

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1630]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies" (VICH GL22); Availability; Request for Comments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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry (#115) entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies" (VICH GL22). This draft guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal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). This draft VICH guidance document recommends a basic battery of tests that can be used to evaluate the reproduction safety of veterinary drug residues in human food.

DATES: Submit written comments concerning the draft guidance to ensure their adequate consideration in preparation of the final document by February 20, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

Copies of the draft guidance entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies" (VICH GL22) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/fda/TOCs/guideline.html>. Persons without Internet access may submit written requests for single copies of the draft

guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

Regarding VICH: Sharon R. Thompson, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1798, e-mail:

sthompso@cvm.fda.gov, or Carole R. Andres, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6524, e-mail: candres1@cvm.fda.gov.

Regarding the guidance document: 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 the differences in technical requirements for drug development among regulatory agencies.

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; 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 the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Reproduction Studies

The VICH Steering Committee held a meeting on June 14 through 16, 2000, and agreed that the draft guidance entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies" (VICH GL22) should be made available for public comment.

This draft guidance is intended to provide harmonized guidance on the core recommendation for a multigeneration study for the safety evaluation of veterinary drug residues in human food. The current draft guidance is one of a series of guidances developed to facilitate the mutual acceptance of safety data necessary for the determination of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the safety evaluation of veterinary residues in human food (VICH Guidance on General Testing Approach) will be made available at a later time. VICH GL22 was developed after consideration of the existing ICH guidance for pharmaceuticals for human use on "Detection of Toxicity to Reproduction for Medicinal Products" and its addendum, "Toxicity to Male Fertility," in conjunction with the current practices for evaluating veterinary drug residues in human food in the European Union, Japan, the United States, Australia, and New Zealand. (Information collection is covered under OMB Control Nos. 0910-0117 and 0910-0032).

III. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). For example, the documents have 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." Similarly, words such as "requirement" or "acceptable" have been replaced by "recommendation" or "recommended" as appropriate to the context.

This draft guidance represents the agency's current thinking on reproduction safety studies for veterinary drug residues in human food. This draft 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. Comments about the draft guidance documents will be considered by FDA and the VICH Safety Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidances and publish them as future guidances.

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 to the Dockets Management Branch (address above) written comments regarding this draft guidance. Submit written comments to ensure adequate consideration in preparation of the final guidance by February 20, 2001. 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 and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 7, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-32197 Filed 12-18-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health/National Institute of Environmental Health Sciences

Submission for OMB Review; Comment Request; Environmental Factors in the Development of Polycystic Ovary Syndrome

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), 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 September 1, 2000, page 53326 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, 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: Environmental Factors in the Development of Polycystic Ovary Syndrome. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* We will administer a brief telephone survey to 2032 twin women from the Mid-Atlantic Twin Registry (MATR) who previously reported having irregular periods and/or cystic ovaries on a MATR General Health History Survey. Question in the proposed survey focus on the two hallmark features of Polycystic Ovary Syndrome (PCOS), hyperandrogenism and anovulation, and other relevant physical characteristics, other if the woman has a living female twin sister. Women will also be asked for permission to recontact them for potential participation in future PCOS studies. The data will be used in statistical modeling analyses to identify those women with a high probability of having PCOS and estimate the number of potential candidates for future PCOS studies. *Frequency of Response:* One time. *Affected Public:* Individuals; *Type of Respondents:* Adult women. The annual reporting burden is as follows: *Estimated Number of Respondents:* 2,100; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 0.167; and *Estimated Total Annual Burden Hours Requested:* 350.7. The annualized cost to respondents is estimated at: \$3,507.00. There are no Capital Costs to report. There are no Operating 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 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.

Direct Comments to OMB

Written comment 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 proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Patricia C. Chulada, Clinical Research Scientist, Clinical Research Office, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541-7736 or E-mail your request, including your address to: chulada@niehs.nih.gov.

DATES: Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received on or before January 18, 2001.

Dated: December 7, 2000.

Francine Little,

Associate Director for Management, NIEHS.

[FR Doc. 00-32221 Filed 12-18-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Family Health Study (Validation of a Family History of Cancer Questionnaire for Risk Factor Surveillance)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal**