contact Claire Driscoll at *cdriscol@mail.nih.gov* or 301–594–2235 for more information.

Dated: November 13, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E9–27925 Filed 11–19–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0614]

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 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: Submit written or electronic comments on agency guidances at any time.

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 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 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 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 guidance explains how the Office of New Animal Drug Evaluation (ONADE) categorizes possible changes to approved new animal drugs that require reevaluation of safety and/or effectiveness data and explains which administrative vehicle—a new original new animal drug application (NADA) (new NADA) or a Category II supplemental application to the original new animal drug application (Category II supplemental NADA)—a sponsor should use when applying for approval of these changes. The goal of this guidance is to create greater consistency in how such applications are handled by sponsors and by ONADE.

In the **Federal Register** of December 16, 2008 (73 FR 76363), FDA published the notice of availability for a draft guidance entitled ''Changes to Approved NADAs—New NADAs vs. Category II Supplemental NADAs,'' which gave interested persons until February 17, 2009, to comment on the draft guidance. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. In addition to some of the changes based on the comments received, CVM made a few minor changes to the guidance to add clarity and accuracy. The guidance announced in this notice finalizes the draft guidance dated December 16, 2008.

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 agency's current thinking on the 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 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 (expiration date April 30, 2010).

IV. Comments

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.

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.

V. Electronic Access

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

Dated: November 13, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–27926 Filed 11–19–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which