PART 71—[Amended]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designation and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL SD E5 Spearfish, SD [Revised]

Black Hills-Clyde Ice Field, SD
(lat. 44°28′49″N, long. 103°46′37″W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Black Hills-Clyde Ice Field Airport and within 2.1 miles each side of the 305° bearing from the airport extending from the 7-mile radius to 8.3 miles northwest of the airport; and that airspace extending upward from 1,200 feet above the surface within an area bounded by a line beginning at lat. 44°29′22″N, long. 103°56′48″W; to lat. 44°13′37″N, long. 104°14′00″W; to lat. 44°18′41″N, long. 104°23′24″W; to lat. 44°44′11″N, long. 103°57′49″W; to lat. 44°50′13″N, long. 103°28′11″W; to lat. 44°47′27″N, long. 102°57′40″W; to lat. 44°39′31″N, long. 102°56′34″W; to lat. 44°38′27″N, long. 103°12′26″W; to lat. 44°25′29″N, long. 103°38′30″W; then clockwise via the 7-mile radius of the airport to the point of beginning.

* * * * *

Issued in Des Plaines, Illinois on February 5, 1997.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 97–4073 Filed 2–18–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

[Docket No. 96N–0364]

RIN 0910–AA20

Regulation of Medical Foods; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to April 28, 1997, the comment period for the advance notice of proposed rulemaking for the regulation of medical foods that published in the Federal Register of November 29, 1996. This action is being taken in response to several requests from interested persons for an extension of the comment period on this document.

DATES: Written comments by April 28, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4605.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 29, 1996 (61 FR 60661), FDA published an advance notice of proposed rulemaking for the regulation of medical foods. Interested persons were given until February 27, 1997, to comment on the advance notice of proposed rulemaking.

FDA has received requests for an extension of the comment period from: Manufacturers, a trade organization representing manufacturers of medical foods, and a professional society representing health care providers and research scientists. The interested parties stated in their requests for an extension of the comment period that such an extension would help ensure that the agency receives comprehensive and carefully researched information from experts to consider in response to the notice. After careful consideration of the requests submitted to the agency, FDA has decided to grant an extension of the comment period until April 28, 1997.

Interested persons may, on or before April 28, 1997, submit to the Dockets Management Branch (address above) written comments regarding this advanced notice of proposed rulemaking. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This document is issued under sections 4, 5, and 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); sections 201, 301, 402, 403, 404, 405, 409, 411, 412, 501, 502, 503, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 344, 345, 348, 350, 350a, 351, 352, 353, 355, 371); and 21 U.S.C. 360ee(b)(3) (section 5(b)(3) of the Orphan Drug Amendments of 1988, as amended by Pub. L. 100–290).

Dated: February 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4021 Filed 2–18–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 808

[Docket No. 96N–0249]

RIN 0910–AB03

Exemption From Preemption of State and Local Cigarette and Smokeless Tobacco Requirements; Applications for Exemption Submitted by Various State Governments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (the act) preempts State and local device requirements that are different from, or in addition to, Federal requirements under the act. The act also provides that the Food and Drug Administration (FDA) may, by regulation, exempt State and local device requirements from preemption. FDA is responding to applications for exemption submitted by the States of Alabama, Alaska, Utah, and Washington. FDA is proposing to grant exemptions from Federal preemption for certain cigarette and smokeless tobacco requirements in the States of Alabama, Alaska, and Utah. The requirements in the State of Washington are not preempted, and therefore no exemption needs to be granted. Elsewhere in this issue of the Federal Register, FDA is announcing an opportunity for interested persons to request a public hearing on the proposed regulation.

DATES: Written comments by March 21, 1997. FDA proposes that any final rule that may be issued based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Anne M. Kirchner, Office of Policy (HF–23), Food and Drug Administration,

5600 Fishers Lane, Rockville, MD 20857, 301–827–5321.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 28, 1996 (61 FR 44396), FDA published a final rule (the tobacco rule) restricting the sale and distribution of nicotine-containing cigarettes and smokeless tobacco in order to protect children and adolescents. The tobacco rule included provisions prohibiting retailers from selling nicotine-containing cigarettes or smokeless tobacco to any person younger than 18 years of age (see § 897.14(a) (21 CFR 897.14(a))) and requiring retailers to verify, by means of photographic identification containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age (see § 897.14(b)). The age verification requirement applies except where the purchaser is over age 26.

Section 521(a) of the act (21 U.S.C. 360k(a)) provides that,

> [a]fter May 28, 1976, no State or political subdivision of a State may establish or continue in effect, with respect to a device intended for human use, any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the device's safety or effectiveness, or to any other matter included in a requirement applicable under the act (§ 808.1(b)(21 CFR 808.1(b))).

Because FDA is regulating cigarettes and smokeless tobacco as nicotine-delivery devices under the act, any State or local cigarette or smokeless tobacco requirement that is different from, or in addition to, the specific requirements for cigarettes and smokeless tobacco established under the tobacco rule is preempted under section 521(a) of the act.

In implementing section 521(a) of the act, FDA has historically interpreted that provision narrowly and found it to have preemptive effect only for those State and local requirements that in fact clearly impose specific requirements with respect to specific devices that are manifestly in addition to analogous Federal requirements. Consistent with this narrow scope of preemption under section 521(a) of the act, a State or local requirement that is narrower in coverage than the Federal requirement is not preempted to the extent that it is similar to the Federal requirement.

Examples of such similar, yet narrower, coverage by State or local requirements include additional statutory elements or defenses in conjunction with minimum age restrictions on sales of cigarettes and smokeless tobacco. For instance, numerous States have statutes that prohibit retailers from ''negligently'' or ''knowingly'' selling cigarettes or smokeless tobacco to persons under the age of 18. Other States have fashioned their age prohibition statutes such that retailers can assert as a defense to any penalties that they properly checked and relied upon an identification presented by an underage purchaser.

Such statutes are narrower in scope than the strict liability provision of the tobacco rule because they require proving a retailer's negligence or knowledge in an underage sale. However, because these statutes are similar to the tobacco rule's prohibition of sales to persons under the age of 18, they are not preempted merely because of their narrower coverage. A State or local government clearly could choose to have no statute whatsoever in effect regarding age restrictions. FDA believes it logically follows that a State or local government may enact a statutory level of enforcement that falls somewhere between the level of no enforcement and the level implemented in the tobacco rule.

The narrow preemption in these situations is based on the Supreme Court's recent decision in *Medtronic, Inc.* v. *Lohr,* 116 S. Ct. 2240 (1996). The Court held that common law tort claims that are similar to, but narrower than, FDA requirements are not preempted under section 521 of the act. (See *Lohr,* 116 S. Ct. at 2255.) In so holding, the Court reasoned as follows:

> Nothing in [section 521] denies [a State] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of [State] law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be ''different from'' the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. *Id.*

Section 521(b) of the act provides that FDA may, upon application by a State or political subdivision, and by regulation issued after notice and an opportunity for an oral hearing, exempt a State or local device requirement from preemption under such conditions as FDA may prescribe if the requirement is: (1) More stringent than an FDA requirement applicable to the device, or (2) required by compelling local conditions, and compliance with it would not cause the device to be in violation of any applicable requirement under the act.

In the Federal Register of November 7, 1996 (61 FR 57685), FDA published a notice (the exemption notice) inviting State and local governments to file applications for exemption from preemption for cigarette and smokeless tobacco requirements. In order to facilitate and expedite review of submitted applications, FDA is considering the applications in two separate groups, which are based on the effective dates for different requirements under the tobacco rule. This proposed rule covers those applications, designated in the exemption notice as Group 1, which are for State and local requirements that are different from, or in addition to, FDA requirements under § 897.14(a) and (b) of the tobacco rule. (See 61 FR 57685 at 57686.) Applications for other State and local requirements pertaining to cigarettes and smokeless tobacco will be considered in another proposed rule which will be published in the future.

II. Descriptions of the Requests for Exemption from Preemption

A. State of Alabama

On October 28, 1996, the State of Alabama applied for exemption from preemption for section 13A–12–3 of the Alabama Code. The provision reads as follows:

> § 13A–12–3. Selling cigarettes to minors.
>
> Any person who sells, barters, exchanges or gives to any minor any cigarettes, cigarette tobacco or cigarette paper, or any substitute for either of them shall, on conviction, be fined not less that $10.00 nor more than $50.00 and may also be imprisoned in the county jail or sentenced to hard labor for the county for not more than 30 days.

Section 26–1–1 of the Alabama Code establishes age 19 as the age of majority.[1] Consequently, section 13A–

[1] The text of section 26–1–1 of the Alabama Code is as follows:

> § 26–1–1. Age of majority designated as 19 years.
>
> (a) Any person in this state, at the arrival at the age of 19 years, shall be relieved of his disabilities of minority and thereafter shall have the same legal rights and abilities as persons over 21 years of age. No law of this state shall discriminate for or against any person between and including the ages of 19 and 21 years solely on the basis of age.
>
> (b) This section shall also apply to any person who arrived at the age of 19 and 20 years before July 22, 1975, but shall not abrogate any defense or abridge any remedy available to him prior to such date.
>
> (c) All laws or parts of laws which read ''under the age of 21 years'' hereafter shall read ''under the age of 19 years.'' Wherever the words ''under the age of 21 years'' appear in any law limiting the legal rights and abilities of persons under such age, such

Continued

12–3 of Alabama Code, when interpreted in light of section 26–1–1 of Alabama Code, prohibits, in part, any person from selling, bartering, exchanging, or giving cigarettes, cigarette tobacco or cigarette paper, or any substitute to persons under 19 years of age in Alabama.

The prohibition under section 13A–12–3 of the Alabama Code against selling, bartering, or exchanging tobacco products to anyone under 19 years of age is different from the age restriction contained in the tobacco rule at § 897.14(a), which prohibits sales of cigarettes and smokeless tobacco to anyone under age 18.[2] FDA believes, however, that Alabama's higher minimum age for the sale, barter, and exchange of cigarette and smokeless tobacco will provide increased public health benefits and will not impose a significant burden on retailers. Therefore, to the extent that the age restriction on the sale, barter, and exchange of tobacco products found in section 13A–12–3 of the Alabama Code is preempted, FDA is proposing to grant an exemption from preemption.

In addition, section 13A–12–3 of the Alabama Code prohibits giving cigarettes, cigarette tobacco or cigarette paper, or any substitute to anyone under the age of 19. Because the restriction on distribution of tobacco products found in section 13A–12–3 of the Alabama Code does not prohibit the distribution of free samples of cigarettes and smokeless tobacco to persons over the age of 19, section 13A–12–3 of the Alabama Code is narrower in scope than the complete prohibition against distribution of free samples of cigarettes and smokeless tobacco established in the tobacco rule under § 897.16(d) (21 CFR 897.16(d)).[3] Despite its narrower scope of coverage, this portion of the statute is not preempted because it is similar to the tobacco rule's restrictions on the distribution of free samples of cigarette and smokeless tobacco. FDA notes, however, that the narrower scope of coverage at the State level in Alabama as established under section 13A–12–3 of the Alabama Code in no way narrows or limits the scope of coverage of Federal requirements contained in the tobacco rule.

Finally, to the extent that section 13A–12–3 of the Alabama Code applies to products other than cigarettes or smokeless tobacco, the statute is not preempted by the tobacco rule because the tobacco rule does not establish ''specific counterpart regulations'' or other specific requirements with respect to products other than cigarettes or smokeless tobacco.

B. State of Alaska

On November 27, 1996, the State of Alaska applied for an exemption from preemption for sections 11.76.100 and 11.76.105 of the Alaska Statutes. The request, in part, concerned Alaska's prohibition against selling, exchanging, or giving cigarettes, cigars, tobacco, or tobacco-containing products to persons under age 19, as well as its prohibition against the possession of cigarettes, cigars, tobacco, or tobacco-containing products by persons under age 19. The relevant provisions of section 11.76.100 of the Alaska Statutes read as follows:

Sec. 11.76.100. Selling or giving tobacco to a minor.

(a) A person commits the offense of selling or giving tobacco to a minor if the person is 19 years of age or older and

(1) negligently sells, exchanges, or gives a cigarette, a cigar, tobacco, or a product containing tobacco to a person under 19 years of age;

* * * * *[4]

(f) The provisions of (a) of this section do not apply to a person who sells or gives tobacco to a minor if the minor is a prisoner at an adult correctional facility.

The prohibition under section 11.76.100(a) of the Alaska Statutes against selling or exchanging tobacco to anyone under 19 years of age is different from the age restriction contained in § 897.14(a), which prohibits sales of cigarettes and smokeless tobacco to anyone under age 18.[5] FDA believes, however, that Alaska's higher minimum age for the sale and exchange of cigarettes and smokeless tobacco will provide increased public health benefits and will not impose a significant burden on retailers. Therefore, to the extent that the age restriction on the sale and exchange of cigarettes and smokeless tobacco found in section 11.76.100(a) of the Alaska Statutes is preempted, FDA is proposing to grant an exemption from preemption.

Section 11.76.100(a) of the Alaska Statutes also prohibits giving tobacco products to anyone under the age of 19. Because the restriction on distribution of tobacco products found in section 11.76.100(a) of the Alaska Statutes does not prohibit the distribution of free samples of cigarettes and smokeless tobacco to persons over the age of 19, section 11.76.100(a) of the Alaska Statutes is narrower in scope than the complete prohibition against distribution of free samples of cigarettes and smokeless tobacco established under § 897.16(d) of the tobacco rule.[6] Although section 11.76.100(a) of the Alaska Statutes has a narrower scope of coverage than the tobacco rule with regard to distribution of tobacco products, this portion of the statute is not preempted because it is similar to the tobacco rule's restrictions on cigarette and smokeless tobacco distribution. FDA notes, however, that the narrower scope of coverage at the State level in Alaska as established under section 11.76.100(a) of the Alaska Statutes does not narrow or limit the scope of coverage of Federal requirements contained in the tobacco rule.

Because section 11.76.100(a) of the Alaska Statutes prohibits the ''negligent'' selling or giving of tobacco to a minor, that section is narrower in scope than the strict liability provisions found in the tobacco rule. However, because section 11.76.100(a) of the Alaska Statutes is similar to the tobacco rule's restrictions on cigarette and smokeless tobacco sales and distribution, the statute is not preempted merely because of its narrower coverage. As stated above, the narrower coverage of section 11.76.100(a) of the Alaska Statutes does not narrow or limit the scope of Federal coverage under the tobacco rule.

To the extent that section 11.76.100(a) of the Alaska Statutes applies to

words shall be construed to mean under the age of 19 years.

(d) Notwithstanding the provisions of subsection (c) of this section, nothing in this section shall be deemed to repeal any provision of Chapter 19 of Title 15 of this Code.

[2] Under § 897.14(a), ''[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age.'' This prohibition on ''selling'' cigarettes or smokeless tobacco extends to transactions involving ''bartering'' or ''exchanging'' these products for other items that ultimately have some value.

[3] Although the focus of this proposed rule is upon requests for exemption from preemption with respect to the requirements of § 897.14(a) (involving retail sales) and § 897.14(b) (involving verification of purchaser's age), section 13A–12–3 of the Alabama Code also contains distribution restrictions that are analogous to those restrictions found in § 897.16(d) (involving free distribution). For reasons of expediency, FDA will address the issue of preemption of section 13A–12–3 of the Alabama Code, in that section's entirety, in this rulemaking.

[4] The remaining portions of section 11.76.100 of the Alaska Statutes for which Alaska seeks exemption from preemption concern vending machine sales. FDA will address the vending machine sales portions of section 11.76.100 of the Alaska Statutes in a future proposed rulemaking.

[5] Under § 897.14(a), ''[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age.'' This prohibition on ''selling'' cigarettes or smokeless tobacco extends to transactions involving ''exchanging'' these products for other items that ultimately have some value.

[6] Despite the focus of this proposed rule upon State and local requirements regarding retail sales of cigarettes and smokeless tobacco, and verification of purchaser's age, FDA will also address the issue of preemption of the age restrictions on distribution of tobacco products found in section 11.76.100(a) of the Alaska Statutes.

products other than cigarettes or smokeless tobacco, the statute is not preempted by the tobacco rule because the tobacco rule does not establish ''specific counterpart regulations'' or other specific requirements with respect to products other than cigarettes or smokeless tobacco.

Section 11.76.100(f) of the Alaska Statutes is not preempted by section 521 of the act. Section 11.76.100(f) of the Alaska Statutes provides an exception to the State's prohibition of underage sales and distribution of tobacco products. Under this exception a person may ''sell[ ] or give[ ] tobacco to a minor if the minor is a prisoner at an adult correctional facility.''

This exception is narrower in scope of coverage than the Federal prohibitions found in §§ 897.14(a) and 897.16(d). Clearly, the Alaskan State legislature could have chosen not to enact any prohibitions whatsoever regarding underage sales and distribution of tobacco products. The level of prohibition actually enacted, however, falls between a no-prohibition level and the level of enforcement at the Federal level under the tobacco rule.

Despite the narrower scope of section 11.76.100(f) of the Alaska Statutes, the statute is not preempted because the State's prohibition of underage sales and distribution of tobacco products is similar to the tobacco rule's restrictions on cigarette and smokeless tobacco sales and distribution. However, the narrower coverage of section 11.76.100(f) of the Alaska Statutes does not narrow or limit the scope of Federal coverage under the tobacco rule; thus, for example, the sale of cigarettes or smokeless tobacco to any person under the age of 18, including such a person who is a prisoner at an adult correctional facility, would violate the prohibitions contained in the tobacco rule.

The State of Alaska has also applied for exemption from preemption for section 11.76.105 of the Alaska Statutes. The relevant provisions of section 11.76.105 of the Alaska Statutes read as follows:

Sec. 11.76.105. Possession of tobacco by a minor.

(a) A person under 19 years of age may not knowingly possess a cigarette, a cigar, tobacco, or a product containing tobacco in this state. This subsection does not apply to a person who is a prisoner at an adult correctional facility.

Because FDA has not established any specific counterpart regulation regarding underage possession of tobacco products, section 11.76.105 of the Alaska Statutes is not preempted. Consequently, an exemption from preemption for this section is not necessary.

C. State of Utah

In December 1996, the State of Utah applied for an exemption from preemption for section 76–10–104 of the Utah Code Annotated.[7] The provision reads as follows:

76–10–104. Furnishing cigars, cigarettes, or tobacco to minors—Penalties.

Any person who sells, gives, or furnishes any cigar, cigarette, or tobacco in any form, to any person under 19 years of age, is guilty of a class C misdemeanor on the first offense, a class B misdemeanor on the second offense, and a class A misdemeanor on subsequent offenses.

The age restriction on ''sell[ing] * * * any cigar, cigarette, or tobacco in any form, to any person under 19 years of age'' that is found in section 76–10–104 of the Utah Code Annotated differs from the requirement in § 897.14(a), which prohibits the sale of cigarettes and smokeless tobacco to anyone under age 18. FDA believes, however, that Utah's higher minimum age for cigarette and smokeless tobacco sales will provide increased public health benefits and will not impose a significant burden on retailers. Therefore, to the extent that the age restriction on sales of cigarettes and smokeless tobacco found in section 76–10–104 of the Utah Code Annotated is preempted, FDA is proposing to grant an exemption from preemption.

Section 76–10–104 of the Utah Code Annotated also prohibits, in part, a person from giving or furnishing cigarettes or smokeless tobacco to persons under age 19. Because this restriction on distribution of tobacco products does not prohibit the distribution of free samples of cigarettes and smokeless tobacco to persons over the age of 19, section 76–10–104 of the Utah Code Annotated is narrower in scope than the complete prohibition against distribution of free samples of cigarettes and smokeless tobacco established under § 897.16(d).[8] Although section 76–10–104 of the Utah Code Annotated has a narrower scope of coverage than the tobacco rule with regard to distribution of tobacco products, this portion of the statute is not preempted because it is similar to the tobacco rule's restrictions on cigarette and smokeless tobacco distribution. FDA notes, however, that the narrower scope of coverage at the State level in Utah as established under section 76–10–104 of the Utah Code Annotated does not narrow or limit the scope of coverage of Federal requirements contained in the tobacco rule.

Finally, to the extent that section 76–10–104 of the Utah Code Annotated applies to products other than cigarettes or smokeless tobacco, the statute is not preempted by the tobacco rule because the tobacco rule does not establish ''specific counterpart regulations'' or other specific requirements with respect to products other than cigarettes or smokeless tobacco. (See § 808.1(d).)

D. State of Washington

On December 6, 1996, the State of Washington applied for an exemption from preemption for section 26.28.080 of the Revised Code of Washington (RCW) (a State law) and section 314–10–050 of the Washington Administrative Code (WAC) (a State administrative regulation). RCW 26.28.080 contains a prohibition against underage sales and distribution of certain enumerated tobacco products. WAC 314–10–050 contains a similar prohibition, but also establishes a requirement that purchasers of tobacco products provide proof of age, and lists acceptable forms of identification. The relevant provisions read as follows:

RCW 26.28.080 Selling or giving tobacco to minor—Belief of representative capacity, no defense—Penalty.

Every person who sells or gives, or permits to be sold or given to any person under the age of eighteen years any cigar, cigarette, cigarette paper or wrapper, or tobacco in any form is guilty of a gross misdemeanor.

It shall be no defense to a prosecution for a violation of this section that the person acted, or was believed by the defendant to act, as agent or representative of another.

WAC 314–10–050 Sales to persons under 18 years of age

(1) No person may sell or give or in any way provide tobacco products to any person under 18 years of age.

(2) Any person attempting to purchase tobacco products must present identification to show he/she is at least 18 years of age upon the request of any tobacco licensee, employee of a tobacco licensee or

[7] The original request sought an exemption from preemption for section 76–10–105 of the Utah Code Annotated. That provision states that any person under age 19 who buys, accepts, or has in his possession any cigar, cigarette, or tobacco in any form is guilty of a class C misdemeanor. The provision also discusses the jurisdiction of the juvenile court for such offenses and the authority of a compliance officer to issue citations. However, the request was later amended after FDA noted that this provision in the Utah Code Annotated is not preempted (because there is no specific FDA counterpart regulation concerning underage persons who buy, accept, or possess tobacco products), but that section 76–10–104 might be preempted absent an exemption from preemption.

[8] Despite the focus of this proposed rule upon State and local requirements regarding retail sales of cigarettes and smokeless tobacco as well as verification of purchaser's age, FDA will address the issue of preemption of the age restrictions on distribution of tobacco products found in section 76–10–104 of the Utah Code Annotated.

enforcement officer as defined by RCW 7.8.040.

(3) All identification used to prove age must be officially issued and contain the bearer's age, signature and photograph. The only forms of identification which are acceptable as proof of age for the purchase of tobacco products are:

(a) A liquor control authority card of identification issued by a state of the United States or a province of Canada,

(b) A driver's license, instruction permit or identification card issued by a state of the United States or a province of Canada,

(c) A United States military identification card,

(d) A passport, or

(e) A merchant marine identification card issued by the United States Coast Guard.

RCW 26.28.080 prohibits, in part, a person from giving ''to any person under the age of eighteen years any cigar, cigarette, cigarette paper or wrapper, or tobacco in any form.'' Similarly, WAC 314–10–050(1) prohibits, in part, a person from ''giv[ing] or in any way provid[ing] tobacco products to any person under 18 years of age.'' Because these restrictions on distribution of tobacco products do not prohibit the distribution of free samples of cigarettes and smokeless tobacco to persons over the age of 18, RCW 26.28.080 and WAC 314–10–050(1) are narrower in scope than the complete prohibition against distribution of free samples of cigarettes and smokeless tobacco established under § 897.16(d).[9] Although RCW 26.28.080 and WAC 314–10–050(1) have a narrower scope of coverage than the tobacco rule with regard to distribution of tobacco products, these portions of the statute and the regulation are not preempted because they are similar to the tobacco rule's restrictions on cigarette and smokeless tobacco distribution. FDA notes, however, that the narrower scope of coverage at the State level in Washington as established under RCW 26.28.080 and WAC 314–10–050(1) does not narrow or limit the scope of coverage of Federal requirements contained in the tobacco rule.

To the extent that RCW 26.28.080 and WAC 314–10–050(1) apply to products other than cigarettes or smokeless tobacco, they are not preempted by the tobacco rule because the tobacco rule does not establish ''specific counterpart regulations'' or other specific requirements with respect to products other than cigarettes or smokeless tobacco. (See § 808.1(d).)

WAC 314–10–050(2) requires any person attempting to purchase tobacco products to present identification to establish the purchaser's age, and WAC 314–10–050(3) specifies requirements for the types of identification that the purchaser must present. FDA has not established any specific counterpart regulation that places an affirmative duty upon the purchaser to present identification as proof of age. Rather, § 897.14(b) requires the retailer to ''verify by means of photographic identification * * * that no person purchasing the product is younger than 18 years of age.'' Because there is no specific counterpart regulation under the act, neither WAC 314–10–050(2) nor WAC 314–10–050(3) is preempted.

In conclusion, RCW 26.28.080 and WAC 314–10–050 are not preempted. Thus, no exemption is necessary for either provision.

E. The Notice of Opportunity for Hearing

FDA's regulation in 21 CFR 808.25(c) provides that, when the agency issues in the Federal Register a proposed rule either granting or denying requests for exemption from preemption, the agency will also issue in the Federal Register a notice of opportunity for interested persons to request an oral hearing before FDA to present views on the applications and the proposed rule. Elsewhere in this issue of the Federal Register, FDA is issuing such a notice.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this document has been reviewed by the Office of Management and Budget as a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would exempt certain pre-existing statutory or regulatory provisions in Alabama, Alaska, and Utah from preemption, the Commissioner of Food and Drugs certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Interested persons may, on or before March 21, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 808

Intergovernmental relations, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 808 be 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: Secs. 521, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k, 371).

2. New § 808.51 is added to subpart C to read as follows:

§ 808.51 Alabama.

To the extent that the age restriction on the sale, barter, and exchange of cigarettes and smokeless tobacco found in Alabama Code, section 13A–12–3, is preempted under section 521(a) of the act, the Food and Drug Administration has exempted it from preemption under section 521(b) of the act.

3. New § 808.52 is added to subpart C to read as follows:

[9] Despite the focus of this proposed rule upon State and local requirements regarding retail sales of cigarettes and smokeless tobacco as well as verification of purchaser's age, FDA will address the issue of preemption of the age restrictions on distribution of tobacco products found in RCW 26.28.080 and WAC 314–10–050(1).

§ 808.52 Alaska.

To the extent that the age restriction on the sale and exchange of cigarettes and smokeless tobacco found in Alaska Statutes, sections 11.76.100(a), is preempted under section 521(a) of the act, the Food and Drug Administration has exempted it from preemption under section 521(b) of the act.

4. New § 808.94 is added to subpart C to read as follows:

§ 808.94 Utah.

To the extent that the age restriction on sales of cigarettes and smokeless tobacco found in the Utah Code Annotated, section 76–10–104, is preempted under section 521(a) of the act, the Food and Drug Administration has exempted it from preemption under section 521(b) of the act.

Dated: February 7, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–4045 Filed 2–13–97; 2:19 pm]

BILLING CODE 4160–01–F

21 CFR Part 808

[Docket No. 96N–0249]

RIN 0910–AB03

Medical Devices; Opportunity for Oral Hearing on Proposed Action on Applications for Exemption From Preemption From Cigarette and Smokeless Tobacco Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of opportunity for oral hearing.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for interested persons to request an oral hearing on a proposed rule that would grant exemption from Federal preemption for certain cigarette and smokeless tobacco requirements in various States. The proposed rule is published elsewhere in this issue of the Federal Register.

DATES: Requests for an oral hearing by March 21, 1997.

ADDRESSES: Written requests to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Anne M. Kirchner, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5321.

SUPPLEMENTARY INFORMATION: FDA's regulation in § 808.25 (21 CFR 808.25) provides procedures for processing applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k). Section 808.25(c) provides that, when FDA issues in the Federal Register a proposed rule either to grant or to deny a request for exemption from preemption, the agency will also issue in the Federal Register a notice of opportunity for interested persons to request an oral hearing before FDA to present views on the application and the proposed rule.

Elsewhere in this issue of the Federal Register, FDA is issuing a proposed rule responding to the following applications for exemption from preemption:

(1) An application from the State of Alabama for exemption from preemption for section 13A–12–3 of the Alabama Code;

(2) An application from the State of Alaska for exemption from preemption for sections 11.76.100 and 11.76.105 of the Alaska Statutes;

(3) An application from the State of Utah for exemption from preemption for section 76–10–104 of the Utah Code Annotated; and

(4) An application from the State of Washington for exemption from preemption for section 26.28.080 of the Revised Code of Washington and for section 314–10–050 of the Washington Administrative Code.

Therefore, in accordance with § 808.25(c), FDA is announcing an opportunity for interested persons to request an oral hearing on its proposal to grant exemption from Federal preemption for certain State requirements pertaining to cigarettes and smokeless tobacco.

FDA advises that, under § 808.25(d), any request for a hearing is required to be submitted to the Dockets Management Branch (address above) and to include an explanation of why an oral hearing, rather than submission of written comments only, is essential to the presentation of views on the application for exemption from preemption and on the proposed regulation. Further, to ensure expeditious review of requests for an oral hearing and final action on the applications for exemption and on the proposed rule, FDA has limited the period for requesting an oral hearing to 30 days from the date of publication of the proposed rule and this notice in the Federal Register.

Under § 808.25(e), if a timely request for a hearing is made, FDA will review the request and will determine whether a hearing should be granted. If FDA determines that an oral hearing should be held, it will announce the time, date, and place of the hearing in a future issue of the Federal Register. The procedures that will govern any such oral hearing are those applicable to a public hearing under part 15 (21 CFR part 15) of FDA's administrative practices and procedures regulations.

Interested persons may, on or before March 21, 1997, submit to the Dockets Management Branch (address above) written requests for an oral hearing on this matter. Two copies of any requests are to be submitted, except that individuals may submit one copy. Requests are to be identified with the docket number found in brackets in the heading of this document. Received requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under FDA's authority in section 521 of the act and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10).

Dated: February 7, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–4046 Filed 2–13–97; 2:19 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 40

RIN 1076–AA10

Grant Program for Higher Education

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Indian Affairs (BIA) is proposing to amend its regulations on Higher Education Grant Programs to improve the clarity of the regulations and understanding of the public as mandated by Executive Order 12866.

DATES: Comments must be received on or before May 20, 1997.

ADDRESSES: Mail comments to Joann S. Morris, Director, Office of Indian Education Programs, Bureau of Indian Affairs, Department of the Interior, 1849 C St. NW., Mail Stop 3512–MIB, Washington, DC 20240; or, hand deliver them to Room 3512 at the above address. Comments will be available for inspection at this address from 9 a.m. to 4 p.m., Monday through Friday beginning approximately March 5, 1997.