of guidance documents related to medical devices regulated by CBER.

II. Comments

Written comments should be identified with the docket number found in brackets in the heading of this document and submitted to the Dockets Management Branch (address above). All comments should be identified with the docket number found in brackets in the heading of this document. Stakeholders are encouraged to submit their written comments by Friday, October 1, 1999, in order to have the comments addressed at the meeting. Written comments may also be submitted after the meeting to the Dockets Management Branch (address above) by December 15, 1999. Two copies of any comments should be submitted, except that individuals may submit one copy. Received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Scheduled Meetings

The teleconference will be held in several locations throughout the country. The scheduled times and locations are listed as follows:

TABLE 1.—TELECONFERENCE SCHEDULES

Address/Food and Drug Administration (FDA) District	Scheduled Time of Teleconference
Denver District: Sixth & Kipling Sts., Denver Federal Center, Bldg. 20, rm. B1409, Denver, CO 80225–0087	11 a.m. to 2 p.m. Mountain Time.
San Francisco District: 1431 Harbor Bay Pkwy., Alameda, CA 94502	10 a.m. to 1 p.m. Pacific Time.
Los Angeles District: 19900 MacArthur Blvd., suite 300, Irvine, CA 92715–2445	10 a.m. to 1 p.m. Pacific Time.
Minneapolis District: 240 Hennepin Ave., Minneapolis, MN 55401	12 noon to 3 p.m. Central Time.
New England District: One Montvale Ave., Fourth Floor, Stoneham, MA 02180	1 p.m. to 4 p.m. Eastern Time.

IV. Registration

Send registration information (including name, title, firm name, address, telephone, and fax number) for the public meeting or teleconference, by mail, fax or e-mail to the contact person by Monday, November 8, 1999. Registration at the site will be done on a space available basis on the day of the meeting. There is no registration fee for the meeting. Space is limited, therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Melanie N. Whelan (address above) at least 7 days in advance.

V. Transcripts

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript of the meeting will also be available on the CBER web site at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: September 10, 1999

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–24236 Filed 9–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–3089]

Draft Affirmative Agenda for International Activities—Center for Food Safety and Applied Nutrition; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the document entitled ''Draft Affirmative Agenda for International Activities'' (Draft International Affirmative Agenda) for FDA's Center for Food Safety and Applied Nutrition (CFSAN). The Draft International Affirmative Agenda presents, consistent with the center's mission and resources, CFSAN's international priorities for the next 3 years (2000–2002).

DATES: Written comments by November 1, 1999.

ADDRESSES: The Draft International Affirmative Agenda is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.1061, Rockville, MD 20852. To view the document electronically or to print copies: World Wide Web at ''http://vm.cfsan.fda.gov/''.

FOR FURTHER INFORMATION CONTACT: To obtain a single copy of the Draft International Affirmative Agenda: John W. Jones, Office of Constituent Operations, Center for Food Safety and Applied Nutrition (HFS–550), 200 C St. SW., Washington, DC 20204, 202–205–4311.

SUPPLEMENTARY INFORMATION:

I. Background

CFSAN participates in numerous international activities pertaining to the safety, quality, and labeling of foods and cosmetics. These activities are intended, first and foremost, to enhance FDA's ability to ensure that foods and cosmetics available to American consumers are safe and appropriately labeled, whether the products are produced in or imported into the United States.

The international environment in which CFSAN operates has changed dramatically in the last 20 years. International trade in foods and cosmetics has grown markedly and international trade agreements have introduced new requirements that affect FDA's traditional approaches for regulating such products. Furthermore, resources available for CFSAN to accomplish its international activities are finite and limited.

Thus, CFSAN must establish priorities that are consistent with FDA's mission and resources. CFSAN's Draft International Affirmative Agenda is intended to present achievable, international priorities for the next 3 years for those areas where it is critical for the safety and regulation of foods and/or cosmetics that the center maintain a strong presence.

CFSAN is actively seeking comments on this Draft International Affirmative Agenda and will, if interest is sufficient, consider holding a public meeting to enable further dialogue on its contents. The center would appreciate hearing in the next two weeks from persons regarding the need for a public meeting on the draft document. Comments on the document, itself, may be submitted within the next 45 days.

II. Comments

Interested persons may, on or before November 1, 1999, submit to the Dockets Management Branch (address above) written comments on the draft document. 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 at the head of this notice. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday.

Dated: September 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–24207 Filed 9–16–99; 8:45 am]

BILLING CODE 4160–01–F

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