

additional restrictions designed to prevent new users from becoming addicted to nicotine-containing tobacco products and to provide information to current users on how to quit.

As discussed earlier in this document, cigarettes and smokeless tobacco products have substantial "potentiality for harmful effect" because they are both addictive and pose a significant risk to the health of users. The most effective way to provide reasonable assurance of the safety and effectiveness of tobacco products is to prevent future generations from using and becoming addicted to these products in the first instance, and as explained elsewhere in this document, tobacco use is typically initiated during childhood and adolescence. The mean average age when people become daily smokers is 17.7 years of age.<sup>7</sup> Moreover, those who start smoking in childhood are more likely to become heavier smokers than those who start smoking in adolescence, and those who start as adolescents are more likely to become heavier smokers than those who start as adults. Thus, the age at which an individual starts smoking is an important factor that influences the intensity of that person's smoking as an adult, and consequently his or her ultimate health risks. These facts are echoed in one of the major conclusions of the 1994 Surgeon General's Report: "Nearly all first use of tobacco occurs before high school graduation; this finding suggests that if adolescents can be kept tobacco-free, most will never start using tobacco."<sup>8</sup>

The proposed restrictions on sale and distribution of tobacco products are therefore designed to substantially reduce the number of children and adolescents who become addicted to tobacco. The proposed regulations would restrict young people's access to tobacco (see proposed §§ 897.12, 897.14, and 897.16), decrease the allure of the advertising and promotion of these products (see proposed §§ 897.30, 897.32, 897.34, and 897.36), and provide educational messages aimed at young people to combat pervasive pro-tobacco messages and thus to help them resist tobacco use (see proposed § 897.29).

**Access.** Although State and local laws impose certain restrictions on the access of young people to tobacco, over a million children and adolescents continue to become regular tobacco users each year. Unless additional measures are imposed to substantially reduce this number, cigarettes and smokeless tobacco will continue to cause disease and death in each subsequent generation. Thus, without additional restrictions designed to

eliminate or substantially reduce the initiation of cigarettes and smokeless tobacco use by children and adolescents, there cannot be reasonable assurance of the safety of these products.

**Advertising.** For the many reasons described in this document, advertising plays a role in influencing a young person's decision to purchase and use these products. This advertising is particularly attractive to persons under the age of 18. Sections 502 (q) and (r) of the act give the agency specific authority over the advertising of restricted devices to ensure that it is truthful, nonmisleading, and contains important information about the risks associated with the use of the product. Thus, section 502(q) of the act declares misbranded any restricted device whose advertising is "false or misleading in any particular" (see proposed § 897.36) and section 502(r) requires that "all advertisements and other descriptive printed matter" associated with a restricted device must contain certain specified information, including a brief statement of "relevant warnings, precautions, side effects, and contraindications" (see proposed § 897.32).

In addition, the agency has proposed restrictions on the sale of these products, specifically to prohibit all sales to those under the age of 18. Advertising with attractive imagery, brand identifiable non-tobacco items, and sponsorship of events are appealing to young people under age 18 and are effective in influencing their decision to use tobacco products. The advertising techniques that would be prohibited by the proposed rule encourage an unauthorized use of these products and thus cause them to be misbranded.

Most importantly, FDA also has been granted broad authority in section 520(e) of the act, under which the agency may place restrictions on the sale, the distribution, or the use of certain devices where the potentiality for harm makes these restrictions necessary. The broad sweep of this language implies authority to regulate many aspects of the commercialization of a restricted device. FDA is interpreting this section to authorize restrictions on the product's distribution, its offering for sale (including inducements to sale), the sale itself, and the consumer's use (including the product's misuse). This reading of section 520(e) of the act is required if the agency is to have the ability to regulate restricted devices effectively and avoid having its efforts undercut. For example, the agency is proposing to prohibit the sale of tobacco products to

those under age 18. If a manufacturer advertises its tobacco products in such a way that it has the effect of encouraging underage individuals to purchase these products, the restriction on the sale of the product would be significantly undermined. In such a case, section 520(e) of the act provides the agency the additional authority to curtail the advertising practices that threaten the effectiveness of its sale restrictions.

Just as restrictions must be placed on young people's access to tobacco products in order to limit their ability to purchase these products, it is equally important to place restrictions on the marketing practices (including advertising and promotion) of the tobacco industry. Certain advertising and promotional practices of the tobacco industry play a significant and important contributory role in a young person's decision to use cigarettes and smokeless tobacco products.

As detailed more fully in Chapter III, subpart D, individual studies illustrate the profound effect that certain tobacco campaigns have had upon the youth market. Moreover, studies have indicated that comprehensive restrictions on advertising can help reduce children's demand for these products.

Restrictions on advertising are necessary in order to reduce the demand for tobacco products by young people and therefore their desire to purchase these products. Accordingly, placing restrictions on certain marketing and advertising practices of the tobacco industry is necessary to restrict the "sale, distribution, or use" of these products.

**Information and Educational Messages.** FDA has determined that an educational program about cigarettes and smokeless tobacco products is a restriction that is necessary because of the "potentiality for harmful effect" of these products. As discussed above, it is necessary to impose restrictions to discourage children and adolescents from using and becoming addicted to these products and to provide important health information to those who are currently addicted to these products to allow them to decrease or cease their use of these products. The brief statements that would be mandated by the proposed rule will be designed to provide some information for current users, but are not specifically addressed to, nor narrowly targeted to, the adolescent nonuser. Consequently, given the effect of the pervasive and long standing pro-tobacco messages on young people, FDA is proposing an educational campaign, national in scope