

# ENFORCEMENT OF CURRENT GOOD MANUFACTURING PRACTICES

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## 1 INTRODUCTION AND BACKGROUND

The legal authority for the Food and Drug Administration (FDA) to impose minimum manufacturing standards is set forth in the federal Food and Drug and Cosmetic Act (FDCA), 21 U.S.C. sec. 301 et seq. Section 351(a)(2)(B) of 21 U.S.C. requires manufacturers of drugs to operate in conformance with manufacturing regulations established by the FDA. The regulations are primarily contained in Title 21 of the U.S. *Code of Federal Regulations* (CFR), Parts 210 and 211, and are called the current good manufacturing practice (cGMP) regulations.

The cGMP regulations stem from congressional concern that impure and otherwise adulterated drugs might escape detection under a system predicated only on seizure of drugs shown to be *in fact* adulterated. That is, the U.S. Congress desired