

CHAPTER 1INTRODUCTION

The use of poisonous preservatives and dyes in foods and the cure-all claims for worthless and dangerous patent medicines led to the enactment of the Federal Food and Drugs Act of 1906 (21 U.S.C. 1-5, 7-15). The 1906 Act was the first step taken to prevent the sale of misbranded and adulterated foods and drugs in interstate commerce. The Food and Drug Administration's authority has been expanded several times since 1906 to include many other consumer products. The Food and Drug Administration (FDA), headed by a Commissioner, is an agency within the Department of Health, Education, and Welfare (HEW). FDA activities are carried out principally through its headquarters and 19 district offices.

The Congress enacted the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301), and the Federal Hazardous Substances Act, as amended (15 U.S.C. 1261), to protect the consumer from adulterated, misbranded, ineffective, or potentially harmful products. Although industry has overall responsibility for insuring that its products are safe and effective, the Congress gave FDA the responsibility for protecting the consumer through enforcement of the statutes.

The Federal Food, Drug, and Cosmetic Act (FD&C Act), defines FDA's regulatory activities for foods, drugs, medical devices, and cosmetics. The act prohibits the introduction of, or delivery of, adulterated, misbranded, or illegally marketed products for introduction into interstate commerce. Adulterated refers to defects in the ingredients or the conditions under which products are processed or packed. Misbranded refers to false or misleading labeling or packaging. Illegally marketed refers to new drugs which have not been approved by FDA for safety and efficacy, as required by the FD&C Act. (In this report adulterated, misbranded, or illegally marketed products are identified as violative products.)

FDA's ability to protect the consumer depends largely on its authority to identify and quickly remove from the market products suspected or known to be violative. FDA