1. Section 897.1—Scope

Proposed § 897.1(a) would state that part 897 is intended to establish conditions under which nicotinecontaining cigarettes and smokeless tobacco products may be sold, distributed, or used. The proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act. FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products. Proposed § 897.1(b) would note that all references to regulatory sections in the Code of Federal Regulations are to Title 21 unless otherwise noted.

2. Section 897.2—Purpose

Proposed 897.2(a) would state that part 897 is intended to help prevent persons younger than 18 years of age from becoming addicted to nicotine, thereby avoiding the life-threatening consequences often associated with tobacco use. The proposed rule would accomplish this goal by reducing the appeal of and access to cigarettes and smokeless tobacco products by persons under 18 years of age; it would preserve access to cigarettes and smokeless tobacco products by persons 18 years of age and older. Proposed § 897.2(b) would add that the provisions are intended to provide important information about product use to users and potential users.

3. Section 897.3—Definitions

Proposed 897.3 would establish definitions of terms used in the proposed rule, such as "cigarette" (897.3(a)) and "distributor" (897.3(c)). In drafting the definitions, FDA examined existing definitions in Federal laws and regulations and paid special attention to existing definitions in other FDA regulations. These definitions are contained in the proposed codified language.

Proposed 897.3(e) contains the definition of "nicotine," which is based, in part, on the chemical name and formula for nicotine in the "Merck Index" (10th Edition). The agency also notes that, while the proposed rule defines "cigarette," in part, as a product that "contains or delivers nicotine," it is aware that some companies are trying to develop chemical substances that are pharmacologically active or are as addictive as nicotine or that would be used to enhance nicotine's

pharmacological qualities. The agency's investigation has focused primarily on cigarettes and smokeless tobacco products that contain nicotine, and FDA would therefore consider a cigarette-like product that contains a pharmacologically active or addictive substance in place of nicotine to be a "new" drug delivery device that would be outside the scope of this regulation. To be legally marketed, such a product would require premarket approval.

B. Subpart B—Sale and Distribution to Persons Under 18 Years of Age

Subpart B would establish certain conditions or requirements for the sale and distribution of cigarettes and smokeless tobacco pursuant to section 520(e) of the act. These provisions are intended to reduce access to cigarettes and smokeless tobacco products by children and adolescents. Studies show that it is easy for most young people to obtain tobacco products. The University of Michigan Monitoring the Future Study in 1993 reported that 75 percent of 8th graders and nearly 90 percent of 10th graders said it would be fairly easy or very easy to get cigarettes.1 According to a 1990 survey of 9th graders, 67 percent of current smokers said they usually buy their own cigarettes.2 Further, interviews conducted by the Department of Health and Human Services' (DHHS) Office of the Inspector General in 1986 found that 94 percent of junior and high school students said that "it was either never or only rarely difficult" to buy smokeless tobacco products.3

Most children and adolescents who smoke purchase their own cigarettes. A 1991 study showed that an estimated 516 million packs are consumed by young people every year; almost half of these packs are sold to minors. The 1994 Surgeon General's Report examined 13 studies of over-the-counter sales and determined that approximately 67 percent of minors are able to purchase tobacco illegally. Moreover, successful cigarette purchases by children and adolescents averaged 88 percent in studies of vending machines.

A significant percentage of young people can also easily purchase smokeless tobacco products directly from retailers. Studies examining smokeless tobacco product purchases by young people suggest that direct successful underage purchases range from 30 percent (for junior high school students) to 62 percent (for senior high school students). Interviews conducted by the DHHS' Office of the Inspector General in 1986 found that 90 percent of smokeless tobacco users in junior and

senior high schools said they purchased their own smokeless tobacco products.⁷

Youth access restrictions have been found to be effective in reducing illegal sales and some studies have demonstrated that efforts to reduce access have led to a decrease in tobacco use by young people. In Woodridge, IL, for example, a comprehensive community intervention involving retailer licensing, regular compliance checks, and penalties for merchant violations significantly reduced illegal sales from 70 percent to less than 5 percent almost 2 years later. Further, rates of experimentation and regular smoking dropped by more than 50 percent among seventh and eighth graders.8

In contrast, attempts to reduce sales to young people by relying exclusively on educational programs for retailers were not nearly as effective. For example, one study found that minors were able to buy cigarettes in 73 percent of stores receiving informational packages on preventing illegal sales to minors. After a comprehensive retailer education program was conducted, illegal sales to minors decreased to 68 percent of stores. However, after citations were issued to violative establishments, overthe-counter illegal sales dropped to 31 percent. 10

The proposed rule would prohibit the sale and distribution of cigarettes and smokeless tobacco products to individuals younger than 18. This restriction parallels the age restrictions established by almost all States. Moreover, it is based on the fact that most people who become regular smokers do so at a young age. For instance, the IOM reported that the average age when people become "daily" smokers is 17.7 years.11 According to the National Household Surveys on Drug Abuse (1991), 53 percent of people who ever smoked became regular smokers by the time they were 18 years old. 12 Further, 82 percent of those who had ever smoked daily first tried a cigarette before the age of 18.13

Available data documenting the course of a young person's ability to quit smoking after initiating smoking support the need for an age restriction. A study tracking students from grades 6 to 12 in six Minnesota communities noted a "striking pattern" that:

* * * once students become weekly smokers, they are unlikely to give up cigarettes. Of the students who were current smokers, an increasing percentage remained smokers over the years of follow-up; they were either unable or unwilling to quit smoking. Of the self-reported quitters, 13% to