

notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 21, 2004.

**Bill Atkinson,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 04-9584 Filed 4-27-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0146]

#### Draft Guidance for Industry: Validation of Analytical Procedures for Type C Medicated Feeds

**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#135) entitled "Validation of Analytical Procedures for Type C Medicated Feeds." This draft guidance represents the agency's current thinking on the characteristics that should be considered during the validation of non-microbiological analytical procedures for the analysis of drugs in Type C medicated feeds included as part of original and supplemental new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) for Type A medicated articles submitted to the FDA. This draft guidance is the first in a series of three guidances that will discuss assay methods for Type C medicated feeds.

**DATES:** Submit written or electronic comments on the draft guidance by July 12, 2004, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 guidance document. Submit written comments to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance via the Internet at <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Mary G. Leadbetter, Center for Veterinary Medicine (HFV-141), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6964, e-mail: [mleadbet@cvm.fda.gov](mailto:mleadbet@cvm.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

This draft guidance document provides assistance and recommendations to industry on how to consider the various validation characteristics for each analytical procedure used in medicated feed assays submitted as part of original and supplemental NADAs and ANADAs.

##### II. Paperwork Reduction Act of 1995

According to the Paperwork Reduction Act of 1995, a collection of information must display a valid OMB control number. The existing valid OMB control numbers for this information collection are 0910-0032 and 0910-0154. This draft guidance contains no new collections of information.

##### III. Significance of Guidance

This draft Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent 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 alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

##### IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written comments to the Division of Dockets Management (see **ADDRESSES**) regarding this draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management

between 9 a.m. and 4 p.m., Monday through Friday.

#### V. Electronic Access

Copies of the draft guidance document entitled "Validation of Analytical Procedures for Type C Medicated Feeds" may be obtained from the CVM Home Page (<http://www.fda.gov/cvm>) and from the Division of Dockets Management Web site (<http://www.fda.gov/ohrms/dockets/default.htm>).

Dated: April 19, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-9566 Filed 4-27-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of an Exclusive License: Interleukin-2 Stimulated T Lymphocyte Cell Death for the Treatment of Autoimmune Diseases, Allergic Responses, and Graft Rejection

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), announces that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent No. 6,083,503, entitled "Interleukin-2 stimulated T lymphocyte cell death for the treatment of autoimmune diseases, allergic responses, and graft rejection;" U.S. Patent No. 5,989,546, entitled "Interleukin-2 stimulated T lymphocyte cell death for the treatment of allergic responses;" and U.S. Patent No. 5,935,575, entitled "Interleukin-4 stimulated T lymphocyte cell death for the treatment of allergic disorders" to Kasha Corporation, having a place of business in Rockville, Maryland. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to therapeutics for the treatment of autoimmune diseases.

**DATES:** Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before June 28, 2004 will be considered.