widespread use of these products in this country, it is not unreasonable to assume that a black market and/or smuggling would develop to supply addicted users with the products they require. The products that would be available through a black market could very well be more dangerous (e.g., cigarettes containing more tar or nicotine, or more toxic additives) than products currently on the market. Thus, FDA believes that a ban on all tobacco products would not eliminate smoking and would not be in the best interest of the public health at this time.

Given the dangerous health consequences of the continued use of cigarettes and smokeless tobacco products, however, the agency believes that some strong action is necessary to protect the public health. As explained in the next section, FDA has chosen to regulate these combination products using the Act's device provisions, rather than the drug provisions, because application of the device authorities would allow the continued marketing of the affected products under certain prescribed conditions established under notice and comment rulemaking procedures.

As discussed above, the primary jurisdiction over these combination products within FDA lies in CDER. This designation is appropriate because of CDER's expertise in pharmacology and drug delivery; addiction, the disease associated with tobacco use; and the regulation of pre-filled drug delivery systems. CDER, however, has the authority to use drug provisions, device provisions, or a combination of drug and device provisions in regulating these products.

4. Regulation of Cigarettes and Smokeless Tobacco Under the Device Authorities

As currently marketed, cigarettes and smokeless tobacco products are not safe and effective. Chronic use of tobacco products causes disease and premature death in a significant proportion of users.

Both the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990 were designed to provide an array of regulatory tools that could provide reasonable assurance of the safety and effectiveness of devices. Since tobacco products are plainly not safe, one regulatory tool available under the statute is to ban the products, making their sale illegal. The legal basis for such a ban would be that tobacco products present an unreasonable and substantial risk of illness or injury. See section 516 of the act. Because of the addictiveness of tobacco products, however, tobacco products present special problems not ordinarily associated with devices. As discussed in the preceding section, in the case of cigarettes and smokeless tobacco products, a ban would not be in the best interest of the public health.

While premarket approval of a device has generally been regarded as the regulatory control that provides the greatest assurance of safety and effectiveness, on occasion the agency has chosen not to use premarket approval for critical devices that potentially raise significant safety and efficacy issues. For example, the agency has announced that it will no longer enforce premarket approval requirements for heart valve allografts. See the Federal Register of October 14, 1994 (59 FR 52078). FDA took this action after concluding that other regulatory controls would be more appropriate than premarket approval to provide reasonable assurance of the safety and effectiveness of these products. See also Heckler v. Chaney, 470 U.S. 821 (1985) (upholding agency's decision not to enforce premarket approval requirements for use of prescription drugs for lethal injection).

The Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990 provide the agency with considerable flexibility in identifying the most appropriate scheme for regulating products. These device provisions authorize the agency to use the regulatory tools that most appropriately protect the public from unsafe or ineffective devices. Moreover, these device provisions permit the agency to tailor the regulatory controls authorized under the statute to address the specific risks associated with individual devices. The following tools, among others, may be used to help provide reasonable assurance of safety and effectiveness for individual devices: special controls (section 514 of the act); premarket approval (section 515 of the act); product development protocols (section 515 of the act); notification and recall (section 518 of the act); device tracking (section 519(e) of the act); custom devices (section 520(b) of the act); restrictions on sale, distribution, and use (section 520(e) of the act); and postmarketing surveillance (section 522 of the act). Where the public cannot be appropriately protected from a hazardous device using the tools on which the agency might otherwise rely for a device posing a substantial risk, FDA has discretion to employ other, more appropriate regulatory controls provided by the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990.

In the situation presented by widespread addiction to cigarettes and smokeless tobacco, where restrictions on supply would not be effective, the goals of the statute can best be achieved by preventing future users from becoming addicted to tobacco products. Restrictions on the sale and distribution of cigarettes and smokeless tobacco products to young people, as well as restrictions on advertising that fosters appeal and creates a demand for tobacco products among young people, are therefore the appropriate tools to attain the goal of reasonable assurance of safety and effectiveness for cigarettes and smokeless tobacco products, even if the goal can only be reached over one or more generations.⁶

The agency believes that the measures proposed in this regulation will reduce the exposure of children and adolescents to the health risks associated with tobacco use; will greatly reduce the number of individuals who are now, or may in the future become, addicted to nicotine in these products; and, from an epidemiological perspective, the combined effects of the proposed measures will, under the unique circumstances of these products, provide the most reasonable assurance of their safety.

The Medical Device Amendments provide authority to restrict the sale and distribution of products, like tobacco, for which there cannot otherwise be reasonable assurance of safety and effectiveness. Section 520(e) of the act, which authorizes FDA to restrict the sale and distribution of certain devices, provides regulatory tools that would enable FDA to achieve the goal of reducing demand for tobacco products. Therefore, FDA is proposing to declare cigarettes and smokeless tobacco products "restricted devices" and to impose restrictions on the underage sale and distribution of these tobacco products, pursuant to section 520(e) of the act.

5. Restricted Device Authority Under Section 520 of the Act

Section 520(e)(1)(B) of the act authorizes FDA to issue regulations restricting the sale, distribution, or use of a device:

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

Because of the potentiality for harmful effects from cigarettes and smokeless tobacco products, there cannot be reasonable assurance of the safety and effectiveness of these products short of