

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0055]

Draft Guidance for Industry: Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products," dated February 2008. The draft guidance document provides manufacturers of cellular and gene therapy products with recommendations on the validation of growth-based Rapid Microbiological Methods (RMMs) for sterility testing of their products. This draft guidance addresses considerations for method validation and determining equivalence of an RMM to sterility assays. This draft guidance applies to somatic cellular therapy and gene therapy products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

DDM

Display Date 2-8-08
Publication Date 2-11-08
Certifier D. Hawkins

CB0640 FDA-2008-D-0055

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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Paul E. Levine, Jr. Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products," dated February 2008. This draft guidance applies to somatic cellular therapy and gene therapy products. This draft guidance does not apply directly to human cells, tissues, and cellular and tissue products (HCT/Ps) which are regulated solely under section 361 of the Public Health Service Act as described under 21 CFR 1271.10, or HCT/Ps which are regulated as medical devices under 21 CFR part 820. Such products are not subject to the sterility testing provision in § 610.12

(21 CFR 610.12), or to the requirement in 21 CFR 610.9 to demonstrate that an alternative RMM is equivalent to the sterility method specified in the regulations. However, HCT/P and device establishments seeking to validate an RMM may find these recommendations useful.

The principles of RMM validation described in this draft guidance apply only to growth-based RMMs. Growth-based RMMs, like traditional methods of detecting viable microorganisms as described in § 610.12, rely on the ability to recover and detect organisms from the product and demonstrate their viability by multiplication in liquid media. The specific recommendations in this document may not be applicable for non-growth-based RMMs which detect microbiological surrogates. This draft guidance focuses on RMMs with qualitative results (i.e., detection of microorganisms). If the RMM does not have the capability to speciate microorganisms, an additional method for speciation will be needed for investigation of detected contaminants. Early discussions with product review staff at CBER are encouraged for individuals intending to use or develop an RMM at any time in the product lifecycle using growth-based, viability-based, surrogate-based, or RMMs that provide quantitative results.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA'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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft 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 to which this draft guidance refers are covered by 21 CFR parts 601 (on BLAs) and 312 (on INDs), and were approved under OMB Control No. 0910–0338 and 0910–0014, respectively.

III. Comments

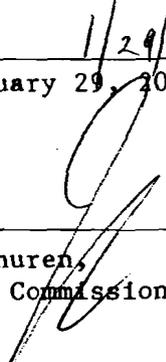
The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic 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 the brackets in the heading of this document. A copy of the draft 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 draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 1/29/08
January 29, 2008.

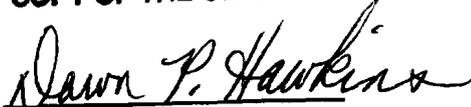


Jeffrey Shuren,
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