smoke cigarettes or use smokeless tobacco products, thereby exposing themselves to the long-term health risks associated with those products. Consequently, FDA has carefully drafted the proposed rule to convey information regarding warnings, precautions, side effects, and contraindications in order to inform consumers about the use of these products. The advertising requirements in proposed subpart D are also narrowly drafted to allow advertising to continue under certain conditions rather than prohibit all advertising. This will enable adults to continue receiving advertising messages while decreasing the advertisements' appeal to young people.

Vending machines and self-service displays offer young people easy access to cigarettes and smokeless tobacco products even though State laws prohibit cigarette sales to minors and some States or localities require locking devices on or specific placement of vending machines. Thus, the requirement that retailers physically provide the product to the consumer substantially advances the purpose of protecting the public health by eliminating easy, unmonitored access to such products by underage persons. This requirement is not disproportionate to the risk presented by vending machines and self-service displays because many studies demonstrate how easily minors can purchase cigarettes from vending machines, and other documents indicate that shoplifting is another method young people use to acquire these products.

Non-tobacco items and sponsored events that bear the brand name, logo, symbols, mottos, selling messages, or any other indicia of a cigarette or smokeless tobacco product act like advertising, conveying images of status, sophistication, maturity, and adventure or excitement that appeal to young people. Reports demonstrate that many young people, even those under the legal age, possess these items or seek coupons or certificates to obtain these items. The items, in conjunction with labeling, other advertising activities, and sponsored events, create the impression that smoking or smokeless tobacco product use is more prevalent and acceptable in society than it actually is and, as a result, increase the risk that young people will smoke cigarettes or use smokeless tobacco products and expose themselves to the long-term health risks associated with those products. Thus, banning tobacco promotions on non-tobacco items and in conjunction with sponsored events is appropriate.

As for the estimated potential cost to the government in the event that a court finds a taking to exist, FDA is unable to provide an approximate figure. There is little publicly available and precise data or information on each activity that would arguably be the subject of a regulatory taking, and section 704 of the act prohibits FDA from requiring financial, sales, or pricing data during an inspection. Consequently, the agency would appreciate receiving information to enable it to determine the potential cost to the government if a court found the actions described in this proposed rule to be a taking.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8), (a)(11), and (e)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

A. Introduction and Summary

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (Pub. L. 96-354) and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in Section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000, (adjusted annually for inflation). That Act also requires (in Section 205) that the agency identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objective of the rule. The following analysis, in conjunction with the remainder of this preamble, demonstrates that this proposed rule is consistent with the

principles set in the Executive Order and in these two statutes. In addition, this document has been reviewed by the Office of Management and Budget as an economically significant regulatory action under Executive Order 12866.

The estimated benefits of the proposed rule were based on FDA's finding that compliance with the proposed requirements would help to achieve the Department's "Healthy People 2000" goals. Each year, an estimated 1 million adolescents begin to smoke cigarettes. This analysis calculates that at least 24 percent of these youngsters will ultimately die from causes related to their nicotine habit. (Other epidemiological studies suggest even higher rates of excess mortality. For example, CDC projections indicate that 1 in 3 adolescents who smoke will die of smoking-related disease.) As a result, FDA projects that the achievement of the "Healthy People 2000" goals would prevent well over 60,000 early deaths, gaining over 900,000 future life-years for each year's cohort of teenagers who would otherwise begin to smoke. At a 3 percent discount rate, the monetary value of these benefits are projected to total from about \$28 to \$43 billion per year and are comprised of about \$2.6 billion in medical cost savings, \$900 million in productivity gains from reduced morbidity, and \$24.6 to \$39.7 billion per year in willingness-to-pay values for averting premature fatalities. (Because of the long periods involved, a 7 percent discount rate reduces total benefits to about \$9.1 to \$10.4 billion per year.) In addition, the proposed rule would prevent numerous serious illnesses associated with the use of smokeless tobacco products.

The full realization of this goal would require the active support and participation of State and local governments, civic and community organizations, tobacco manufacturers, and retail merchants. Even if only a fraction of the goal were achieved, the benefits would be substantial. For example, as shown in Table 1, halting the onset of smoking for only ¹/₂₀ of the 1 million adolescents who become new smokers each year would provide annual benefits valued at from \$2.9 to \$4.3 billion a year.

To comply with the initial requirements of the rule, FDA projects that manufacturers and retailers of tobacco products would incur one-time costs ranging from \$26 to \$39 million and annual operating costs of about \$227 million (see Table 2). Manufacturers would be responsible for about \$15 to \$28 million of the one-time costs and \$175 million of the annual