DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2002-D-0147 (formerly Docket No. 2002D-0449)]

Administrative Applications and the Phased Review Process; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (GFI) #132 entitled "Administrative Applications and the Phased Review Process." This guidance defines the "phased review process" for reviewing application-level information during the investigational period of new animal drug development, and an "administrative" new animal drug application (NADA) or abbreviated new animal drug application (ANADA), the content, the procedures a sponsor should follow to submit such an application, and the intended time frame for its review.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance 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 guidance document.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT: Katherine Weld, Center for Veterinary Medicine (HFV-108), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0846, Katherine.Weld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 6, 2002 (67 FR 67631), FDA published the notice of availability for a draft guidance entitled "The Administrative New Animal Drug Application Process" giving interested persons until January 21, 2003, to comment on the draft guidance. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance was updated to clarify current processes and include information about generic new animal drugs. The guidance announced in this notice finalizes the draft guidance dated November 6, 2002.

To be legally marketed, a new animal drug must be the subject of either an approved application under section 512(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b), a conditional approval under section 571 of the FD&C Act (21 U.S.C. 360ccc), or an index listing under section 572 of the FD&C Act (21 U.S.C. 360ccc-1). Sections 512(b)(1) and 512(n)(1) of the FD&C Act describes the information that must be submitted to FDA, specifically the Center for Veterinary Medicine (CVM), as part of an NADA or ANADA, respectively.

CVM encourages sponsors to submit data for review at the most appropriate and productive times in the drug development process. Rather than submitting all data for review as part of a complete application, we have found that the submission of data supporting discrete technical sections during the investigational phase of the new animal drug is the most appropriate and productive. This "phased review" of data submissions has created efficiencies for CVM and the animal pharmaceutical industry. These increased efficiencies have facilitated the approval of both pioneer and generic new animal drugs.

This guidance defines what an administrative (A)NADA is, defines and describes the phased review process, and briefly discusses how sponsors should submit an administrative (A)NADA and the time frame for review.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Administrative Applications and the Phased Review Process. It does establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910-0032. The collections of information in section 512(n)(1) of the FD&C Act have been approved under OMB control number 0910-0669.

IV. Comments

Interested persons may submit either 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.

V. Electronic Access

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

Dated: April 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

4164-01-P

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