4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1050]

Report of the Center for Veterinary Medicine Working Group on the Regulation of Animal Drug Availability Act Combination Drug Medicated Feeds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report of a Center for Veterinary Medicine (CVM) working group proposing possible changes to the current review processes for new animal drug applications (NADAs) providing for the use of multiple new animal drugs in combination drug medicated feeds. This report was developed for the use of the CVM committee that will be participating in discussions concerning the reauthorization of the animal drug user fee program for 5 additional years through fiscal year 2023 (per the Animal Drug User Fee Amendments (ADUFA) IV).

ADDRESSES: 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 report 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 requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV-120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0829, linda.wilmot@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 9, 2014 (79 FR 53431), CVM announced that it was beginning to explore possible changes to the current review processes for NADAs for the use of multiple new animal drugs in combination drug medicated feeds. In the same Federal Register notice, FDA announced the opening of a docket to receive input from the public on this issue. This effort is consistent with the stated performance goal in the Animal Drug User Fee Amendments of 2013 (ADUFA III) goals letter.

In the Federal Register of April 29, 2016 (81 FR 25677), FDA published a notice of availability of a draft CVM report, giving interested persons until July 29, 2016, to comment. Those comments were considered as the CVM working group report was finalized without substantive changes. This report was developed for the discussions with the regulated industry for reauthorization of ADUFA.

Persons with access to the Internet may obtain this document on the CVM ADUFA Meetings Web page:

http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm.

Dated: November 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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