

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 808 and 820

[Docket No. 00N-1561]

DMB

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Exemption From Federal Preemption of State and Local Cigarette and Smokeless Tobacco Requirements; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its regulation governing the exemption from Federal preemption of State and local medical device requirements for the sale and distribution of 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. On March 31, 2000, FDA removed its regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. Because these regulations are not in effect, the State requirements are not preempted. Therefore, FDA is revoking its regulations exempting the State and local requirements from preemption. This rule is also adding a regulation that was inadvertently removed in a previous document.

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

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2970.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 28, 1996 (61 FR 44398), FDA issued a final regulation restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. In the **Federal Register** of November 28, 1997 (62 FR 63271), FDA issued a final rule granting exemption from preemption under section 521 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k) for certain cigarette and smokeless tobacco requirements in Alabama, Alaska, and Utah. These requirements were preempted under section 521 of the act because they were different from FDA's requirements but they could be exempted because they were more stringent than FDA's requirements.

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, the agency issued a final rule in the **Federal Register** of March 31, 2000 (65 FR 17135), removing its regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. The agency inadvertently failed to remove the regulations granting exemptions from Federal preemption for these three States. Because the FDA regulations are not in effect, the State requirements are not preempted and may remain in effect. The agency also inadvertently removed § 820.1(e) (21 CFR 820.1(e)) (65 FR 17135). Section 820.1(e) did not relate to tobacco. Therefore, it is being added in this rule.

List of Subjects

21 CFR Part 808

Intergovernmental relations, Medical devices.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 808 and 820 are amended as follows:

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

1. The authority citation for 21 CFR part 808 continues to read as follows:

Authority: 21 U.S.C. 360j, 360k, 371.

§ 808.51 [Removed]

2. Remove § 808.51.

§ 808.52 [Removed]

3. Remove § 808.52.

§ 808.94 [Removed]

4. Remove § 808.94.

PART 820—QUALITY SYSTEM REGULATION

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

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

6. Section 820.1 is amended by adding paragraph (e) to read as follows:

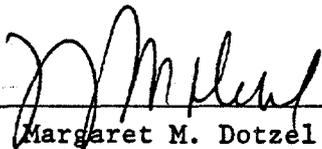
§ 820.1 Scope.

* * * * *

(e) *Exemptions or variances.* (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 1-301-443-6597, FAX 301-443-8818.

(2) FDA may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

Dated: 10/30/00
October 30, 2000.



Margaret M. Dotzel
Associate Commissioner for Policy

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