4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs for Use in Animal Feeds; Bambermycins

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove dairy replacement heifers from the pasture cattle class for which free-choice, loose-mineral medicated feeds containing bambermycins are approved. This action is being taken because a level of selenium for inclusion in such feeds has not been established for dairy cattle under the food additive regulation for selenium.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Amey L. Adams, Center for Veterinary Medicine (HFV-120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8108, email: amey.adams@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA has noticed that the animal drug regulations for bambermycins free-choice, loose-mineral Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers) specify formulations including trace mineral premixes that include selenium. However, the food additive regulation for selenium in salt-mineral mixtures for free-choice feeding (21 CFR 573.920(c)(3)) does not provide for use

in dairy cattle. For this reason, FDA is revising the regulations to remove dairy replacement heifers from the pasture cattle class for which free-choice medicated feeds containing bambermycins are approved. This action is being taken to improve the accuracy of the regulations.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. In § 558.95, revise the introductory text in paragraphs (d)(4)(iii) and (d)(4)(iv), and the first sentence in paragraph (d)(4)(iii)(d) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(4) * * *

(iii) Used as a free-choice Type C medicated loose-mineral feed for pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers) as follows:

* * * * *

(d) Limitations. For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers). * * *

(iv) Use free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers) as follows:

* * * * *

Dated: December 11, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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