milestones for accomplishing project tasks and ensuring quality.

Criterion 5: Budget (10 Points)

The extent to which the proposed project costs are reasonable and justified in terms of scope, approach, staff time commitment, and anticipated results. Refers to the budget information presented on Standard Forms 424 and 424 A and the applicant's budget justification.

The extent to which the application describes the fiscal control and accounting procedures that will be used to ensure prudent use, proper and timely disbursement, and accurate accounting of funds received under this announcement.

*3. Review and Selection Process*

Initial Screening for Eligibility and Conformance

*Review and Selection Process:* Each application will undergo an eligibility and conformance review by Federal Child Care Bureau staff. Applications that pass the eligibility and conformance review will be evaluated on a competitive basis according to the specified evaluation criteria.

Competitive Review Process

The competitive review will be conducted in the Washington, DC metropolitan area by panels of Federal and non-Federal experts knowledgeable in the areas of literacy, early learning, child care, early childhood education, and other relevant program areas.

Application review panels will assign a score to each application and identify its strengths and weaknesses.

Application Consideration and Selection

The Child Care Bureau will conduct an administrative review of the applications and results of the competitive review panels and make recommendations for funding to the Commissioner, ACYF.

Subject to the recommendation of the Child Care Bureau's Associate Commissioner, the Commissioner, ACYF, will make the final selection of the applications to be funded. Application may be funded in whole or in part depending on: (1) The ranked order of applicants resulting from the competitive review; (2) staff review and consultations; (3) the combination of projects that best meets the Bureau's objectives; (4) the funds available; and (6) other relevant considerations. The Commissioner may also elect not to fund any applicants with known management, fiscal, reporting, program, or other problems that make it unlikely they would be able to provide effective services.

Approved but Unfunded Applications

In cases where more applications are approved for funding than ACF can fund with the money available, the Grants Officer shall fund applications in their order of approval until funds run out. In this case, ACF has the option of carrying over the approved applications up to a year for funding consideration in a later competition of the same program. These applications need not be reviewed and scored again if the program's evaluation criteria have not changed. However, they must then be placed in rank order along with other applications in the later competition.

## VI. Award Administration Information

*1. Award Notices*

Successful applicants will be notified through the issuance of a Financial Assistance Award document, which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

*2. Administrative and National Policy Requirements*

Conference Attendance. The grantee must attend and present a poster at the Annual Meeting of the Child Care Policy Research Consortium each year of the grant. This conference is typically scheduled during the spring. In addition, the applicant may be asked to attend and present at the annual State Administrators' Meeting typically held each summer in Washington, DC. The budget should reflect travel funds for both conferences. Grantees with graduate students are encouraged to bring at least one student to these meetings.

Archiving and Publishing. The grantee must agree to archive final data sets, reports and other research products with the Child Care Research and Collaboration Archive (CCRCA).

45 CFR part 74 and 45 CFR part 92.

*3. Special Terms and Conditions of Award*

None.

*4. Reporting Requirements*

Programmatic Reports: Semi-annually and a final report is due 90 days after the end of the grant period.

Financial Reports: Semi-annually and a final report due 90 days after the end of the grant period.

## VII. Agency Contacts

*Program Office Contacts:*

Dr. Ivelisse Martinez-Beck, Program Area Manager, 330 C Street, SW., Room 2046, Washington, DC 20447; (202) 690–7885, *imartinez-beck@acf.hhs.gov.*

Ms. Karen Tvedt, Director, Policy and Research Division, 330 C Street, SW., Room 2046, Washington, DC 20447; (202) 401–5130, *ktvedt@acf.hhs.gov.*

*Grants Management Office Contact:*

William Wilson, Grants Officer, 330 C Street, SW., Room 2070, Washington, DC 20447; (202) 205–8913, *wwilson@acf.hhs.gov.*

## VIII. Other Information

None.

Dated: May 18, 2004.

**Joan E. Ohl,**

*Commissioner, Administration on Children, Youth and Families.*

[FR Doc. 04–11816 Filed 5–24–04; 8:45 am]

**BILLING CODE 4184–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2001D–0357]**

### International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products; Guidance for Industry on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#141) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing'' (VICH GL28). This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which

was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). The objective of this VICH guidance document is to help ensure that the assessment of carcinogenic potential is appropriate to human exposure to residues of veterinary drugs in human food in the European Union, Japan, and the United States.

**DATES:** Submit written or electronic comments 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic or written comments at any time 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.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: *lmulliga@cvm.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government in Canada, and one representative from the industry in Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

## II. Guidance on Carcinogenicity Testing

In the **Federal Register** of August 28, 2001 (66 FR 45319), FDA published the notice of availability of the VICH draft guidance, giving interested persons until September 28, 2001 to submit comments. No comments were received. At a meeting held on October 10–11, 2002, the VICH Steering Committee endorsed the guidance for industry, VICH GL28.

This guidance is one of a series of VICH guidances developed to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the evaluation of veterinary drug residues in human food (''VICH Guidance on General Testing Approach'') will be made available at a later time.

VICH developed this guidance after consideration of the existing ICH guidances for pharmaceuticals for human use: ''Final Guideline on the Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals''; and ''S1B Testing for Carcinogenicity of Pharmaceuticals.'' Notices of availability for these guidances published in the **Federal Register** of March 1, 1996, (61 FR 8153) and February 23, 1998, (63 FR 8983) respectively. The guidance has been adapted for veterinary use by the VICH from the aforementioned guidances regarding pharmaceuticals for human use. VICH also took into account the Organisation for Economic Cooperation and Development methodological guidances and the current practices for evaluating the safety of veterinary drug residues in human food in the European Union, Japan, the United States of America, Australia and New Zealand. (Information collection for new animal drug applications is covered under OMB control number 0910–0032.)

## III. Significance of Guidance

This document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding unless specifically supported by statute or regulation, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH documents have been substituted with ''should'' or ''it is recommended.''

This guidance document represents the agency's current thinking on carcinogenicity testing for veterinary drug residues in human food. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

## IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the 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 guidance document entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing'' (VICH GL28) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: May 18, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–11781 Filed 5–24–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection: Comment Request; Revision of OMB No. 0925–0001 exp. 05/31/04, ''Research and Research Training Grant Applications and Related Forms''

**SUMMARY:** In compliance with the requirement section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director (OD), Office of Extramural Research (OER), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 19, 2004, Volume 69, No. 33, page 7763 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Proposed Collection:**

*Title:* Research and Training Grant Applications and Related Forms. *Type of Information Collection Request:* Revision, OMB 0925–0001, Expiration Date 5/31/04. *Form Numbers:* PHS 398, 2590, 2271, 3734 and HHS 568. *Need and Use of Information Collection:* The application is used by applicants to request Federal assistance for research and research-related training. The other related forms are used for trainee appointment, final invention reporting, and to relinquish rights to a research grant. *Frequency of response:* Applicants may submit applications for published receipt dates. If awarded, annual progress is reported and trainees may be appointed or reappointed. *Affected Public:* Individuals or Households; Business or other for-profit, Not-for-profit institutions; Federal Government;l and State, Local or Tribal Government. *Type of Respondents:* Adult scientific professionals. The annual reporting burden is as follows: *Estimated Number of Respondents:* 122,000; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 8.5; and *Estimates Total Annual Burden Hours Requested:* 1,032,439. The estimated operating cost to respondents is $500,000.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automatted, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the propose project or to obtain a copy of the data collection plans and instruments, contact Mr. Mikia Currie, Division of Grants Policy, Office the Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3505, 6705 Rockledge Drive, Bethesda, MD 20892–7974, or call non-toll-free number (301) 435–0941, or E-mail your request, including your address to: [*curriem@od.nih.gov*].

*Comments Due Date:* Comments regarding this informaiton collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: May 13, 2004.

**Dr. Charles Mackay,**

*Chief, Project Clearance Branch, OPERA, OER, National Institutes of Health.*

[FR Doc. 04–11708 Filed 5–24–04; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[NV–025–1232–EA); Special Recreation Permit # NV–025–04–01]**

### Notice of Temporary Closure of Public Lands: Pershing, Washoe, & Humboldt Counties, NV

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice to the public of temporary closures on public lands administered by the Bureau of Land Management, Winnemucca Field Office, Nevada.

**SUMMARY:** Pursuant to 43 CFR 8364.1, notice is hereby given that certain public lands will be temporarily closed to all public use in and around the Paragon Astronautics rocket launch site, located in Pershing, Washoe and Humboldt counties, Nevada, from 0700 to 1200 hours, June 7th through June 11 and June 14 through June 18, 2004. These closures are being made in the interest of public safety at and around the location of an amateur high-altitude rocket launch site. This event is expected to attract approximately 50 participants. The public lands involved with the event are located northeast of Gerlach, Nevada in the Mount Diablo Meridian.

**DATES:** Closure to all public use from 0700–1200 hours, June 7 through June 11 and June 14 through June 18, 2004 with the exception of BLM personnel, law enforcement, emergency medical services, and Paragon Astronautics staff as designated by the BLM authorized officer.

**ADDRESSES:** A map showing these temporary closures, restrictions and prohibitions is available from the following BLM offices:

BLM-Winnemucca Field Office, 5100 East Winnemucca Blvd, Winnemucca, Nevada 89445–2921.

BLM-State Office, 1340 Financial Blvd., Reno, Nevada 89520–0006.

The map may also be viewed on the Winnemucca Field Office website at: *www.nv.blm.gov/winnemucca.* In