INTRODUCTION

Part One of this document (Legal Analysis of Jurisdiction over Tobacco Products) consists of three main sections. Section I demonstrates that nicotine's addictive and other pharmacological properties are effects on the "structure or any function of the body" within the meaning of the Act's definition of a drug. Section II demonstrates that tobacco manufacturers intend their products to have these effects within the meaning of the Act because: these effects are widely known and foreseeable to the industry; most consumers use tobacco products to obtain these effects; and tobacco manufacturers understand that consumers use tobacco products to obtain nicotine's pharmacologic effects and design their products to be used for these effects. Section III explains why regulation of cigarettes and smokeless tobacco products as devices is most appropriate at this time.

Part Two of this document (Findings) consists of two main sections. Section I presents the scientific evidence of nicotine's addictive and other pharmacological effects. This section also explains how marketed tobacco products deliver pharmacologically active doses of nicotine, and how consumers use these products to obtain various drug effects. Section II describes the statements, extensive research, and other actions by tobacco manufacturers regarding nicotine's pharmacological effects. This section identifies the industry's numerous acknowledgments that nicotine in tobacco acts as a drug and is addictive, and the industry's extensive research on nicotine's drug effects on the body. Section II also describes the considerable industry research on supplying sufficient nicotine to provide "satisfaction," determining the minimum and maximum dose of nicotine required by consumers, and assessing how consumers "compensate" to achieve an adequate dose of

nicotine.

Section II provides further evidence that manufacturers intend to market these products for their pharmacological effects, including explanations of the industry's: product development research to ensure that their products deliver doses of nicotine adequate to achieve pharmacological effects; manipulation and control of nicotine in marketed products; development of nicotine substitutes and alternative products that provide nicotine's drug effects; knowledge that nicotine's sensory effects are secondary to its pharmacological effects; and failure to remove nicotine from tobacco despite the available technology to do so.

Part Three of this document (Regulatory Objectives) summarizes FDA's objectives in regulating cigarettes and smokeless tobacco products. This section explains why, despite the significant public health problem caused by cigarettes and smokeless tobacco products, it would not be appropriate to remove them from the market because approximately 40 million Americans are addicted to these products. The section summarizes the evidence that almost all tobacco use begins during childhood or adolescence, and that the prevalence of tobacco use by children and adolescents is increasing. Therefore, the goal of FDA's regulatory action will be to reduce tobacco use by children and teenagers and prevent future generations from becoming addicted to nicotine-containing tobacco products.