in new veterinary medicinal products. 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.

II. Comments

Interested persons should submit written comments on or before August 23, 1999, to the Dockets Management Branch (address above) regarding this draft guidance. 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: July 15, 1999

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–18688 Filed 7–21–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2249]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on Stability Testing for Medicated Premixes; Availability; Request for Comments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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment on the following draft guidance for industry document entitled ''Stability Testing for Medicated Premixes.'' This draft guidance document has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance document is an annex to the parent guidance VICH GL3 entitled ''Stability Testing of New Drug Substances and Products in the Veterinary Field.'' This draft guidance document is the annex and addresses the recommendations for stability testing of veterinary medicinal Type A medicated articles (referred to as medicated premix drug products in the draft guidance) intended for submission for approval to the European Union, Japan, and the United States.

DATES: Written comments should be submitted by August 23, 1999. NOTE: FDA will accept comments after the deadline, but to assure consideration, we must receive them by August 23, 1999.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document.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 See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Regarding VICH: Sharon Thompson (HFV–3), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail ''sthompso@cvm.fda.gov''.

Regarding the guidance document: William G. Marnane (HFV–140), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6966, e-mail ''wmarnane@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 seeking 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 registration of human pharmaceutical 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 meetings are held under the auspices of the Office International des Épizooties (OIE). 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 U.S. Food and Drug Administration; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; 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 the industry in Australia/New Zealand, one representative from MERCOSUR (Argentina, Brazil, Uruguay, and Paraguay), and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. 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.

At a meeting held on October 20–22, 1998, the VICH Steering Committee agreed that the draft guidance document entitled ''Stability Testing for Medicated Premixes'' should be made available for public comment.

This draft guidance addresses the generation of acceptable stability information for submission in new animal drug applications (referred to as registration applications in the draft guidance) for Type A medicated articles containing new molecular entities. Comments about this draft guidance document will be considered by the FDA and the VICH Quality Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as future guidance.

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

This draft guidance document represents the FDA's current thinking on acceptable stability testing of Type A medicated articles. 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.

II. Comments

Interested persons may, on or before August 23, 1999, submit to the Dockets Management Branch (address above) written comments 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 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.

III. Electronic Access

Copies of the draft guidance document entitled ''Stability Testing for Medicated Premixes'' may be obtained on the internet within the CVM home page at ''http://www.fda.gov/cvm/fda/TOCs/guideline.html''.

Dated: July 15, 1999

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–18692 Filed 7–21–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2215]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); VICH GL10 Draft Guidance on ''Impurities in New Veterinary Drug Substances;'' 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 developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH GL10 draft guidance for industry entitled ''Impurities in New Veterinary Drug Substances'' is intended to assist in developing registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments August 23, 1999; FDA must receive comments before the deadline in order to ensure their consideration at the next VICH committee meeting, but the agency will accept comments after the deadline.

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 and the docket number found in the heading of this document.

Copies of the draft guidance entitled ''Impurities in New Veterinary Drug Substances'' 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 Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

Regarding VICH: Sharon 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''.

Regarding the guidance document: Kevin Greenlees, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6977, E-mail ''kgreenle@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 seeking 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 registration of human pharmaceutical 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 registration of veterinary medicinal products 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 U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering