

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]

BILLING CODE 4163-18-P

**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**Draft Guidance for Industry: Validation of Analytical Procedures for Type C Medicated Feeds**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#135) entitled "Validation of Analytical Procedures for Type C Medicated Feeds." This draft guidance represents the agency's current thinking on the characteristics that should be considered during the validation of non-microbiological analytical procedures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 This draft guidance is the first in a series of three guidances that will discuss assay methods for Type C medicated feeds.

**DATES:** Submit written or electronic comments on the draft guidance by July 12, 2004, to ensure their adequate consideration in preparation of the final document.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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 Submit electronic comments on the draft guidance via the Internet at 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 Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.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]

BILLING CODE 4160-01-S

**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.

**ADDRESSES:** Requests for copies of the patent and/or patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Mojdeh Bahar, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-2950; Facsimile: (301) 402-0220; E-mail: [baharm@od.nih.gov](mailto:baharm@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** The technology claimed in the aforementioned patents is a method for the treatment or prevention of autoimmune diseases, allergic or atopic disorders, and graft rejections. The instant method comprises inducing the death by apoptosis of a subpopulation of T lymphocytes that is capable of causing such diseases, while leaving the majority of other T lymphocytes unaffected. Cell death is achieved by cycles comprising challenging via immunization these T cells with antigenic substance at short time intervals, or by immunization followed by administering interleukin-2 (IL-2) when these T cells are expressing high levels of IL-2 receptor so as to cause these T cells to undergo apoptosis upon re-immunization with the antigenic peptide or protein.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 21, 2004.

**Steven M. Ferguson,**

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

[FR Doc. 04-9568 Filed 4-27-04; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Public Meeting

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The National Institutes of Health (NIH) is announcing a public meeting to enable invited individuals, organizations, and other stakeholders to comment on the use of the government march-in authorities under 35 U.S.C. 203 for Norvir® (ritonavir) manufactured by Abbott Laboratories using inventive technologies developed with NIH funds.

**Time and Date:** The public meeting will be held on May 25, 2004 from 9 a.m. to 12 p.m.

**Place:** The public meeting will be held in the first-floor conference room, Building 50 (at the corner of Center and South Drives), National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892. Parking will be limited and there may be delays entering the NIH campus due to increased security. We recommend arriving by Metro, if possible. NIH is accessible from the Metro's red line at the Medical Center/NIH stop.

**FOR FURTHER INFORMATION CONTACT:** Mary Martinez, Office of Technology Transfer, Office of the Director, National Institutes of Health, 6011 Executive Blvd, Suite 325, Rockville, MD 20852, e-mail: [martinm1@mail.nih.gov](mailto:martinm1@mail.nih.gov)

**Registration and Participation:** No registration is required to attend the public meeting. Seating will be on a first-come, first-serve basis.

Participation as a presenter is by invitation only. The agency will notify each invited speaker of the time allotted to the participant and the approximate time the participant's comments are scheduled to begin.

If you need special accommodations due to disability, please inform Mary Martinez, the contact person listed in this document.

Dated: April 22, 2004.

**Mark L. Rohrbaugh,**

*Director, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 04-9569 Filed 4-27-04; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Draft Revised Recovery Plan for the Sihek or Guam Micronesian Kingfisher (*Halcyon cinnamomina cinnamomina*)

**AGENCY:** U.S. Fish and Wildlife Service, Interior.

**ACTION:** Notice of document availability for review and comment.

**SUMMARY:** The U.S. Fish and Wildlife Service ("we"), announces the availability of the Draft Revised Recovery Plan for the Sihek or Guam Micronesian Kingfisher (*Halcyon cinnamomina cinnamomina*) for public review and comment.

**DATES:** Comments on the draft revised recovery plan must be received on or before June 28, 2004.

**ADDRESSES:** Copies of the draft revised recovery plan are available for inspection, by appointment, during normal business hours at the following location: U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3-122, Honolulu, Hawaii 96850 (phone: (808) 792-9400). Requests for copies of the draft revised recovery plan and written comments and materials regarding this plan should be addressed to the Field Supervisor, Ecological Services, at the above Honolulu address. An electronic copy of the draft revised recovery plan is also available at: <http://endangered.fws.gov/recovery/index.html#plans>.

**FOR FURTHER INFORMATION CONTACT:** Fred Amidon, Fish and Wildlife Biologist, at the above Honolulu address.

**SUPPLEMENTARY INFORMATION:**

#### Background

Recovery of endangered or threatened animals and plants is a primary goal of our endangered species program and the Endangered Species Act (Act) 16 U.S.C. 1531 *et seq.* Recovery means improvement of the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act. Recovery plans describe actions considered necessary for the conservation of the species, establish criteria for downlisting or delisting listed species, and estimate time and cost for implementing the measures needed for recovery.

The Act requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act requires that public notice and an opportunity for