SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 6, 1999 (65 FR 24406), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0389. The approval expires on June 30, 2002. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: July 27, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–19795 Filed 8–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2406]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on VICH GL9 Good Clinical Practices; Request for Comments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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of the following draft guidance document entitled: VICH GL9 ''Good Clinical Practices.'' This draft guidance document was developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). It is intended to provide a unified standard for designing, conducting, monitoring, recording, and reporting studies used in registration applications for approval of veterinary products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments by September 2, 1999. FDA must receive comment before the deadline in order to ensure their consideration.

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

Copies of the draft guidance document entitled ''Good Clinical Practices'' 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 guidances 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 R. Thompson (HFV–3), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail: ''sthompso@bangate.fda.gov''.

Regarding the guidance document: Herman M. Schoenemann (HFV–120), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0220, e-mail: ''hschoene@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 approval of human pharmaceutical products among the European Union, Japan and the United States. The VICH is a parallel initiative for veterinary products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary 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 Epizooties (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. 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 Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from Mercado Comun Sudamericano (MERCOSUR) representing 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 Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative participates in the VICH Steering Committee meetings.

At a meeting held on October 20 through 22, l998, the VICH Steering Committee agreed that the draft guidance document entitled ''Good Clinical Practices'' should be made available for public comment.

The draft guidance is intended to be an international ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing and reporting clinical studies evaluating veterinary products. Comments about these draft guidance documents will be considered by the FDA and the VICH Good Clinical

Practices Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as future guidance for sponsors of domestic animal drug approvals or as proposed regulations for future comment and final rulemaking.

This document has been revised to conform to FDA's good guidance practices 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'' in the original VICH document have been substituted with the verb ''should.'' These revisions are identified by placing the original word in brackets followed by the substitute verb.

This draft document represents current FDA thinking on design and conduct of all clinical studies of veterinary products in the target species. 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 September 2, 1999 to the Dockets Management Branch (address above) regarding this 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: July 27, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–19871 Filed 8–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Scale-Up and Postapproval Changes, Supplements, and Other Postapproval Changes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Drug Evaluation and Research, and the Southeast Region Small Business Assistance Office, in cooperation with the North Carolina Regulatory Affairs Forum (NCRAF) is announcing the following workshop: FDA/Industry Exchange Workshop on Scale-Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes. The workshop is intended to review the scientific, regulatory, and quality basis of SUPAC; discuss current issues; and provide attendees with information on the impact of the SUPAC guidances that have been finalized, as well as future agency efforts in this area.

Date and Time: The workshop will be held on Tuesday, August 17, 1999, from 8 a.m. to 5 p.m. Send information regarding registration by August 10, 1999.

Location: The workshop will be held at the Durham Marriott at the Civic Center, 201 Foster St., Durham, NC 27701, 919–768–6000, FAX 919–768–6037. Persons needing hotel rooms should mention that they are attending the SUPAC workshop. A special rate is available until July 23, 1999.

Contact: Barbara Ward-Groves, Industry and Small Business Representative, Food and Drug Administration, 60 Eighth St. NE., Atlanta, GA 30309, 404–253–2238.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), along with a $75 check (which will cover refreshments, lunch, and materials) made payable to NCRAF, P.O. Box 13474, Research Triangle Park, NC 27709, c/o Jamie Morgan, 919–845–8055, by August 10, 1999. Space is limited, therefore, interested parties are encouraged to register early. Limited on-site registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact Jamie Morgan at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshop meets the requirements set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C 393) and discussed in the FDA Plan for Statutory Compliance, which include working more closely with stakeholders; maximizing the availability of, and clarifying information about the process for review and submissions; and ensuring access to needed scientific and technical expertise.

The workshop also complies with the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121) that requires outreach activities by Government agencies directed to small businesses.

The topics to be discussed include the following: (1) The history of SUPAC development; (2) comparison of SUPAC immediate-release solid dosage forms, modified-release oral dosage forms, and semisolid-topical dosage forms; (3) bulk actives postapproval changes; (4) postapproval changes sterile aqueous solutions; (5) FDA field staff's involvement in SUPAC; (6) description and use of the equipment addenda to SUPAC; and (7) facts, figures, and future directions.

Dated: July 27, 1999

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–19791 Filed 8–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D092013]

Draft ''Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics.'' This draft guidance, once finalized, will supersede the guidance entitled ''FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics,'' previously made available in the **Federal Register**, that describes innovative arrangements among applicants who wish to cooperate in the manufacture of a licensed biological product. This draft guidance is now being revised to reflect recent changes in the biologics regulations and to provide for additional flexibility in cooperative manufacturing arrangements. The draft guidance is intended to assist manufacturers in the development and production of both conventional and biotechnology-derived biological products, and to increase flexibility in the licensing options for biological products without diminishing the protection of public health.