FOR FURTHER INFORMATION CONTACT: Maribeth Badura, Director, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, HRSA, Room 18–12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–0543; e-mail *MBadura@hrsa.gov*.

Dated: April 21, 2009.

Marcia K. Brand,

Deputy Administrator.

[FR Doc. E9–9517 Filed 4–24–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0430] (formerly Docket No. 2007D–0166)

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Guidance for Industry on ''Target Animal Safety for Veterinary Pharmaceutical Products,'' VICH GL43; 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 (#185) entitled ''Target Animal Safety for Veterinary Pharmaceutical Products,'' VICH GL43. The purpose of this harmonized guidance is to provide recommendations regarding target animal safety (TAS) evaluation for regulatory submission of an Investigational Veterinary Pharmaceutical Product (IVPP), which is appropriate for determining the safety of an IVPP in the target animal. The guidance includes recommendations on including identification of target organs, where possible, and confirmation of margin of safety, using the minimum number of animals appropriate for the studies.

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.

Submit written comments 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Steven Vaughn, Center for Veterinary Medicine, (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8300, e-mail: *steven.vaughn@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations 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 then reduce 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 Approval of Pharmaceuticals for Human Use (VICH) 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 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.

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 the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Guidance on Target Animal Safety for Veterinary Pharmaceutical Products

In the **Federal Register** of May 18, 2007 (72 FR 28058), FDA published the notice of availability for a draft guidance entitled ''Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products,'' which gave interested persons until June 18, 2007, to comment on the draft guidance. FDA received a few comments on the draft guidance and those comments as well as those received by other VICH member regulatory agencies were considered as the guidance was finalized. Based on the comments received, the VICH Expert Working Group on Target Animal Safety clarified the guidance's recommendations regarding the development and conduct of TAS studies. In particular, the Expert Working Group revised the sections addressing necropsy and histopathology examinations and mammary gland studies to clarify the recommendations regarding these topics. At a meeting held in July 2008, the VICH Steering Committee endorsed the final guidance for industry, (VICH GL43). The guidance announced in this notice finalizes the draft guidance dated May 18, 2007.

This guidance document is intended to cover TAS evaluation for any IVPP used in the following species: Bovine, ovine, caprine, feline, canine, porcine, equine, and poultry (chickens and turkeys). The recommendations in this guidance may not be appropriate for registration by national or regional authorities of products for use in minor species or minor uses. The guidance does not provide information for the design of TAS studies in other species, including aquatic animals. For other species and for minor uses, TAS studies should be designed following national or regional guidance.

III. Significance of Guidance

This guidance 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.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement. The guidance represents agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in sections 1–5 of the guidance have been approved under OMB control no. 0910–0032 (expiration date April 30, 2010).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov*.

Dated: April 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–9521 Filed 4–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control, Initial Review Group, (NCIPC, IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC announces the following meeting of the aforementioned review group:

Times and Dates:

8 a.m.–8:15 a.m., April 27, 2009 (Open).

8:15 a.m.–4 p.m., April 27, 2009 (Closed).

Place: Teleconference, Toll Free Number: (877) 468–4185, Participant Pass code: 447–5689.

Status: Portions of the meetings will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications submitted in response to Fiscal Year 2009 Requests for Applications related to the following individual research announcement: CE09–009, Youth Violence Prevention through Economic, Environmental, and Policy Change (U01).

Agenda items are subject to change as priorities dictate.

Due to programmatic issues that had to be resolved, the **Federal Register** notice is being published less than fifteen days before the date of the meeting.

Contact Person for More Information: Lisa T. Garbarino, B.S., NCIPC, Extramural Research Program Office, CDC, 4770 Buford Highway, NE., M/S F62, Atlanta, Georgia 30341–3724, *Telephone:* (404) 723–1527.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 21, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–9503 Filed 4–24–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Computational Modeling for Cardiovascular Devices; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Computational Modeling for Cardiovascular Devices.'' FDA is co-sponsoring the conference with the National Heart, Blood and Lung Institute of the National Institutes of Health and the National Science Foundation. The purpose of the public workshop is to facilitate discussion among FDA and other interested parties on the use of computational modeling in the design, development, and evaluation of cardiovascular medical devices.

Date and Time: The public workshop will be held on June 1 and 2, 2009, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Hilton Washington DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Donna R. Lochner, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4043, e-mail: *donna.lochner@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to facilitate discussion among FDA and other interested parties on the use of computational modeling in cardiovascular device design, development, and evaluation.

II. What Are the Topics We Intend to Address at the Public Workshop?

We hope to discuss a large number of issues at the public workshop, including, but not limited to:

- Multi-scale modeling.
- Imaging for cardiovascular device modeling.
- Physiologic input data for cardiovascular device modeling.
- Device-specific issues related to modeling, including a focus on heart valves, drug-eluting and bare metal stents, endovascular stents, cardiac rhythm management, and mechanical and circulatory support devices.