4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1049]

Exploring the Expansion of Conditional Approval to Appropriate Categories of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is beginning the exploration process described in a stated performance goal in the Animal Drug User Fee Amendments of 2013 (ADUFA III) goals letter. Consistent with the performance goal, the FDA is inviting comments in regard to the Agency exploring the use of statutory changes to expand the use of conditional approval beyond new animal drugs intended for minor species or for minor uses in major species to additional categories of new animal drugs as appropriate.

DATES: Although you can comment on this document at any time, to ensure that the Agency considers your comment before finalizing work on the exploration process described in this document, submit either electronic or written comments by March 9, 2015.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Matthew Lucia, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., rm. E444, Rockville, MD 20855, 240-402-0811, matthew.lucia@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA considers the timely review of the safety and effectiveness of new animal drugs to be central to the Agency's mission to protect and promote the public health. Before 2004, the timeliness and predictability of the new animal drug review program was a concern. The Animal Drug User Fee Act enacted in 2003 (Public Law 108-130; hereinafter referred to as "ADUFA I"), authorized FDA to collect user fees for 5 years--fiscal year (FY) 2004 to FY 2008--that were to be dedicated to expediting the review of new animal drug applications according to certain performance goals and to expand and modernize the new animal drug review program. The Agency agreed to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. The implementation of ADUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the new animal drug application review process.

In 2008, before ADUFA I expired, Congress passed the Animal Drug User Fee Amendments of 2008 (Public Law 110-316; hereinafter referred to as "ADUFA II") which included an extension of ADUFA for an additional 5 years--FY 2009 to FY 2013. ADUFA II performance goals were established based on ADUFA I FY 2008 review timeframes. In addition, FDA provided program enhancements to reduce review cycles and improve communications during reviews.

In 2013, before ADUFA II expired, Congress passed the Animal Drug User Fee Amendments of 2013 (Public Law 113-14; hereinafter referred to as ADUFA III), which was signed by the President on June 13, 2013. Like its predecessors, ADUFA III included its own comprehensive set of performance goals. One such goal, as stated in the ADUFA III goals letter, was: "Beginning in early FY 2014, the Agency agrees to explore, in concert with industry, the feasibility of pursuing statutory revisions, consistent with the Agency's mission to protect and promote the public health, that may expand the use of conditional approvals to other appropriate categories of new animal drug applications and develop recommendations by September 30, 2015."

The conditional approval provisions are found in section 571 of the Federal Food, Drug and Cosmetic Act (the FD&C Act). These provisions allow an applicant to market a new animal drug intended for a minor species or a minor use in a major species after the applicant has demonstrated that the drug is safe and can be manufactured according to standards applicable to approval of applications under section 512(b)(1) of the FD&C Act (21 U.S.C. 360b(b)(1)), but before meeting the full requirements for demonstrating effectiveness by providing "substantial evidence" that the drug is effective. Instead, the applicant seeking conditional approval must demonstrate a "reasonable expectation of effectiveness" and has up to 5 years to meet the requirements for demonstrating "substantial evidence" of effectiveness and receive complete approval of an application filed under section 512(b) of the FD&C Act.

Today, FDA is announcing that it is beginning the exploration process described in the ADUFA III goals letter. With this document, FDA is requesting comments in regard to the Agency exploring the use of statutory changes to expand the use of conditional approval to appropriate categories of new animal drugs beyond those intended for use either in minor species

or for minor uses in major species. FDA is opening a public docket to receive comments on the issue. In particular, FDA is inviting comments on the following specific questions:

1. Which categories of new animal drugs, if any, beyond those intended for minor species or minor uses in major species, should be considered by FDA for conditional approval in accordance with the current conditional approval process and why?
2. How would expanding conditional approval positively or negatively affect animal health?

FDA will be reviewing the docket and considering comments submitted as it moves forward with this process. The docket will remain open for 180 days following publication of this document in the Federal Register.

II. Comments

Interested persons may submit electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: September 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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