possibility of consumer confusion or deception"); *Bates*, 433 U.S. at 384.

As noted above, on several occasions the agency has imposed similar educational requirements—e.g., user instructional brochures—in order to reduce consumer confusion or to prevent the misuse of a device. In those circumstances, the agency has required that the company use agency approved language. Courts have approved of similar "corrective" or "coerced" speech ordered by other federal agencies. See Warner-Lambert Co. v. FTC, 562 F.2d 749 (D.C. Cir. 1977), cert. denied, 435 U.S. 950 (1978) (corrective advertising is appropriate where company has engaged in a long history of deceptive advertising and the misperceptions continue even in the absence of current advertising); United States v. Frame, 885 F.2d 1119 (3rd Cir. 1989) (court upheld legislation that required beef producers, including those who objected, to pay an assessment to fund pro-beef commercials written and disseminated by a quasi-government board), cert. denied, 493 U.S. 1094 (1990).

In conclusion, the agency believes that the evidence would support a ban on all advertising and, therefore, that the more limited restrictions imposed by this proposed rule are reasonable as proportionate to the agency's desired goal—to reduce tobacco-related illnesses and deaths by helping to prevent young people from becoming addicted to the nicotine in cigarettes and smokeless tobacco products. The requirements proposed here serve to prevent distribution of these products to young people, to reduce the effectiveness of advertising and promotion on young people, and to ensure that an appropriate educational campaign is aimed at young people. Thus, the means chosen are a reasonable fit to the substantial interest and, consequently, pass the final prong of the Central Hudson test.

V. Paperwork Reduction Act of 1980

The proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980.

The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents.

Description: The proposed rule would collect information from manufacturers and retailers of cigarettes and smokeless tobacco products. The proposed rule would require such persons to: use established names for cigarettes and smokeless tobacco products; establish and maintain educational programs; observe certain format and content requirements for labeling and advertising; and submit labels, labeling, and advertising to FDA.

Description of Respondents: Businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

CFR Section	Annual No. of re- sponses	Annual frequency	Average burden per response	Annual burden hours
897.24 897.29 897.32 897.40	1,000 1,000 200,000 200,000	1 1 1 1	40 hours	40,000 1 million 66,667 66,667
Total				1,173,334

The agency has submitted a copy of the proposed rule to OMB for its review of these information collections. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. Comments should be sent to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office, Washington, DC 20503, Attn: Desk Officer for FDA.

VI. Executive Orders

A. Executive Order 12606: The Family

Executive Order 12606 directs Federal agencies to determine whether policies and regulations may have a significant impact on family formation, maintenance, and general well-being. FDA has analyzed this proposed rule in accordance with Executive Order 12606, and has determined that it has no potential negative impact on family formation, maintenance, and general well-being.

FDA has determined that this rule will not affect the stability of the family, and particularly, the marital commitment. It will not have any significant impact on family earnings.

The proposed rule would not impede the parental authority and rights in the education, nurture, and supervision of children. Rather, the proposed rule would, if finalized, help the significant majority of American families that seek to discourage their children from using cigarettes and smokeless tobacco products. The pervasive promotion and easy availability of these products, despite existing laws in all 50 States prohibiting their sale to children, severely hinder the individual family from carrying out this function by itself.

Section 1(g) of Executive Order 12606 requires that FDA assess the proposed rule in light of the message, if any, it sends to young people "concerning the relationship between their behavior, their personal responsibility, and the norms of our society." The proposed rule would, if finalized, help reduce the conflict between the anti-smoking messages issued by Federal and State authorities and the pro-tobacco messages seen in advertising. This would enable young people to understand how prevalent tobacco use is in society and also appreciate how their decisions regarding cigarette and smokeless tobacco use can affect their health.