addiction and disease fostered by tobacco products.

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- 6. The Medical Device Amendments also provide authority to remedy unsafe products by forcing corrections in their design. See sections 514 and 518 of the Act. FDA has determined, however, that there are insufficient data available at this time to permit the conclusion that modifications in cigarettes and smokeless tobacco products would make them safe or even substantially safer.
- 7. 1994 SGR, p. 67.
- 8. 1994 SGR, p. 5.
- 9. 15 U.S.C. 1335 and 15 U.S.C. 4402(f).

## B. Other Requirements

As explained above, FDA is proposing to regulate cigarettes and smokeless tobacco products as devices and, in accordance with section 520(e) of the act, is proposing to restrict their sale, distribution, and use. As devices, the products would also be subject to various pre-existing requirements in the statute and the regulations. These regulations include the general labeling

requirements for devices at 21 CFR part 801 (excluding § 801.62); establishment registration and device listing requirements at 21 CFR part 807; and good manufacturing practice requirements at 21 CFR part 820.

Under section 502(q)(2) of the act, a restricted device that is sold, distributed, or used in violation of regulations prescribed under section 520(e) of the act shall be deemed to be misbranded. Therefore, nicotinecontaining cigarettes and smokeless tobacco products that are marketed in violation of the proposed rule would be regarded by FDA as misbranded. It is already the case under the laws of all 50 States that retailers are liable when a sale of cigarettes or smokeless tobacco products is made to an underage individual. Perhaps the most significant effect of the proposed rule with regard to potential legal liability is that manufacturers, as well as retailers and distributors, could be held responsible for violations of the regulations. As with other violative manufacturer activities under the act, such a finding could result in various sanctions, including: fines, injunctions, civil money penalties, product seizure, and prosecution.

C. Preemption Under the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act

Although sections 502(q), 502(r), and 520(e) of the act give FDA authority to regulate the sale, distribution, and use of a restricted device and to impose certain requirements on all advertisements and other descriptive printed matter, both the Cigarette Act and the Smokeless Act contain provisions that limit the exercise of Federal, State, and local authorities. The agency has reviewed its statutory authority in light of these two statutes and concludes that neither the Cigarette Act nor the Smokeless Act preclude FDA from regulating these products or enacting each of the provisions in the proposed regulation.

## 1. The Cigarette Act

The Cigarette Act requires, among other things, specific warning notices on cigarette packages and advertisements. The Cigarette Act contains express language regarding other Federal and State regulation:

(a) No statement relating to smoking and health, other than the statement required by [15 U.S.C. 1333], shall be required on any cigarette package.

(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

15 U.S.C. 1334. The proposed rule takes into account the Federal preemption provision of the Cigarette Act and is consistent with this statutory prohibition.

The preemption provision of the Cigarette Act regarding advertising and promotion applies only to State action. Hence, because the proposed rule would impose Federal, not State, requirements, the proposed rule's labeling and advertising requirements are permissible under 15 U.S.C. 1334(b).

In addition to being permissible under the Cigarette Act, the proposed rule would actually further Congressional intent to protect cigarette packages from diverse, nonuniform, and confusing cigarette labeling and advertising regulations. The proposal would require inclusion of certain information in cigarette advertisements, and these requirements would apply to cigarettes sold and distributed throughout the United States. Under this scheme, States could not impose "diverse, nonuniform, and confusing" labeling or advertising requirements, Cigarette Act, Public Law 89-92, as amended by Public Law 91-222 (April 1, 1970) and Public Law 93-109 (September 21, 1973); 15 U.S.C. 1331 (1973).

Two recent cases support the interpretation that the Cigarette Act does not establish an absolute prohibition against Federal action. In Cipollone v. Liggett Group, Inc., the Supreme Court considered whether the Cigarette Act preempted an action by an individual against a cigarette manufacturer for breach of express warranty that cigarettes "did not present any significant health consequences,' failure to warn consumers about health hazards, fraudulent misrepresentation of health hazards to consumers, and conspiracy to "deprive the public of medical and scientific information about smoking." 112 S. Ct. 2608, 2613-14 (1992). The Court examined the preemption provision in the Cigarette Act and the amendments contained in the Public Health Cigarette Smoking Act and stated that,

When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a "reliable indicium of congressional intent with respect to state authority," \* \* \* "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions" of the legislation \* \* \* Congress" enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.