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J. M. Anderson

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 807, 820, and 897

[Docket No. 95N-0253]

RIN 0910-AA48

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its regulations governing access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents. This action is being taken in response to the Supreme Court decision of March 21, 2000 in which the court held that Congress has not given FDA the authority to regulate tobacco products as customarily marketed. This action will result in the removal of the regulations.

DATES: This rule is effective [*Insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Anne Kirchner, Office of the Commissioner (HF-13), 5600 Fishers Lane, Rockville, MD 20857, 301-827-0585.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 11, 1995 (60 FR 41314), We (FDA) issued proposed regulations to restrict the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. In addition, we issued a jurisdictional determination that cigarettes and smokeless tobacco products are combination products consisting of a drug (nicotine) and device components

intended to deliver nicotine to the body. We issued final regulations based on this proposal in the **Federal Register** of August 28, 1996 (61 FR 44398).

On March 21, 2000, in *Food and Drug Administration vs. Brown & Williamson Tobacco Corp., et al.*, the Supreme Court ruled that Congress has not granted FDA jurisdiction to regulate tobacco products as customarily marketed. In accordance with this ruling, we are hereby removing our regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)). We are also addressing the additional steps necessitated by the courts ruling, such as termination of state contracts to help enforce the age and photo identification requirements of the regulations.

List of Subjects

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 897

Advertising, Cigarettes, Labeling, Sale and distribution, Smokeless tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 801, 803, 807, and 820 are amended and part 897 is removed as follows:

Part 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

§ 801.126 [REMOVED]

2. Remove § 801.126.

Part 803—MEDICAL DEVICE REPORTING

3. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

4. Amend § 803.19 by removing paragraphs (f) and (g).

**Part 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR
MANUFACTURERS AND INITIAL DISTRIBUTORS OF DEVICES**

5. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360e, 360c, 360i, 360j, 371, 374.

6. Amend § 807.65 by removing paragraph (j).

Part 820—QUALITY SYSTEM REGULATION

7. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: 351, 352, 360, 360c, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

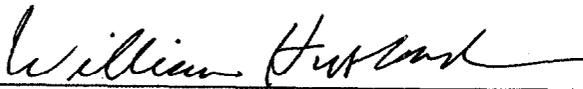
8. Amend § 820.1 by removing paragraphs (e) and (f).

~~Part 897—Cigarettes and Smokeless Tobacco Products~~

Part 897 [Removed]

9. Remove part 897.

Dated: March 28, 2000



William K. Hubbard
Senior Associate Commissioner for Policy, Planning, and Legislation

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