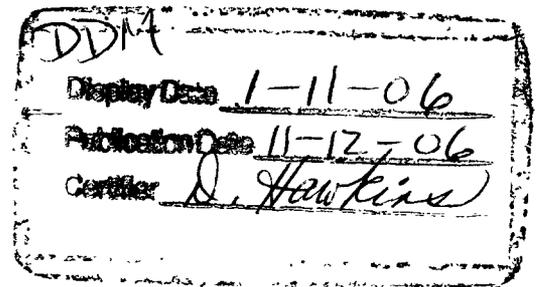


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0386 (formerly Docket No. 03D-0386)]



Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice; 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 entitled “Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.” The guidance describes a formal, two-tiered dispute resolution process intended to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP) that arise during FDA inspections of pharmaceutical manufacturers.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448; or Communications Staff (HFV-12), Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855.

The guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1-800-835-4709 or 301-827-1800. 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 28052. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Edward M. Sherwood, Center for Drug Evaluation and Research (HFD-3), Food and Drug Administration, White Oak 21, rm. 3528, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-1605.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.” The guidance was developed as part of the FDA initiative “Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach,” which was announced in August 2002. The initiative focuses on FDA’s current CGMP program and covers the manufacture of veterinary and human drugs, including human biological drug products.

The agency formed the Dispute Resolution Working Group comprising representatives from the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Veterinary Medicine (CVM). The working

group met weekly on issues related to the dispute resolution process and met with stakeholders in December 2002 to seek their input.

The guidance was initiated in response to industry's request for a formal dispute resolution process to resolve differences related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections. In addition to encouraging manufacturers to use currently available dispute resolution processes, the guidance describes a formal two-tiered dispute resolution process that provides a mechanism for requesting review and decision on issues that arise during inspections.

On September 5, 2003 (68 FR 52777), the FDA announced the availability of the draft version of this guidance. The public comment period closed on March 5, 2004. A number of comments were received, which the agency considered carefully as it finalized the guidance and made appropriate changes. The agency conducted a pilot program with industry for a 12-month period. During that time, the agency received one Tier 1 request for dispute resolution and it was resolved. In addition, FDA met with representatives from industry trade associations in September 2004, near the end of the pilot period, to discuss the draft guidance and receive input.

Most of the changes to the guidance were made to clarify statements in the draft guidance. The following changes in the final guidance are noteworthy: (1) The time period for manufacturers to ask for clarification of a disputed scientific or technical issue was extended from 10 to 30 days; (2) if a request for formal dispute resolution reaches the agency's Dispute Resolution Panel and is considered appropriate for review, the panel will schedule a meeting to discuss the issue within 90 days of the request instead of the indefinite

time period indicated in the draft guidance; (3) the guidance directs manufacturers to the Center for Devices and Radiological Health for disputes involving combination products when medical device components are the focus of the dispute, but clarifies that disputes solely involving medical devices are outside the scope of this guidance; and (4) the guidance clarifies that, during the dispute resolution process, a manufacturer may include relevant information that was not presented during the inspection, if FDA determines that a reasonable explanation was given on why the information was not presented during the inspection.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on formal dispute resolution: scientific and technical issues related to pharmaceutical CGMP. 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 the applicable statutes and regulations.

II. 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.

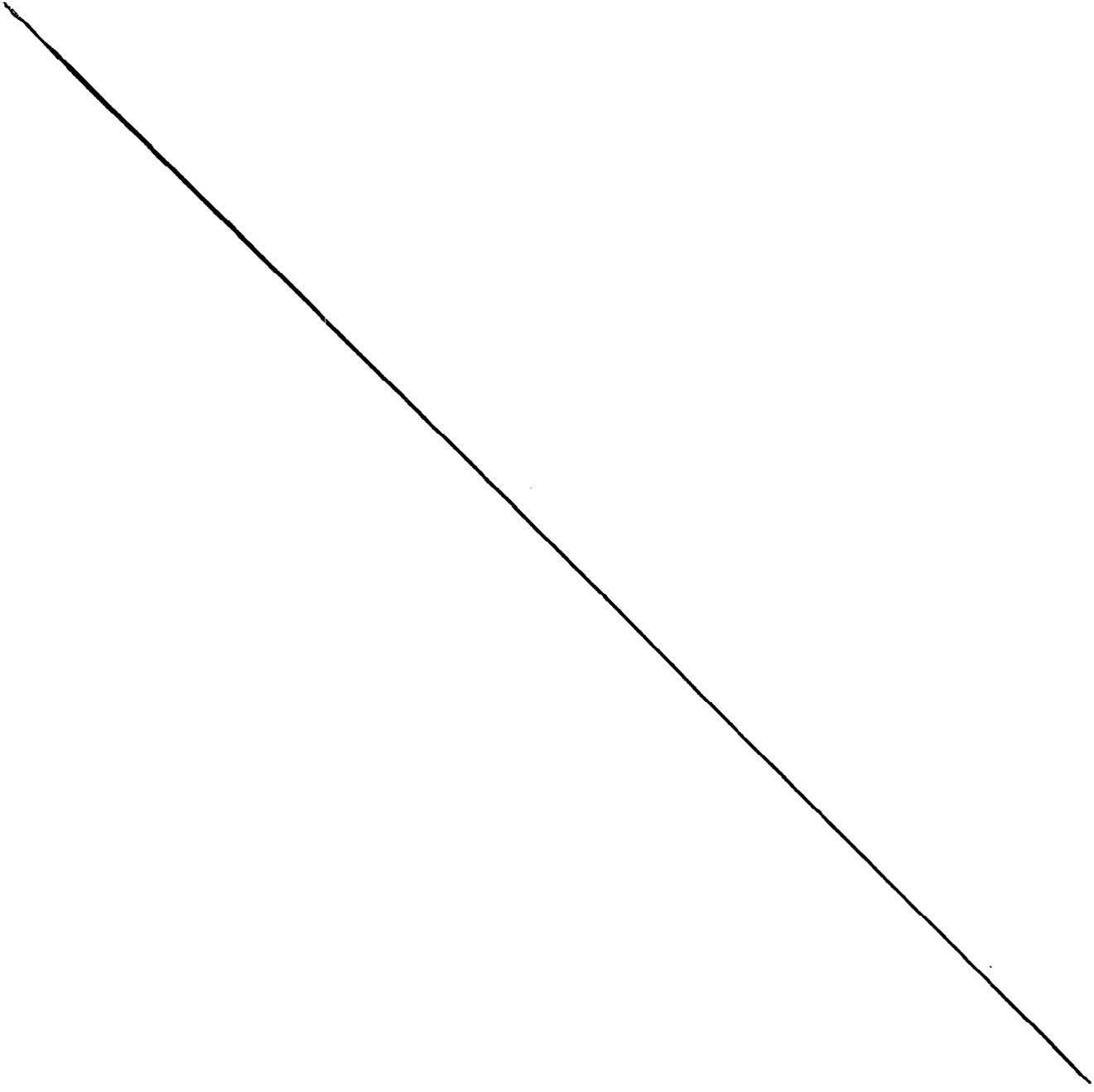
III. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork

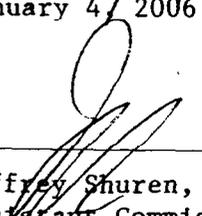
Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0563.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance document at the following *<http://www.fda.gov/cder/guidance/index.htm>* or *<http://www.fda.gov/ohrms/dockets/default.htm>* or *<http://www.fda.gov/cber/guidelines.htm>* or *<http://www.fda.gov/cvm/guidance/guidance.html>*.



Dated: 1/4/06
January 4, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

> [FR Doc. 05-⁶????? Filed ??-??-06⁶; 8:45 am]

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