Although Executive Order 12606 does not require that individuals or organizations be permitted to participate in proposed rulemaking proceedings, FDA expressly requests all such interested parties to submit comments and suggestions regarding this rule's effect on the family.

B. Executive Order 12612: Federalism

Executive Order 12612 requires Federal agencies to carefully examine regulatory actions to determine if they would have a significant effect on federalism. Using the criteria and principles set forth in the order, FDA has considered the proposed rule's impact on the States, on their relationship with the Federal Government, and on the distribution of power and responsibilities among the various levels of government. FDA concludes that this proposal is consistent with the principles set forth in Executive Order 12612.

Executive Order 12612 states that agencies formulating and implementing policies are to be guided by certain federalism principles. Section 2 of Executive Order 12612 enumerates fundamental federalism principles. Section 3 states that, in addition to these fundamental principles, executive departments and agencies shall adhere, to the extent permitted by law, to certain listed criteria when formulating and implementing policies that have federalism implications. Section 4 lists special requirements for preemption.

¹ Executive Order 12612 recognizes that Federal action limiting the discretion of State and local governments is appropriate "where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope" (section 3(b)). The constitutional basis for FDA's authority to regulate drugs and devices is well established.

Moreover, in developing the provisions of this proposed rule, the agency carefully considered the provisions of the proposed rule implementing section 1926 of the Public Health Service Act, the Substance Abuse Prevention and Treatment block grant program. As a condition of receipt of such grants, a State must have in place a law that prohibits the sale or distribution of any tobacco product to individuals under age 18 and enforce the law in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18. The statute prescribes random, unannounced inspections, but otherwise allows the States considerable flexibility in designing their enforcement programs. By imposing the explicit obligations on manufacturers, distributors, and retailers to control access by children and adolescents to nicotine-containing cigarettes and smokeless tobacco products, the FDA proposals will help States achieve their goals under their substance abuse programs. FDA therefore believes that the two programs complement each other.

The proposed rule would establish uniform minimum standards with respect to the labeling, advertising, sale, and distribution of nicotine-containing cigarettes, cigarette tobacco, and smokeless tobacco products. The proposed rule would expressly provide, however, that these regulations do not preempt State and local laws, regulations, and ordinances that establish higher standards with respect to these products, or affect these products in areas not covered by the proposed rule, e.g., environmental smoke.

The proposed regulation of nicotinecontaining cigarettes, cigarette tobacco, and smokeless tobacco is narrowly drawn. First, it focuses on reducing methods of promotion that are either expressly designed to appeal to American youths, or that are designed without regard to their appeal to American youths. Second, it focuses on reducing the easy access of these nicotine containing products by American youths.

The agency concludes that the policy proposed in this document: Has been assessed in light of the principles, criteria, and requirements in Executive Order 12612; is not inconsistent with that Order; will assist States in fulfilling their obligation under the Substance Abuse Prevention and Treatment block grant program; will not impose additional costs or burdens on the States; and will not affect the States' ability to discharge traditional State governmental functions.

Section 4 of Executive Order 12612 states that an executive department or agency proposing to act through rulemaking to preempt State law is to provide all affected States notice and opportunity for appropriate participation in the proceedings. As required by the Executive Order, States have, through this notice of proposed rulemaking, an opportunity to participate in the proceedings (section 4(e)). Consistent with Executive Order 12612, FDA requests information and comments from interested parties, including but not limited to State and local authorities, on these issues of federalism.

C. Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights

Executive Order 12630 directs Federal agencies to "be sensitive to, anticipate, and account for, the obligations imposed by the Just Compensation Clause of the Fifth Amendment in planning and carrying out governmental actions so that they do not result in the imposition of unanticipated or undue additional burdens on the public fisc.' Section 3(a). Section 3(c) of the order states that actions taken to protect the public health and safety "should be undertaken only in response to real and substantial threats to public health and safety, be designed to advance significantly the health and safety purpose, and be no greater than is necessary to achieve the health and safety purpose." Additionally, section 4(d) requires, as a prerequisite to any proposed action regulating private property use for the protection of public health and safety, each agency to: (1) Clearly identify the public health or safety risk created by the private property use that is the subject of the proposed action; (2) establish that the proposed action substantially advances the purpose of protecting the public health and safety against the identified risk; (3) establish, to the extent possible, that the restrictions imposed on private property are not disproportionate to the extent to which the use contributes to the overall risk; and (4) estimate, to the extent possible, the potential cost to the government should a court later determine that the action constitutes a taking.

The agency has considered whether the proposed rule would result in a "taking" of private property. The proposed rule would, if finalized, restrict outdoor advertising from being placed within 1,000 feet of any elementary or secondary school or playground, eliminate cigarette vending machines and self-service displays, ban all brand identifiable non-tobacco items, such as hats and tee shirts, prohibit the use of a trade name of a non-tobacco item for any tobacco product, and require established names and a brief statement on labels, labeling, and/or advertising. In addition, the proposed rule would require that all sponsored events be carried out only in the corporate name. While these requirements might affect private property, they do not constitute 'takings.'

In determining whether a governmental action has resulted in a "taking," recent court decisions have