

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DDM

Display Date 12-15-08
Publication Date 12-16-08
Certifier A. Corbin

[Docket No. FDA-2008-D-0614]

Draft Guidance for Industry on Changes to Approved New Animal Drug Applications—New Animal Drug Applications Versus Category II Supplemental New Animal Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #191 entitled “Changes to Approved NADAs—New NADAs vs. Category II Supplemental NADAs”. This guidance is intended to assist sponsors who wish to apply for approval of changes to approved new animal drugs that require FDA to reevaluate safety and/or effectiveness data. The goal of this guidance is to create greater consistency in how such applications are handled by sponsors and by FDA’s Center for Veterinary Medicine (CVM).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), 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.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Suzanne J. Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8105, e-mail: suzanne.sechen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #191 entitled “Changes to Approved NADAs—New NADAs vs. Category II Supplemental NADAs”. In the past, applications for changes to approved new animal drugs may have been handled inconsistently by sponsors and the agency. Inconsistency in handling such applications has been confusing for sponsors and for CVM, particularly when reviewing and referencing the history of specific new animal drug applications (NADAs). This guidance is intended to improve consistency in the way applications for changes are handled. We believe that consistent handling of these types of applications also will help maintain clarity in the administrative record, which is an important part of protecting the public health.

When proposing a change to an approved new animal drug that may affect the safety and/or effectiveness of the drug, such changes generally must be submitted to FDA either as a new NADA or a supplemental application to the

original NADA. Category II supplemental NADAs are the type of supplement that is used to propose changes that may require a reevaluation of certain safety or effectiveness data in the parent application. Specific changes meeting the requirements for a Category II supplemental NADA are described in 21 CFR 514.106(b)(2). This guidance provides examples and makes specific recommendations about when a change to an approved NADA that requires FDA to review safety and/or effectiveness data should be submitted as a new NADA and when such a change should be submitted as a Category II supplemental NADA. In addition, the guidance addresses how to handle submissions relating to certain types of proposed changes at the investigational stage.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft 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 have been approved under OMB Control No. 0910–0032.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit

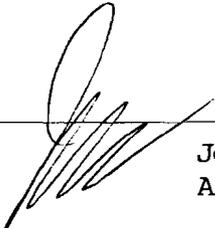
a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *<http://www.regulations.gov>*.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cvm> or <http://www.regulations.gov>.

Dated: 12/8/08
December 8, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

