Dated: March 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–6250 Filed 3–19–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0057]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Final Guidance for Industry: How to Use E-Mail to Submit a Protocol

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Final Guidance for Industry: How to Use E-Mail to Submit a Protocol'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 27, 2003 (68 FR 61220), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0524. The approval expires on February 28, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: March 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0103]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Special Protocol Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 the (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the guidance for industry on special protocol assessment.

DATES: Submit written or electronic comments on the collection of information by May 21, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.39(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Special Protocol Assessment (OMB Control Number 0910–0470)—Extension

The ''Guidance for Industry on Special Protocol Assessment'' describes agency procedures to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the agency to act on such requests. The guidance provides information on how the agency will interpret and apply provisions of the Food and Drug Administration Modernization Act of 1987 and the specific Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products.

The guidance describes the following two collections of information: (1) The submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol and (2) the submission of a request for special protocol assessment.

A. Notification for a Carcinogenicity Protocol

As described in the guidance, a sponsor interested in agency assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol

assessment at least 30 days prior to submitting the request. With such notification, the sponsor should submit relevant background information so that the agency may review reference material related to carcinogenicity protocol design prior to receiving the carcinogenicity protocol.

B. Request for Special Protocol Assessment

In the guidance, CDER and CBER ask that a request for special protocol assessment be submitted as an amendment to the investigational new drug application (IND) for the underlying product and that it be submitted to the agency in triplicate with Form FDA 1571 attached. The agency also suggests that the sponsor submit the cover letter to a request for special protocol assessment via facsimile to the appropriate division in CDER or CBER. Agency regulations (21 CFR 312.23(d)) state that information provided to the agency as part of an IND is to be submitted in triplicate and with the appropriate cover form, Form FDA 1571. An IND is submitted to FDA under existing regulations in part 312 (21 CFR part 312), which specifies the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of investigational drugs and biological products. The information collection requirements resulting from the preparation and submission of an IND under part 312 have been estimated by FDA and the reporting and recordkeeping burden has been approved by OMB until January 31, 2006, under OMB control number 0910–0014.

FDA suggests that the cover letter to the request for special protocol assessment be submitted via facsimile to the appropriate division in CDER or CBER to enable agency staff to prepare for the arrival of the protocol for assessment. The agency recommends that a request for special protocol assessment be submitted as an amendment to an IND for the following two reasons: (1) To ensure that each request is kept in the administrative file with the entire IND and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the evaluation of the protocol and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance recommends that the following information should be submitted to the appropriate center with each request for special protocol assessment so that the center may quickly and efficiently respond to the request:

- Questions to the agency concerning specific issues regarding the protocol; and
- All data, assumptions, and information needed to permit an adequate evaluation of the protocol, including the following: (1) The role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for a stability protocol, product characterization and relevant manufacturing data.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the agency under the act or section 351 of the PHS Act who requests special protocol assessment.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for requests for special protocol assessment. The procedures for requesting special protocol assessment that are set forth in the guidance document have not been previously described by the agency, although the PDUFA goals and the requirements of section 505(b)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(4)(B)), have been in effect since October and November 1998, respectively.

Notification for a Carcinogenicity Protocol. Based on data collected from the review divisions and offices within CDER and CBER, including the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols submitted in fiscal year (FY) 2003, CDER estimates that it will receive approximately 40 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 20 sponsors. CBER anticipates one notification. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

Requests for Special Protocol Assessment. Based on data collected from the review divisions and offices within CDER and CBER, including the number of requests for special protocol assessment submitted in FY 2003, CDER estimates that it will receive approximately 273 requests for special protocol assessment per year from approximately 102 sponsors. CBER estimates that it will receive approximately 20 requests from approximately 12 sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on the agency's experience with these submissions, FDA estimates approximately 15 hours on average would be needed per response. Overall, FDA estimates that respondents will spend 4,523 hours per year to participate in the programs described in the guidance document.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Notification for Carcinogenicity Protocols	21	1.78	41	8	328
Requests for Special Protocol Assessment	114	2.57	293	15	4,395
Total					4,723

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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