Dated: September 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2975]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); VICH GL6 Draft Guidance on ''Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)-Phase I;'' Availability; Request for Comments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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of the following VICH GL6 draft guidance for industry entitled ''Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)-Phase I.'' This draft guidance document has been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). It is intended to assist in developing harmonized guidance for conducting environmental assessments for VMP's in the European Union, Japan, and the United States.

DATES: Submit written comments by October 18, 1999. FDA must receive comments before the deadline in order to ensure their consideration at the next meeting, but the agency will accept general comments after the deadline at any time.

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 Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document.

Copies of this **Federal Register** notice and the draft guidance document entitled ''Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)-Phase I'' may be obtained from the Center for Veterinary Medicine (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 Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.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

Robert C. Livingston, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5903, e-mail: ''rlivings@cvm.fda.gov''.

Regarding the guidance document: Charles E. Eirkson, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6958, e-mail: ''ceirkson@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 requirements 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 Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (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 VMP's. The VICH is concerned with developing harmonized technical requirements for the approval of VMP's in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

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

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 Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative participates in the VICH Steering Committee meetings.

II. Guidance on Assessing Environmental Impacts of VMP's Other Than Veterinary Biological Products

At a meeting held on October 20 through 22, l998, the VICH Steering Committee agreed that the draft guidance entitled ''Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)-Phase I'' should be made available for public comment.

This draft guidance document presents guidance on how to assess the environmental impact of VMP's other than veterinary biological products. This draft guidance document is intended to be consistent with the laws of the European Union, Japan, and the United States. In an effort to harmonize the different requirements in each of these areas for assessing the environmental impact of VMP's, this draft guidance document adopts the terminology ''Phase I EIA's'' and ''Phase II EIA's.''

In the United States, the environmental impact of VMP's is determined under the requirements established by the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR part 1500 and part 25 (21 CFR part 25)). Under NEPA, an environmental assessment (EA) is conducted to determine whether a VMP may have a significant environmental impact. A particular VMP may be categorically excluded from the requirement of an

EA, or it may require an EA or an environmental impact statement (EIS), or it may require both.

Using the terminology of the draft guidance document, a Phase I EIA is equivalent under NEPA to either a categorical exclusion or an EA that addresses only environmental exposures (40 CFR 1508.4 and 1508.9). A Phase II EIA represents an EA with more extensive data than would be necessary under the U.S. equivalent of a Phase I EIA. A Phase II EIA may lead to a finding of no significant impact or preparation of an EIS under NEPA.

Questions 2, 3, and 4 of the VICH guidance, which respectively address natural substances, nonfood animals, and minor species, directly parallel existing categorical exclusions under NEPA. (See § 25.33(c), (d)(1), and (d)(4).) These classes of actions have been determined not to have significant environmental impacts. Similarly, question 5, which concerns VMP's used to treat a small number of animals, generally parallels categorical exclusions in § 25.33(d)(2), (d)(3), (d)(4), and (d)(5). These questions provide guidance for defining when a categorical exclusion may be appropriate for U.S. environmental reviews.

Even when a VMP might ordinarily be categorically excluded under NEPA, there may be extraordinary circumstances that require the submission of an EA. Questions 11 through 13 and 17 provide guidance on when such extraordinary circumstances exist. Specifically, questions 11 through 13 relate to whether the environmental introduction concentration ($EIC_{aquatic}$) of a VMP released from aquaculture facilities is less than 1 microgram/liter (µg/L). Similarly, question 17 relates to whether the predicted environmental concentration in soil (PEC_{soil}) for VMP's used in terrestrial species is less than 100 µg/kilogram (kg). Based upon information reviewed to support the guidance, $EIC_{aquatic}$ at or above 1 µg/L, or PEC_{soil} at or above 100 µg/kg, could result in an environmental exposure concentration that could potentially have significant impact on the environment. Thus, an $EIC_{aquatic}$ equal to or greater than 1 µg/L or a PEC_{soil} equal to or greater than 100 µg/kg represents a level of exposure that constitutes extraordinary circumstances that require the submission of an EA or an EIS (see § 25.21(a)).

Additionally, for questions 11 through 13 and 17, FDA is concerned that if the VMP is not expected to degrade or may bioconcentrate, then the aggregate level of exposure from repeated uses could exceed the 1 µg/L $EIC_{aquatic}$ or the 100 µg/kg PEC_{soil} guidance. FDA is seeking comment on how to address the degradability and bioconcentration of a VMP when applying these guidance.

There are no categorical exclusions which parallel questions 6 through 17. Consequently, an EA to address the issues identified in these questions will be required under NEPA for U.S. environmental review. The EA must provide data demonstrating that any conditions of the question (e.g., the VMP is extensively metabolized in the treated animal) or any proposed mitigations (e.g., waste disposal by incineration or sewage treatment) will result in no significant environmental impacts from the VMP.

FDA specifically requests comment on questions 8 and 14 and the text following these questions because FDA is concerned that the text might create the mistaken impression that any time incineration is used to dispose of a waste matrix, there will be no significant impact on the environment under NEPA. For any mitigation, including incineration, the sponsor needs to provide data in the EA that demonstrates that the mitigating measures do in fact ensure that the VMP has no significant impact on the environment.

CVM will provide more detailed guidance, including guidance on formatting for EA's submitted to the United States, guidance on other extraordinary circumstances, and guidance on other NEPA-related environmental issues, such as impacts on natural and historical resources.

Comments about this draft guidance document will be considered by FDA and the VICH Ecotoxicity Working Group. Ultimately, FDA intends to adopt and publish the VICH Steering Committee's final guidance.

This document, developed under the VICH process, has been revised to conform to FDA's good guidance practice regulations (62 FR 8961, February 27, l997) . For example, the document has been designated ''guidance'' rather than ''guideline.'' Since guidance documents are not binding, mandatory words such as ''must'' and ''shall,'' and ''will'' in the original VICH document have been substituted with ''should.'' Additionally, the term(s) ''veterinary medicinal products'' and ''veterinary pharmaceuticals products'' may require revision to be consistent with product terms used in other VICH guidance documents.

This draft guidance document represents a portion of FDA's current thinking on the conduct of ecological risk assessment for veterinary medicinal products proposed for marketing in the European Union, Japan, and the United States. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

III. Comments

General comments on agency guidance documents are welcome at any time. However, in order to ensure consideration at the next meeting, interested persons should submit written comments on or before October 18, 1999, to the Dockets Management Branch (address above) regarding this draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the 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.

Dated: September 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0232]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or