III. NICOTINE-CONTAINING CIGARETTES AND SMOKELESS TOBACCO PRODUCTS ARE DRUG DELIVERY SYSTEMS THAT ARE APPROPRIATELY REGULATED AS DEVICES.

Nicotine-containing cigarettes and smokeless tobacco products are "intended to affect the structure or any function of the body" within the meaning of the Act's drug and device definitions. 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3). Based on the agency's analysis of the evidence before it: (1) the nicotine in cigarettes and smokeless tobacco products is a drug, achieving its effect through chemical action within the body; (2) cigarettes and smokeless tobacco are drug delivery systems whose purpose is to deliver nicotine in a manner in which it can be most readily absorbed by the consumer, and are, therefore, devices; and (3) cigarettes and smokeless tobacco products are combination products that the agency has the discretion to regulate using drug authorities, device authorities, or a combination of both authorities. 21 C.F.R. § 3.2(e) (1994). The record before the agency supports regulation of cigarettes and smokeless tobacco products pursuant to the Act's device authorities.

FDA considers device-like products, such as instruments, implements, machines, contrivances, implants, or other similar or related articles, 21 U.S.C. § 321(h), whose primary purpose is delivery of a drug, and that are distributed with a drug product, to be drug delivery systems. Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health § VII.A.1.(b)(October 31, 1991)("Intercenter Agreement"). Examples include contrivances containing drugs, such as pre-filled syringes, transdermal patches, and metered-dose inhalers. Id. Cigarettes and smokeless tobacco products function in a similar manner in that they contain a drug, nicotine; are used to deliver that drug to the site at which the drug will be absorbed into the body, the mouth or lungs; and

after the drug has been delivered, the delivery system, the cigarette butt or smokeless tobacco material, depleted of nicotine, remains and must be disposed of. Only the nicotine delivered by these products achieves its primary intended purpose by chemical action in or on the body.

Specifically, a cigarette is analogous to a metered-dose inhaler, an instrument that converts a drug into an aerosolized form for inhalation and delivery to the lungs for absorption into the bloodstream. Indeed, a cigarette is not simply tobacco, paper, and a filter. It is "a highly engineered product." FDA Docket No. 94P-0069, Response of R.J. Reynolds Tobacco Company, Appendix D, p. 1 (November 2, 1994). A device is an instrument or related article that "does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

The primary purpose of parts of the cigarette, each of which is a device or device component within the Act's meaning, and the cigarette itself, a consciously engineered instrument, is to effectuate the delivery of a carefully controlled amount of the nicotine to a site in the human body where it can be absorbed. The drug, nicotine, is generally contained within the treated rolled tobacco. The delivery system, the nicotine-containing cigarette, must be lit to have its intended effect on the structure or function of the body, and, once lit and used, is discarded. When lit, the cigarette produces nicotine-containing smoke, which is inhaled by the consumer and when absorbed in the lungs, yields on average approximately 1.0 mg of nicotine. As the evidence discussed above reveals, cigarettes are drug delivery systems and, accordingly, are devices within the meaning of the Act.

Smokeless tobacco products function like infusion devices or transdermal patches that

deliver a controlled continuous amount of nicotine to the cheek tissue for absorption into the bloodstream. The device element of smokeless products is the tobacco, which contains the nicotine but is not intended to be consumed. Instead, in normal use, most of the tobacco in the product is not absorbed by the user and is removed from the mouth after absorption of the nicotine through the cheek tissue.

The primary purpose of the tobacco is to provide a palpable vehicle that allows nicotine to be extracted from the tobacco by the user's saliva so that it may be absorbed into the body.[13] The tobacco also delivers chemicals added during the manufacturing process, primarily alkalines, that increase the pH within the oral cavity and affect the rate at which the nicotine is absorbed into the body. See FINDINGS § II.E.2.

Because cigarettes and smokeless tobacco products are drug-device combination products, FDA may regulate them as drugs, devices, or both. See 56 Fed. Reg. 58754, 58754-55 (November 21, 1991); Intercenter Agreement § VII.A.1(b). Based on the record before the agency, regulation of cigarettes and smokeless tobacco products pursuant to the Act's device authorities is most appropriate at this time.[14] The alternative, regulating the products

---

[13] The fact that smokeless tobacco material is largely organic does not remove it from the definition of a device. FDA regulates many organic substances as devices, as well as liquids and gases. For example, FDA regulates as devices: injectable collagen, hemodialysis fluids, lubricants and lubricating jellies, preservation solutions for organ/tissue transport, absorbable sponges and wound dressings, gas mixtures for pulmonary function tests, spray-on dressings, liquids functioning through physical action applied to the body to cool or freeze tissues, and sodium hyaluronate or hyaluronic acids for use as a surgical aid. See Intercenter Agreement § VII.C.

[14] This decision is similar to the determination of the Department of Health, Education, and Welfare (HEW), before authority over biologic drugs was transferred to FDA, regarding radioactive biologic products. Radioactive biologic products are both biologics under the Public Health Service Act (PHSA), 42 U.S.C. § 262, as well as drugs and new drugs, 21 U.S.C. § 321(g), (p), that may be regulated pursuant to the drug provisions of the FDCA. HEW determined that a drug would not be subject to the new drug provisions of the FDCA if it is a drug regulated as a biologic product pursuant to the licensure provisions of the PHSA. 40 Fed. Reg. 31311, 31312 (July 25, 1975); see 21 C.F.R. § 310.4.

pursuant to the Act's drug authorities, might result in the removal of these products from the market. Over 40 million Americans are currently addicted to cigarettes and smokeless tobacco products. Prohibiting the sale of these products, which could be required if FDA were to apply the Act's new drug authorities to them, could have significant health consequences for a substantial number of these nicotine-addicted consumers. In the unique setting of highly addictive products that have already been marketed for a sufficient period to addict a large number of Americans, application of requirements that could result in the abrupt removal of the products from the market is not the most appropriate regulatory response.

By contrast, the Act's device authorities provide flexible tools that allow FDA to establish and move towards the public health protection goals that are most practicable for cigarettes and smokeless tobacco products. Therefore, FDA is proposing a set of regulatory requirements for these products pursuant to the Act's device authorities.

The Medical Device Amendments of 1976, while having as their objective the ultimate assurance of the safety and effectiveness of marketed devices, contain provisions designed to permit a staged, multi-tiered approach to assuring the safety and effectiveness of long-marketed products. The authorities available under the Act's device provisions may be used to help eliminate or greatly reduce the addiction of the next generation of American children and teenagers to cigarettes and smokeless tobacco products.

Based on the record before the agency, all cigarettes and smokeless tobacco products distributed in the United States are drug-device combination products subject to regulation as devices. The record before the agency includes evidence that these products are intended to

affect the structure or any function of the body, based in part on nicotine's well-established pharmacological and addictive effects and the widespread consumer use of cigarettes and smokeless tobacco for pharmacological purposes. These factors are relevant to establishing the intended use of all brands of cigarettes and smokeless tobacco products distributed in the United States.

The Agency has obtained evidence concerning the knowledge of cigarette and smokeless tobacco product manufacturers about the pharmacological and addictive effects of nicotine in cigarettes and smokeless tobacco, and their manipulation of nicotine delivery to satisfy users' physiological need for nicotine, from the major manufacturers of these products and from CTR. Products from these manufacturers account for the vast majority of the U.S. cigarette and smokeless-tobacco market and probably account for close to 100% of that market. Under FDA's traditional approach to device classification, it is appropriate to classify all marketed cigarettes and smokeless tobacco products as drug delivery devices based on the cumulative evidence obtained from manufacturers.