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.

DATES: Written comments may be submitted at any time, however, comments should be submitted by October 4, 1999, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft ''Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics'' to the Office of Communication, Training, and Manufacturers Assistance (HFM0940), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852091448. Send one self-addressed adhesive label to assist the office in processing your request. The document may also be obtained by mail by calling the CBER Voice Information System at 10980009835094709 or 30109827091800, or by fax by calling the FAX Information System at 10988809CBER09FAX or 30109827093844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the document to the Dockets Management Branch (HFA09305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gloria J. Hicks, Center for Biologics Evaluation and Research (HFM0917), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852091448, 30109827096210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics.'' Once finalized, this document will supersede ''FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics,'' published in the **Federal Register** of November 25, 1992 (57 FR 55544). This revised guidance document is intended to advise current and potential manufacturers of biological and biotechnology products subject to licensure under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262) of available cooperative manufacturing arrangements. These arrangements include short supply, divided manufacturing, shared manufacturing, and contract manufacturing.

CBER recognizes that because development of important new biological products is both expensive and time consuming, increasing flexibility in manufacturing arrangements is desirable. In the **Federal Register** of May 14, 1996 (61 FR 24227), FDA published a final rule amending the biologics regulations at 21 CFR 601.2 to eliminate the establishment license application requirements for certain biotechnology and synthetic biological products subject to licensing under the PHS Act. This final rule also amended 21 CFR 600.3(t) to redefine the term ''manufacturer'' as it is used in 21 CFR 600 through 680. The definition was amended to include ''any legal person or entity who is an applicant for a license where the applicant assumes responsibility for compliance with the applicable product and establishment standards.'' This document is intended to provide guidance to those interested in the manufacture of new biological products, to those already engaged in cooperative manufacturing arrangements, and to those considering changing their present manufacturing arrangements. The guidance document may be useful to applicants submitting product, establishment, and biologics license applications and supplements.

This draft guidance represents the agency's current thinking on cooperative manufacturing arrangements for licensed biologics. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Written comments may be submitted at any time, however, comments should be submitted by October 4, 1999, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except 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.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: July 27, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–19796 Filed 8–2–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2212]

Medical Devices; Draft Guidance on Quality Systems Regulation Information for Various Premarket Submissions; 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 on Quality System Regulation Information for Various PreMarket Submissions.'' This draft guidance is intended to assist medical device manufacturers with information they should include in premarket approval applications (PMA) and product development protocols (PDP) to demonstrate that the submissions are in compliance with the revised quality system (QS) regulation. This draft guidance document also describes the information that should be maintained at the manufacturing facility for premarket notifications (510(k)'s). This draft guidance document represents the agency's current thinking on the QS regulation information for various premarket submissions. This guidance is neither final nor is it in effect at this time.

DATES: Written comments concerning this draft guidance must be submitted by November 1, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Draft Guidance on Quality System Regulation Information for Various PreMarket Submissions'' to the Division of Small Manufacturers Assistance (HFZ–220),