

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. FDA-2008-D-0060] (formerly Docket No. 1998D-0021)

Guidance for Industry: Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Container and Closure System Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products," dated February 2008. The guidance document provides recommendations to sponsors for using methods other than sterility testing to confirm the integrity of container and closure systems as part of stability testing for sterile biological products, human and veterinary drugs, and medical devices. The guidance document does not apply to sterility testing methods for product sterility testing prior to release, as container and closure system integrity tests cannot demonstrate a product's initial sterility. The guidance announced in this notice finalizes the draft guidance entitled "Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products," dated January 1998.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448; or to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), 5600 Fishers Lane, Rockville, MD 20857; or to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; or to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. The guidance may also be obtained by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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*.

FOR FURTHER INFORMATION CONTACT:

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17),
Food and Drug Administration, 1401 Rockville Pike, suite 200N,
Rockville, MD 20852-1448, 301-827-6210, or

David Hussong, Center for Drug Evaluation and Research (HFD-805), Food
and Drug Administration, 10903 New Hampshire Ave., Silver Spring,
MD 20993-0002, 301-796-1228, or

Geetha J. Jayan, Center for Devices and Radiological Health (HFZ-470),

Food and Drug Administration, 9200 Corporate Blvd, Rockville, MD
20850, 240-276-3747, or

Mai Huynh, Center for Veterinary Medicine (HFV-140), Food and Drug
Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6963.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled “Guidance for Industry: Container and Closure System Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products,” dated February 2008. The guidance document provides information to sponsors who propose using alternative methods to sterility testing to confirm container and closure integrity for sterile biological products, human and veterinary drugs, and medical devices throughout a product’s dating period. The guidance document is applicable only to stability testing, a means of confirming expiration dating. The alternatives described in the guidance document are not offered as a replacement for sterility testing prior to product release, as container and closure system integrity tests cannot demonstrate a product’s initial sterility.

In the **Federal Register** of January 28, 1998 (63 FR 4272), FDA announced the availability of the draft guidance entitled “Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products,” dated January 1998. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. This guidance document was prepared jointly by CBER, CDER, CVM, and CDRH.

The guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance document represents the agency's current thinking on this 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 the applicable statutes and regulations.

II. 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 21 CFR 211.166 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR 314.70 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR 514.8 have been approved under OMB control number 0910–0032; the collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR 814.39 have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR 820.75 have been approved under OMB control number 0910–0073.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

IV. Electronic Access

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

Dated: 2/12/08
February 12, 2008.

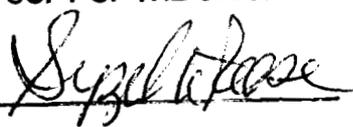


Jeffrey Shuren.
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Suzanne Case