Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Compliance Policy Guide, Chapter 2, Sec. 210.100, Licensing—Changes To Be Reported to the Office of Biologics (CPG 7134.05)	April 26, 1999		
Compliance Policy Guide, Chapter 4, Sec. 460.200, Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-Licensed Pharmacies (CPG 7132.16)	January 8, 1999		

Dated: July 27, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–19978 Filed 8–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2171]

Medical Devices; Draft Guidance for the Accountability Analysis for Clinical Studies for Ophthalmic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled, ''Accountability Analysis for Clinical Studies for Ophthalmic Devices.'' This guidance is intended to provide general information about the analysis of accountability of subjects in clinical studies in ophthalmic device investigational device exemption applications and marketing applications and notifications. By providing a reference point for the reporting of accountability information, FDA hopes that terminology and methods of presentation can be standardized so that the agency and sponsors can more effectively analyze these data. This guidance is not final nor is it in effect at this time.

DATES: Written comments concerning this guidance must be submitted by November 2, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Accountability Analysis for Clinical Studies for Ophthalmic Devices'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to 301–443–8818. Submit written comments on the document to the Dockets Management Branch, (HFA–305), Food and Drug Administration, rm 1061, 5630 Fishers Lane, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Donna R. Lochner, Center for Devices and Radiological Health (HFZ–463), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Accountability Analysis for Clinical Studies for Ophthalmic Devices.'' This guidance document provides background information that FDA and the sponsor can use in preparing accountability analyses for subjects enrolled in clinical studies of ophthalmic devices. It provides definitions of common terminology used in describing accountability, considerations for presentation of a ''lost to follow-up''analysis, and sample formats for presentation of accountability. FDA has noted that there is often a misunderstanding in the meaning of certain terms used to describe accountability, which can confuse the presentation of the accountability data. Further, sponsors have frequently requested that FDA provide them with sample formats for presentation of accountability data. This guidance document attempts to provide some clarity in these areas.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the accountability analysis for ophthalmic devices. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Accountability Analysis for Clinical Studies for Ophthalmic Devices'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1350) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the World Wide Web for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH home page includes the draft guidance entitled ''Accountability Analysis for Clinical Studies for Ophthalmic Devices,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information.

The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

IV. Comments

Interested persons may, on or before November 2, 1999, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Comments should be identified with the docket number found in brackets in the heading of this document.

Dated: July 20, 1999

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–19976 Filed 8–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0017]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Guidance on Validation of Analytical Procedures: Methodology; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Validation of Analytical Procedures: Methodology.'' This 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 adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and published in the **Federal Register**. The guidance provides recommendations on how to consider various validation characteristics for each analytical procedure included as part of registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments at any time.

ADDRESSES: Copies of the final guidance document entitled ''Validation of Analytical Procedures: Methodology'' 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 final 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. Submit written comments on the final guidance document to the Policy and Regulations Team (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT:

Regarding this guidance: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6966, e-mail ''wmarnane@cvm.fda.gov''.

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''.

SUPPLEMENTARY INFORMATION: 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 procedures 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.

FDA has actively participated in the 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 pharmaceutical products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary pharmaceutical 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 Épizooties (OIE). During the initial phase of the VICH, an OIE representative chairs the VICH Steering Committee. 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 industry in Australia/New Zealand, one representative from MERCOSUR (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 Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

This 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 adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and published in the **Federal Register** of May 19, 1997 (62 FR 27464).

In the **Federal Register** of January 27, 1998 (63 FR 3907), FDA published this guidance in draft form, giving interested persons until March 30, 1998, to submit comments. After consideration of comments received, a final draft guidance was submitted to the VICH Steering Committee.

At a meeting held on October 20 through 22, 1998, the VICH Steering Committee endorsed the draft guidance for industry entitled ''Validation of Analytical Procedures: Methodology.'' This guidance discusses common analytical procedures and provides guidance and recommendations on how to consider the various validation characteristics for each analytical procedure included as part of a registration application for approval of veterinary medicinal products. It also indicated the various data that should