



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1999-D-1875]

Compliance Policy Guide Sec. 615.115 on Extralabel Use of Medicated Feeds for Minor Species; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised Compliance Policy Guide (CPG) 615.115 entitled "Extralabel Use of Medicated Feeds for Minor Species." In advance of the January 1, 2017, date on which we anticipate that a number of drugs will convert from over-the-counter (OTC) to veterinary feed directive (VFD) status, this revised CPG clarifies policy and regulatory action guidance to FDA staff on the Agency's exercise of regulatory discretion with regard to the extralabel use of medicated feeds containing those drugs in minor species.

DATES: The Agency is soliciting public comment, but is implementing this CPG immediately because the Agency has determined that prior public participation is not feasible or appropriate.

You may submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov/>. Follow the instructions for submitting comments. Comments submitted electronically, including

attachments, to <https://www.regulations.gov/> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov/>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-1999-D-1875 for “Compliance Policy Guide Sec. 615.115 Extralabel Use of Medicated Feeds for Minor Species.” Received comments will be placed in the docket and, except for those submitted as

“Confidential Submissions,” publicly viewable at <https://www.regulations.gov/> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov/>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov/> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the CPG to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the CPG.

FOR FURTHER INFORMATION CONTACT: Amber McCoig, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5556, Amber.McCoig@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The revised CPG is intended to clarify policy and regulatory action guidance to FDA staff on the Agency's exercise of regulatory discretion with regard to the extralabel use of medicated feed in minor species. We are implementing this CPG without prior public comment because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). Although this CPG is immediately in effect, it remains subject to comment in accordance with FDA's good guidance practices regulation.

The treatment of minor species is especially challenging for two reasons. First, many minor species, such as fish and game birds, have very few drugs approved for their use. As a result, veterinarians often times have to treat these species in an extralabel manner, using drugs that are not approved for them. Further, some minor species cannot practically be medicated in any way other than through the use of medicated feeds. Because extralabel use of medicated

feeds is not permitted, veterinarians face an additional challenge to prevent unnecessary suffering and death of minor species.

In 2001, FDA published CPG 615.115 to provide guidance to FDA staff concerning the Agency's exercise of regulatory discretion with regard to the extralabel use of medicated feeds in minor species. The CPG was silent regarding the different marketing statuses of medicated feeds and did not explicitly address situations involving feeds containing VFD drugs.

In the Federal Register of December 12, 2013, FDA announced Guidance for Industry (GFI) #213 entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With Guidance for Industry #209" (78 FR 75570). As a result of GFI #213, FDA anticipates that, beginning January 1, 2017, a number of drugs, including some drugs used in medicated feeds, will convert from OTC marketing status to VFD marketing status. As this conversion occurs, drugs that previously were available OTC for producers and veterinarians for use in medicated feed will become VFD drugs. Because the current CPG is silent regarding the different marketing statuses of medicated feeds, to avoid potential confusion and harm to minor species requiring treatment with certain drug products converting from OTC to VFD, the Agency has decided to revise CPG 615.115 to explicitly clarify our intent to exercise regulatory discretion over both OTC and VFD feeds. In order to inform stakeholders before January 1, 2017, of the Agency's expectations regarding the extralabel use of VFD feeds in minor species, we are implementing this CPG immediately. We are soliciting public comment on this CPG, but immediate implementation will give stakeholders the opportunity to operate under the provisions of this CPG before they submit comments.

II. Significance of Guidance

This CPG is being issued as a level 1 guidance for FDA staff consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents the current thinking of FDA on the extralabel use of medicated feeds for minor species. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the Internet may obtain the CPG at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: November 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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