## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 804, and 897 [Docket No. 95N-0253]

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products To Protect Children and Adolescents

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing new regulations governing the sale and distribution of nicotine-containing cigarettes and smokeless tobacco products to children and adolescents in order to address the serious public health problems caused by the use of and addiction to these products. The proposed rule would reduce children's and adolescents' easy access to cigarettes and smokeless tobacco as well as significantly decrease the amount of positive imagery that makes these products so appealing to them. The proposed rule would not restrict the use of tobacco products by adults.

Specifically, the proposed rule would establish 18 years of age as the Federal minimum age of purchase and would prohibit cigarette vending machines, free samples, mail-order sales, and selfservice displays. It would also require that retailers comply with certain conditions regarding sales of tobacco, especially verification that the purchaser is at least 18 years of age before a tobacco sale is made. Finally, the proposed rule would limit advertising and labeling to which children and adolescents are exposed to a text-only format; ban the sale or distribution of branded non-tobacco items such as hats and tee shirts; restrict sponsorship of events to the corporate name only; and require manufacturers to establish and maintain a national public education campaign aimed at children and adolescents to counter the pervasive imagery and reduce the appeal created by decades of protobacco messages and thus to help reduce young people's use of tobacco products.

The objective of the proposed rule is to meet the goal of the report "Healthy People 2000" by reducing roughly by half children's and adolescents' use of tobacco products. If this objective is not met within seven years of the date of publication of the final rule, the agency will take additional measures to help

achieve the reduction in the use of tobacco products by young people. FDA is requesting comment regarding the type of additional measures that would be most effective.

DATES: Written comments and recommendations by November 9, 1995. ADDRESSES: Submit written comments and recommendations to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301–827–3380.

## SUPPLEMENTARY INFORMATION:

## I. Introduction

Approximately 50 million Americans currently smoke cigarettes and another 6 million use smokeless tobacco products. These tobacco products are responsible for more than 400,000 deaths each year due to cancer, respiratory illnesses, heart disease, and other health problems.<sup>2</sup> Cigarettes kill more Americans each year than acquired immune deficiency syndrome (AIDS), alcohol, car accidents, murders, suicides, illegal drugs, and fires combined.3 On average, smokers who die from a disease caused by smoking lose 12 to 15 years of life because of tobacco use.4

In a separate document,<sup>5</sup> FDA is addressing the issue of its jurisdiction over nicotine-containing cigarettes and smokeless tobacco products. The results of an extensive investigation and comprehensive legal analysis support a finding at this time that the nicotine in these products is a drug and that these products are nicotine-delivery devices within the meaning of the Federal Food, Drug, and Cosmetic Act (the act). FDA proposes to regulate cigarettes and smokeless tobacco products by employing its restricted device authority, which affords the most appropriate and flexible mechanism for regulating the sale, distribution, and use of these products.

The primary objective of the proposed rule is to reduce the death and disease caused by tobacco products. Rather than banning tobacco products for the millions of Americans who are currently addicted to them, this regulation focuses on preventing future generations from developing an addiction to nicotine-containing tobacco products. In addition, the scientific evidence strongly suggests that nicotine addiction begins when most tobacco users are teenagers or younger and, thus, is a

pediatric disease. Therefore, reducing the number of young people who regularly start to use tobacco products will help to prevent future generations of individuals from becoming addicted to nicotine.

The goal of the proposed rule is to help the country achieve one of the objectives of "Healthy People 2000," which is to reduce the number of children and adolescents who use tobacco products by roughly one half by the year 2000. The agency has modified the goal to include a different measurement tool and established 7 years after publication of the final rule as the goal's endpoint. "Healthy People 2000" discussed national health promotion and disease prevention objectives in this country. It was facilitated by the Institute of Medicine of the National Academy of Sciences, with the help of the U.S. Public Health Service, and included almost 300 national membership organizations and all State health departments.6

To determine the most appropriate regulatory measures, the agency reviewed the current patterns of use of tobacco products. According to the 1994 Surgeon General's Report, "Preventing Tobacco Use Among Young People: A Report of the Surgeon General" (the 1994 Surgeon General's Report), more than 3 million American adolescents currently smoke cigarettes and an additional 1 million adolescent males use smokeless tobacco.7 Every day, another 3,000 young people become regular smokers.8 U.S. data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely to ever begin.9 Eighty-two percent of adults who ever smoked had their first cigarette before age 18, and more than half of them had already become regular smokers by that age. 10 Moreover, the younger one begins to smoke, the more likely one is to become a heavy smoker.11

Many young tobacco users become addicted to nicotine, a chemical substance in tobacco. Although they believe that they will not become addicted to nicotine or become long-term users of tobacco products, they often find themselves unable to quit smoking. <sup>12</sup> In fact, among smokers aged 12–17 years, 70 percent already regret their decision to smoke and 66 percent state that they want to quit. <sup>13</sup> Those who are able to quit experience relapse rates and withdrawal symptoms similar to those reported in adults. <sup>14</sup>

Long-term addiction to nicotine can result in serious chronic diseases and premature death. An adolescent whose cigarette use continues into adulthood increases his or her risk of dying from