Dated: March 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–6252 Filed 3–19–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0369]

International Cooperation on Harmonization 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: Developmental Toxicity Testing; '' 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 (#148) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing'' (VICH GL32). This guidance has been developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This guidance document provides harmonized guidance on the core recommendation for a developmental toxicity study for the safety evaluation of veterinary drug residues in human food.

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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit 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 are to 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, industry associations, and individual sponsors 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 reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use 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 United States' FDA; the United States' 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 industry in Australia/New Zealand, one representative from the Government of Canada, and one representative from industry in Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH steering committee meetings.

II. Guidance on Toxicity Testing

In the **Federal Register** of September 4, 2002 (67 FR 56572), FDA published the notice of availability of the VICH draft guidance, giving interested persons until October 4, 2002, to submit comments. After consideration of comments received, the final draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on October 10 and 11, 2002, the VICH Steering Committee endorsed the guidance for industry, VICH GL32.

This document provides guidance for developmental toxicity testing for those veterinary medicinal products used in food-producing animals. The objective of this guidance is to recommend that developmental toxicity assessment be performed according to an internationally harmonized guidance. This guidance describes recommended testing designed to provide information concerning the effects on the pregnant animal and on the developing organism following prenatal exposure.

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 ''recommended.''

This guidance document represents the agency's current thinking on developmental toxicity testing for those veterinary medicinal products used in food-producing animals. This guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative method as long as it satisfies the requirements of the 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance document. Two paper copies of any comments are to be submitted, except individuals may submit one paper 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: Developmental Toxicity Testing'' (VICH GL32) may be obtained on the Internet from FDA's Center for Veterinary Medicine home page at *http://www.fda.gov/cvm*.

Dated: March 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement

Support for Services to Torture Victims

Funding Opportunity Title: Support for Services to Torture Victims.

Announcement Type: Modification/Renewal.

Funding Opportunity Number: HHS–2004–ACF–ORR–ZT–0002.

CFDA Number: 93.604.

Due Date for Application: May 21, 2004.

Category of Funding Activity: Income Security and Social Services.

Executive Summary: ORR invites applications to support programs of services to persons who have experienced torture. Services may be for medical, psychological, social and legal needs. Activities may also include training and professional development for health care providers who are outside the treatment centers or programs supported by this announcement. Applications are also invited for one cooperative agreement for technical assistance to programs providing services to torture victims and training and development of service providers.

I. Funding Opportunity Description

Legislative Authority: The ''Torture Victims Relief Reauthorization Act of 2003'' took effect October 1, 2003. Pub. L.—108–179, Section 2 (a) Authorization of Appropriations for Domestic Treatment Centers for Victims of Torture amends Section 5(b)(1) of the Torture Victims Relief Act of 1998 (22 U.S.C. 2152 *note*) to read as follows:

(1) Authorization of Appropriations.—Of the amounts authorized to be appropriated for the Department of Health and Human Services for fiscal years 2004 and 2005, there are authorized to be appropriated to carry out subsection (a) (relating to assistance for domestic centers and programs for the treatment of victims of torture) $20,000,000 for fiscal year 2004 and $25,000,000 for fiscal year 2005.

In October 1998, Congress enacted the ''Torture Victims Relief Act of 1998,'' Pub. L. 105–320 (22 U.S.C. 2152 *note*). Sec. 5 (a) of the law provides:

Assistance for Treatment of Torture Victims—The Secretary of Health and Human Services may provide grants to programs in the United States to cover the cost of the following services:

(1) Services for the rehabilitation of victims of torture, including treatment of the physical and psychological effects of torture.

(2) Social and legal services for victims of torture.

(3) Research and training for health care providers outside of treatment centers, or programs for the purpose of enabling such providers to provide the services described in paragraph (1).

Background

This program announcement is the third iteration of the program ''Assistance for Treatment of Torture Survivors.'' The first notice was issued in 2000 resulting in 16 four-year awards with one additional cooperative agreement for technical assistance. A second notice issued in 2001 increased the number of grants by 9 three-year awards for 25 total grants. Programs have been established in 25 communities across the United States. Approximately 3500 victims of torture have been served. Much has been learned about providing services to persons who have been tortured. The grantees have developed a diverse set of services. In this announcement, ORR is interested in continuing the diversity of effective services for the clients. Also noteworthy is that the medical, psychological, social and legal service providers in most of the 25 communities have had access to training and professional development to better serve persons who have been tortured.

Building upon the experience from the current projects, ORR is interested in supporting renewed efforts at identifying effective treatment and service strategies. ORR expects that many of the current grantees will be successful applicants to this notice. However, ORR also is interested in seeing additional grants awarded in communities where no program for torture victims currently is supported by the federal government or other resources but where the prevalence of torture victims is sufficient to warrant a program of services.

While support of individual programs is the means ORR sees in implementing the legislation and providing the services envisioned in the legislation, it is also of interest to ensure that a collaboration across all the programs provides mutual benefit by sharing the promising practices learned, mentoring across programs, applying effective services and treatment strategies, developing stability in organizations and working toward a sustainable set of services with decreased need for federal funds.

Torture and Torture Victims

The psychosocial and health consequences of violence and traumatic stress have emerged as one of the major public health problems of our time. Torture constitutes one of the most extreme forms of trauma, with the potential for long-term psychological and physical suffering. The term torture has been defined in different ways by different organizations and for different purposes. The two most commonly used definitions of torture were formulated by the World Health Organization (WHO) and by the United Nations (UN). The WHO definition, which governs professional standards and ethics for physicians was developed in 1975. It is frequently called the ''Declaration of Tokyo,'' and it represents a popular definition among the medical community. The ''Declaration of Tokyo'' defines torture as:

''* * *the deliberate, systematic or wanton infliction of physical or mental suffering by one or more persons acting alone or on the orders of any authority, to force another person to yield information, to make a confession, or for any other reason.''

The UN definition, developed at the same time and revised in 1989, narrows the concept of torture somewhat by adding the legal and political responsibilities of governments. It states: