Guidance for Industry

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

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)

September 2004
Pharmaceutical CGMPs

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I. INTRODUCTION

This guidance is intended to help manufacturers meet the requirements in the Agency's current good manufacturing practice (CGMP) regulations (2l CFR parts 210 and 211) when manufacturing sterile drug and biological products using aseptic processing. This guidance replaces the 1987 *Industry Guideline on Sterile Drug Products Produced by Aseptic Processing (Aseptic Processing Guideline)*. This revision updates and clarifies the 1987 guidance.

For sterile drug products subject to a new or abbreviated drug application (NDA or ANDA) or a biologic license application (BLA), this guidance document should be read in conjunction with the 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* (Submission Guidance). The 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 guidance compliments the Submission 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 cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[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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