

Sec. 651.100 Ethylenediamine Dihydroiodide (EDDI)

Compliance Policy Guide

Guidance for FDA Staff

This version of the Compliance Policy Guide replaces the version made available May 2000. The document has been revised to current CPG formatting standards and update contact information.

Additional copies are available from:
Policy and Regulations Staff (HFV-6)
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-651100-ethylenediamine-dihydroiodide-eddi>

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 docket number FDA-2013-S-0610.

For further information regarding this document, contact 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**

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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 compliance policy guide as listed on the title page.

I. Introduction

This guidance document represents the Agency's current thinking on animal products containing ethylenediamine dihydroiodide (EDDI) or feeds containing unapproved new drugs under the provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

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 guidances means that something is suggested or recommended, but not required.

II. Background

EDDI has been incorporated into animal feed and drug products for many years for both nutritional and therapeutic purposes. It has been formulated in salt/mineral mixtures and in liquids and powders for adding to feed or drinking water. EDDI has been used as a supplemental source of iodine and is considered generally recognized as safe (GRAS) for nutritional purposes when used at levels consistent with good feeding practices (21 CFR 582.80). EDDI products also have been marketed with claims for the treatment and prevention of certain diseases in several animal species, but primarily for "foot rot," soft tissue "lumpy jaw" and "wooden tongue" in cattle. However, all such EDDI products (including feeds) bearing therapeutic claims are considered adulterated under sections 501(a)(5) or 501(a)(6) of the FD&C Act.

III. Policy

All animal products containing EDDI that bear claims for treatment or prevention of any animal disease (other than the prevention of iodine deficiency) are considered unapproved new animal drugs or feeds bearing or containing unapproved new animal drugs. They are adulterated under section 501(a)(5) of the FD&C Act if they are an unapproved new animal drug or adulterated under section 501(a)(6) of the FD&C Act if they are a feed bearing or containing an unapproved new animal drug.

Contains Nonbinding Recommendations

Cattle products that do not bear claims for treatment or prevention of animal disease and are formulated to provide 50 mg or more/hd/day of EDDI will be evaluated on a case-by-case basis and may be considered adulterated food under section 402(a)(2)(C)(i) of the FD&C Act if they raise safety concerns.

IV. Regulatory Action Guidance

The Center for Veterinary Medicine should be contacted for consultation before considering any possible regulatory action on animal products containing EDDI.

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