DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4071]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); VICH GL18 Draft Guidance on ''Impurities: Residual Solvents;'' Availability; Request for Comments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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of the following VICH GL18 draft guidance for industry entitled ''Impurities: Residual Solvents.'' This draft guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal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 an identically titled guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This draft guidance is intended to recommend acceptable amounts of residual solvents in new animal drugs (referred to as pharmaceuticals or veterinary medicinal products in the draft guidance) for the safety of the target animal as well as for the safety of residues in products derived from treated food-producing animals. It is intended to assist in developing new animal drug applications (referred to as marketing applications in the draft guidance) submitted to the European Union, Japan, and the United States.

DATES: Submit written comments by November 12, 1999.

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 Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

Copies of the draft guidance entitled ''Impurities: Residual Solvents'' may be obtained on the internet from the CVM home page at http://www.fda.gov/cvm/fda/TOCs/guideline.html. Persons without internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.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

Robert C. Livingston, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5903, e-mail: ''rlivings@cvm.fda.gov''.

Regarding the draft guidance: Kevin J. 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 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 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 new animal drugs. The VICH is concerned with developing harmonized technical requirements for the approval of new animal drugs 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 Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. 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.

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 Acceptable Amounts for Residual Solvents

This VICH GL18 draft guidance entitled ''Impurities: Residual Solvents'' has been adapted for veterinary use by the VICH from a guidance regarding pharmaceuticals for human use which was adopted by the ICH and published in the **Federal Register** of December 24, 1997 (62 FR 67377). At a meeting held on May 18 through 20, 1999, the VICH Steering Committee agreed that VICH GL18 should be made available for public comment.

This draft guidance is intended to recommend acceptable amounts for residual solvents in new animal drugs for the safety of the target animal as well as for the safety of residues in products derived from treated food-producing animals. Comments about this draft guidance will be considered by FDA and the VICH Quality Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as a future 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,'' ''shall,'' and ''will'' in the original VICH document have been substituted with ''should'' unless the reference is to a statutory or regulatory requirement.

This draft guidance represents the agency's current thinking on acceptable amounts of residual solvents in new animal drugs. The document does not

create or confer any rights for or on any person and will not operate to bind FDA or the public. You may use alternative methods as long as they satisfy the requirements of the applicable statute and regulation.

III. Comments

General comments are welcome at any time, however, in order to ensure consideration at the next meeting, interested persons should submit written comments by November 12, 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: September 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–26503 Filed 10–8–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Breast Cancer Surveillance Consortium Expansion.

Date: November 1–2, 1999.

Time: 7:00 PM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20853.

Contact Person: Rashmi Gopal, PHD, Scientific Review Administrator, Office of Advisory Activities, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard/EPN–Room 609, Rockville, MD 20892–7410, 301/496–2378.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 30, 1999.

Nancy Middendorf,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–26477 Filed 10–8–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Training Grants Special Emphasis Panel.

Date: October 19–20, 1999.

Time: 3:30 PM to 5:30 PM.

Agenda: To review and evaluate grant applications.

Place: Bethesda Ramada, 8400 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Gopal M. Bhatnagar, PHD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, PHS, DHHS, 9000 Rockville Pike, 6100 Bldg., Room 5E01, Bethesda, MD 20892, (301) 496–1485.

This Notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dates: October 4, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–26473 Filed 10–8–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group, Medical Rehabilitation Research Subcommittee.

Date: October 29, 1999.

Time: 8:00 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Anne Krey, Scientific Review Administrator, Division of Scientific Review: National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Rm 5E03, Bethesda, MD 20892, 301–435–6908.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: October 4, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–26474 Filed 10–8–99; 8:45 am]

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