Guidance for Industry

Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice

DRAFT GUIDANCE

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For questions regarding this draft document contact (CDER) Richard Friedman, 301-594-0098; (CBER) Robert Sausville, 301-827-6201; (ORA) Robert Coleman, 404-253-1295.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

August 2003
Pharmaceutical CGMPs

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I. INTRODUCTION

This draft guidance is intended to help manufacturers meet the requirements in the Agency's current good manufacturing practice (CGMP) regulations (21 CFR parts 210 and 211) when manufacturing sterile drug and biological products using aseptic processing. This guidance, when finalized, will replace the 1987 *Industry Guideline on Sterile Drug Products Produced by Aseptic Processing*. This revision updates and clarifies the 1987 guidance.

For sterile drug products subject to a new or abbreviated drug application (NDA or ANDA), this guidance document should be read in conjunction with the 1994 guidance on the content of sterile drug applications, entitled *Guideline for the Submission of Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products*. The 1994 submission guidance describes the types of information and data that should be included in drug applications to demonstrate the efficacy of a manufacturer's sterilization process. This draft guidance compliments the 1994 guidance by describing procedures and practices that will help enable a sterile drug manufacturing facility to meet CGMP requirements relating, for example, to facility design, equipment suitability, process validation, and quality control.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are

[1] This guidance was developed by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA).

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