and specifically directed to adolescent nonusers. The goal of this effort is to combat the attractive imagery fostered by decades of tobacco advertising, in order to reduce the number of individuals, especially children and adolescents, who will become addicted to the nicotine in these products.

In addition, company-financed educational messages are not an uncommon remedy. FDA has imposed a similar educational requirement for hearing aids, which are also regulated as restricted devices under section 520(e) of the act. The agency requires that a User Instructional Brochure be distributed to each prospective hearing aid user. In addition to providing directions for the safe and effective use of this product, this brochure describes the adverse reactions, side effects, warnings, and limitations associated with the hearing aid. It also encourages prospective users to seek medical evaluation by a licensed physician before purchasing the product. The agency requires that specified user information be provided to educate consumers about the risks of other FDAregulated products such as Shiley heart valves, silicone breast implants, and certain childhood immunizations.

Finally, FDA regulations provide specific language for certain disclosures in prescription and over-the-counter drug labeling, see "Pregnancy—Nursing Warning" for aspirin and aspirincontaining products, 21 CFR 201.63; "Disclosure of Drug Efficacy Study Evaluations in Labeling, and Advertising," 21 CFR 201.200; warning concerning "Isoproterenol Inhalation Preparations," 21 CFR 201.305; and warning concerning "Drugs with Thyroid Hormone Activity," 21 CFR 201.316.

Unlike the users of other restricted devices, however, the youthful potential users of tobacco products are not easily identified. Because tobacco products and tobacco advertising are distributed so widely, and have been so effective at creating positive images of tobacco use, educational information cannot realistically be specifically targeted to those particular individuals susceptible to taking up smoking. Therefore, the most effective way to reach the target audience is to mandate a widespread educational campaign as described in § 897.29 of the proposed rule.

The proposed provision on educational messages is also authorized, in addition to section 520(e) of the act, under sections 502(a), 502(q), and 201(n) of the act (21 U.S.C. 352(a), 352(q), and 321(n)). Sections 502 (a) and (q) of the act state that a device shall be deemed to be misbranded if either its

labeling or advertising is false or misleading in any particular. Section 201(n) of the act directs FDA, in determining whether the labeling or advertising of an article is misleading, to examine the representations made or suggested in the labeling or advertising as well as "the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article * * *." The proposed educational message requirement is consistent with these statutory provisions because it is intended to help ensure that cigarette and smokeless tobacco product advertising and labeling is not false or misleading and to counteract the appeal of these products previously created by advertising, thereby providing important, material information regarding the consequences of cigarette or smokeless tobacco product use by young people in a manner that is appropriate for that age group. FDA's interpretation of sections 502(a)' and 201(n) of the act and its authority to require the dissemination of information to persons who use human drug products has been upheld in federal court. (See Pharmaceutical Manufacturers Association v. Food and Drug Administration, 484 F.Supp. 1179 (D.Del.), aff'd, 634 F.2d 106 (3rd Cir. 1980) (per curiam) (upholding FDA's authority to require mandatory patient package inserts)).

Finally, although the Cigarette and Smokeless Tobacco Acts⁹ prohibit advertising for cigarettes and smokeless tobacco in specified communications media, including television and radio, they do not prohibit all discussions of cigarettes and smokeless tobacco on television. Specifically, they do not prevent broadcasters from airing public service announcements regarding the dangers of tobacco use and they likewise would not prohibit tobacco manufacturers from purchasing air time to broadcast government mandated and approved educational messages to young people to encourage them not to smoke or use smokeless tobacco.

Although the required messages would concern smoking and smokeless tobacco use, they do not constitute "advertising" within the meaning of those acts. The U.S. Court of Appeals for the District of Columbia in *Public Citizen* v. *FTC*, 869 F. 2d 1541 (D.C. Cir. 1989), gave a common sense definition of the word "advertising" in its recent interpretation of the Smokeless Act:

Our understanding of the common meaning of the term "advertising," consistent

with that contained in Webster's Third New Int'l Dictionary (1976), is that it involves any action to 'call public attention to a [a product] * * * so as to arouse a desire to buy.'' At the most basic level this is surely what smokeless tobacco companies are doing when they splash their brand logos and selling messages across T-shirts and other promotional items.

Id. at 1554 (modifications in original). Government approved messages that seek to discourage young people from using tobacco are intended to have the opposite effect of advertising as defined in *Public Citizen* and, therefore, do not constitute advertising.

Information for current smokers. FDA has carefully tailored these restrictions to aspects of the sale and distribution of tobacco products that create a demand for these products among children and adolescents and that permit their continued access to tobacco products despite State and local laws against sale to young people. The most effective regulatory tool available to FDA to help current smokers stop using tobacco products is to require that information be provided through advertising. FDA is therefore proposing to require a brief statement in cigarette advertising giving the health risks of tobacco use. (See §897.32(c)).

6. Conclusion

Without the restrictions contained in this proposed rule designed to prevent future generations from becoming addicted to tobacco products, there cannot be reasonable assurance of the safety and effectiveness of cigarettes and smokeless tobacco products. FDA seeks the most rational regulatory structure for cigarettes, cigarette tobacco, and smokeless tobacco products permitted under the act to achieve an important public health goal, and simultaneously, to avoid what might be widely regarded as an unwanted and ultimately unsuccessful result.

The agency's comprehensive investigation and legal analysis support a finding at this time that cigarettes, cigarette tobacco, and smokeless tobacco are subject to regulation on the basis of their nicotine content and intended use. Each of these products employs a device component to achieve its effect on the body, and therefore each is a drug/ device combination product. As such, FDA may, in its discretion, regulate them using the act's device provisions.

The device provisions permit the continued marketing of the affected products under certain prescribed conditions designed to substantially reduce the number of young people who become addicted to tobacco products and thereby to break the cycle of