Sec. 653.100 Animal Grooming Aids

Compliance Policy Guide

Guidance for FDA Staff

This version of the Compliance Policy Guide replaces the version made available March 1995. The document has been revised to current CPG formatting standards, update contact information, and clarify existing language.

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/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 docket number FDA-2018-N-3188.

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

The purpose of this compliance policy guide (CPG) is to provide guidance for FDA staff on products intended solely to cleanse or beautify animals, commonly referred to as "grooming aids."

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

The Center for Veterinary Medicine (CVM) often receives inquiries concerning the status of products intended for use in animals that are similar to cosmetics. The term cosmetic, as defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), is limited to articles intended for use for humans for cleansing, beautifying, promoting attractiveness or altering the appearance. Products intended solely to cleanse or beautify animals, commonly referred to as "grooming aids," are not subject to the FD&C Act and are not regulated by FDA.

However, if a product purporting to be a grooming aid is intended to cure, mitigate, treat, or, prevent disease in animals or to affect the structure or function of the body of animals, the product is a drug under section 201(g) of the FD&C Act. Additionally, it is a new animal drug under section 201(v) of the FD&C Act if it is not generally recognized as safe and effective. To be legally marketed in the United States, new animal drugs must be the subject of an approved new animal drug application, conditionally approved new animal drug application, or index listing under sections 512, 571, and 572 of the FD&C Act.

III. Policy

Products intended solely to cleanse or beautify the animal, as evidenced by the product's claims, formulation, and other information in the product's labeling and promotional materials, should be considered grooming aids not regulated by FDA. Products for animals that make direct or implied disease or structure/function claims or are otherwise represented as a drug on product labeling or other promotional materials, such as by label reference to the presence of an active ingredient, may be considered drugs.

IV. Regulatory Action Guidance

To determine if a product will be considered a grooming aid or a drug, FDA staff should review product labeling and other promotional materials associated with the product. If Districts have questions about whether a product is an unapproved new animal drug or a grooming aid, or suspect that a product purporting to be a grooming aid is an unapproved new animal drug, they should consult with CVM, Division of Compliance. Unapproved new animal drugs are deemed unsafe under section 512(a) of the FD&C Act, and adulterated under section 501(a)(5) of the FD&C Act, and may be subject to FDA enforcement action.

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