytes
- Dextrose (glucose) and other sugars
- Amino acids, peptides and other protein-fractions
- Vitamins, minerals
- Dextrans, and other plasma expanders

#### **III. Policy**

LVPs may be considered new animal drugs and considered unsafe under section 512(a)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(a)(1)) and adulterated

## Contains Nonbinding Recommendations

under section 501(a)(5) of the FD&C Act (21 U.S.C. 351(a)(5)) if marketed in the absence of an approved new animal drug application. However, CVM generally does not intend to take action against LVPs and those marketing LVPs if all of the following criteria are met and the LVP is not otherwise adulterated or misbranded:

Large volume parenterals must be:

1. Sterile
2. Free of preservatives, unless the LVP is the subject of an approved new animal drug application that specifically establishes the safety of and permits use of the preservative in that particular product
3. Supplied in appropriate volumes to ensure one-time, single-patient use
4. Labeled to indicate that: (a) they contain no preservatives, (b) they must be used promptly upon opening, and (c) any unused portion should be discarded
5. Labeled to clearly indicate concentration of individual ingredients and physiological parameters of the solution
6. Labeled with the U.S. Federal prescription legend: "CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian."
7. In compliance with other applicable labeling requirements in the FD&C Act and its implementing regulations, including 21 CFR Part 201
8. Manufactured in accordance with current Good Manufacturing Practices
9. Manufactured by an establishment that is registered with FDA in accordance with section 510 of the FD&C Act (21 U.S.C. 360)
10. Drug listed with FDA in accordance with section 510 of the FD&C Act (21 U.S.C. 360)

CVM will review labeling and may request batch records to determine compliance with this policy.

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