

§ 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.

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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.

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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.