INTRODUCTION AND SUMMARY

FDA has jurisdiction over consumer products, including foods, drugs, medical devices, biologics, and cosmetics, under the Federal Food, Drug, and Cosmetic Act (FDCA or the Act), 21 U.S.C. §§ 301-394, a statute enacted to "safeguard the public health" and to "protect consumer welfare." H.R. Rep. No. 2139, 75th Cong. 3d Sess. 1-2 (1938).

The Act defines "drug" and "device" in a parallel manner. The term "drug" is defined, in relevant part, as an article "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" or "intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(B), (C). The term "device" is defined as an instrument or other similar article "intended for use in the cure, mitigation, treatment or prevention of disease" or "intended to affect the structure or any function of the body." 21 U.S.C. § 321(h)(2), (3). These definitions are broad in scope and encompass a range of products wider than those ordinarily thought of as drugs or medical devices. Indeed, FDA has regulated such diverse, non-therapeutic products as narcotics without medical claims and tanning booths pursuant to these definitions. The question of whether a product is a drug or device is one that "the FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided [in the FDCA]." Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653 (1973); see id. at 652-54; CIBA Corp. v. Weinberger, 412 U.S. 640, 643-44 (1973); see also Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1377 (9th Cir. 1983).

Under the Act, FDA has jurisdiction over nicotine-containing cigarettes and smokeless tobacco products (hereafter "cigarettes and smokeless tobacco products") if they are intended to treat a disease or to affect the structure or any function of the body. As set forth in greater

detail below, the evidence now available to the agency demonstrates that cigarettes and smokeless tobacco products fall well within the definitions of drug and device.[1] It is well established that nicotine in tobacco is highly addictive, causes other psychoactive effects, such as relaxation and stimulation, and affects weight regulation. These responses to nicotine are effects on the structure or function of the body within the meaning of the Act.

The evidence before the agency also demonstrates that manufacturers intend to market and distribute products that affect the structure or function of the body within the meaning of the Act. Under the Act, Agency regulations, well-established case law, and longstanding Agency practice, discussed in detail below, "intended for use" and "intended to affect" can be demonstrated by evidence that: drug-like (pharmacological) effects in a large proportion of consumers are foreseeable by a reasonable manufacturer; consumers use the product predominantly and even nearly exclusively for its significant pharmacological effects; or manufacturers actually know that the product will be used for its significant pharmacological effects and have taken steps to encourage such use. In determining the intended use of a product, all relevant evidence may be considered, including the product's effect on consumers, consumer behavior and statements regarding the product, manufacturers' conduct and statements, results of scientific studies, and the other circumstances surrounding the distribution of the product.

In 1988, the U. S. Surgeon General issued a report formally recognizing that nicotine in cigarettes causes addiction. He had made a similar finding for smokeless tobacco products

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[1] The quality, quantity, and scope of the evidence available to FDA today is far greater than any other time when FDA has considered regulation of cigarettes and smokeless tobacco products. *See* LEGAL ANALYSIS § I.B.1., *infra,* p. 22.

in 1986. Today, nearly every major public health organization in this country and many experts who consult for the tobacco companies consider tobacco products containing nicotine to be addictive. In fact, recent major studies show that 75% to 90% of frequent smokers of tobacco are addicted. Thus, manufacturers of these products can reasonably be expected to foresee that their products are likely to lead to addiction in a large proportion of consumers.

This evidence also demonstrates that the vast majority of smokers and many smokeless tobacco consumers, because they are addicted to nicotine, use cigarettes and smokeless tobacco to satisfy nicotine dependence. Many of these consumers also use these products to affect mood and to control weight. Consumers use cigarettes predominantly and even "nearly exclusively" for their pharmacological effects.

Finally, internal tobacco industry documents demonstrate the industry's longstanding knowledge of and extensive research on the significant addictive and pharmacological effects of nicotine. Moreover, manufacturers of tobacco products have conducted product development research regarding the levels of nicotine necessary to produce pharmacological effects in tobacco users and also on methods of manipulating the amount of nicotine delivered by cigarettes. FDA's investigation has revealed that tobacco manufacturers actively control the amount and rate at which nicotine from marketed cigarettes and smokeless tobacco is delivered to consumers. Smokeless tobacco manufacturers both manipulate the amount of nicotine delivered by their products and promote the graduation of smokeless tobacco consumers from the lowest to the highest nicotine products, demonstrating an intention to facilitate nicotine dependence.

In summary, the evidence before the agency demonstrates that cigarettes and

smokeless tobacco products are intended to affect the structure and function of the body. Accordingly, the record[1a] before the agency demonstrates that cigarettes and smokeless tobacco products are drug delivery systems whose purpose is to deliver nicotine, a drug, and, hence, are devices under the Act. Given the current evidence, the nature of the products, and the nature of the regulatory framework, cigarettes and smokeless tobacco products should be regulated as devices under the Federal Food, Drug, and Cosmetic Act.

[1a]The phrase "record" as used throughout this document is not used as a term of art, but is used instead to refer to the accumulation of evidence gathered during FDA's investigation.