Dated: August 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–22406 Filed 9–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0369]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing (VICH GL32); Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance document for industry (ı148) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing'' (VICH GL32). This draft guidance document has been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance document provides harmonized guidance on the core recommendation for a developmental toxicity study for the safety evaluation of veterinary drug residues in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DATES: Submit written or electronic comments on the draft guidance document by October 4, 2002 to ensure their adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Comments should be identified with the full title of the draft guidance document and the docket number found in brackets in the heading of this document.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 International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical recommendations 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 recommendations 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; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and Japanese Ministry of Agriculture, Forestry, and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from industry in Australia/ New Zealand. 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. Draft Guidance on Toxicity Testing

The VICH Steering Committee held a meeting in April 2002, and agreed that the draft guidance document entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing'' (VICH GL32) should be made available for public comment.

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

FDA and the VICH will consider comments about the draft guidance document. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as a final guidance.

III. Significance of Guidance

This draft guidance 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.''

The draft guidance document represents the agency's current thinking on developmental toxicity testing for those veterinary medicinal products used in food-producing animals. This draft guidance document 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

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance document. Written or electronic comments should be submitted to the Dockets Management Branch (see **ADDRESSES**). Submit written or electronic comments by October 4, 2002 to ensure adequate consideration in preparation of the final guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. On the Internet site, select ''[insert docket number] 'Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing' '' (VICH GL32) and follow the directions.

Copies of the draft guidance 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 the CVM homepage at *http://www.fda.gov/cvm*.

Dated: August 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–22407 Filed 9–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; an Evaluation of the National Institute Science Enrichment Program (SEP) Parent Survey

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will published periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed collection: Title: An Evaluation of the NCI Science Enrichment Program (SEP) Parent Survey. *Type of Information Collection Request:* Extension of OMB No. 0925–0473, Expiration Date: 09/30/2002. *Need and Use of Information Collection:* This survey is one component of a larger evaluation that will assess the effectiveness of the NCI SEP in making progress toward its goals of: (1) Encouraging under-represented minority and under-served students who have just completed ninth grade to select careers in science, mathematics, and/or research, and (2) broadening and enriching students' science, research, and sociocultural backgrounds. The program is a 5 to 6-week residential program taking place on two university campuses—University of Kentucky, Lexington and San Diego State University. The 5-year evaluation is designed as a controlled, longitudinal study, consisting of the five SEP cohorts and three cohorts of control group students who do not attend the program. The evaluation will provide NCI with valuable information regarding specific components that promote or limit the program's effectiveness, the extent to which the program has been implemented as planned, how much the two regional programs vary, and how the program can be improved or made more effective. NCI will use this information to make decisions regarding continuation and expansion of the program. *Frequency of Response:* Annually. *Affected Public:* Individuals or households and Federal Governments. *Type of Respondents:* Parents of high school students participating in the program. The total annualized cost to respondents is $200.00. The annual reporting burden is as follows:

A.12–1.—ESTIMATE OF HOUR BURDEN: PARENT SURVEY

Type of respondents	Average number of respondents/Yr.	Frequency of response	Average time per response	Average annual hour burden
Parents of SEP Students	120	1	0.167	20
Total	120			20

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

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 automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Mr. Frank Jackson, Office of Special Populations Research, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 602, Rockville, MD 20852, or call non-toll-free number (301) 496–8680, or e-mail your request, including your address to: *fj12i@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of this publication.

Dated: August 27, 2002.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 02–22471 Filed 9–3–02; 8:45 am]

BILLING CODE 4140–01–M