

**§ 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.*

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

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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.

**FOR FURTHER INFORMATION CONTACT:**

Garry R. Martin, Office of Indian Education Programs, Bureau of Indian Affairs at telephone (202) 219-1128.

**SUPPLEMENTARY INFORMATION:** The authority to issue rules and regulations is vested in the Secretary of the Interior by 5 U.S.C. 301 and sections 463 and 465 of the Revised Statutes, 25 U.S.C. 2 and 9.

Publication of the proposed rule by the Department of the Interior (Department) provides the public an opportunity to participate in the rulemaking process. Interested persons may submit written comments regarding the proposed rule to the location identified in the **ADDRESSES** section of this document.

**Executive Order 12778**

The Department has certified to the Office of Management and Budget (OMB) that the proposed rule meets the applicable standards provided in sections 2(a) and 2(b)(2) of Executive Order 12778.

**Executive Order 12866**

This proposed rule is not a significant regulatory action under Executive Order 12866.

**Regulatory Flexibility Act**

This proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

**Executive Order 12630**

The Department has determined that this proposed rule does not have "significant" takings implications. The proposed rule does not pertain to taking of private property interests, nor does it impact private property.

**Executive Order 12612**

The Department has determined that this proposed rule does not have significant federalism effects because it pertains solely to Federal-tribal relations and will not interfere with the roles, rights and responsibilities of states.

**NEPA Statement**

The Department has determined that this proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969.

**Unfunded Mandates Act of 1995**

This proposed rule imposes no unfunded mandates on any

governmental or private entity and is in compliance with the provisions of the Unfunded Mandates Act of 1995.

**Paperwork Reduction Act of 1995**

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Department of the Interior has submitted a copy of these sections to the Office of Management and Budget (OMB) for its review.

All information is to be collected annually from each applicant. The annual reporting and record keeping burden for this collection of information is estimated to average 4 hours for each response for 22 respondents, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The total annual reporting and record keeping burden for this collection is estimated to be 76 hours.

Organizations and individuals desiring to submit comments on the information collection requirement should direct them to the Office of Information and Regulatory Affairs, OMB, Room 10202, New Executive Office Building, Washington, DC 20503; Attention: Interior Desk Officer.

The Department considers comments by the public on this proposed collection of information in:

Evaluating whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;

Evaluating the accuracy of the Department's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

Enhancing the quality, usefulness, and clarity of the information to be collected; and

Minimizing the burden of the collection of information on those who are to respond; including through the use of appropriate automated, electronic, mechanical, or other collection techniques or other forms of information technology.

OMB is required to make a decision concerning the collection of information contained in these proposed regulations between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment to the OMB is best assured of having full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to the Bureau of Indian Affairs on the proposed regulations.

Drafting Information: The primary author of this document is Garry R. Martin, Office of Indian Education Programs, Bureau of Indian Affairs, Department of the Interior.

**List of Subjects in 25 CFR Part 40**

Indians—education, Indians—educational assistance.

For the reasons given in the preamble, Part 40 of Title 25, chapter I of the Code of Federal Regulations is proposed to be revised as set forth below.

**PART 40—HIGHER EDUCATION GRANT PROGRAM**

Sec.

- 40.1 What special terms apply?
- 40.2 What is the purpose of this part?
- 40.3 Who is eligible for a higher education grant?
- 40.4 How do I apply for a higher education grant?
- 40.5 How is my application reviewed?
- 40.6 How will I be notified if I am awarded a grant?
- 40.7 How will I receive the grant?
- 40.8 How long does my financial aid last?
- 40.9 What happens if I withdraw from school?
- 40.10 How do I appeal a grant decision?
- 40.11 What records are kept for the grant program?
- 40.12 How does a tribe estimate allowable administrative costs?
- 40.13 May a tribe prioritize its higher education grant program?
- 40.14 Are there requirements for information collection?

Authority: 25 U.S.C. 2, 9, and 13; Reorganization Plan No. 3 of 1950 (65 Stat. 1262)

**§ 40.1 What special terms apply?**

*Academic year* means a period of time in which a full-time student is expected to complete the equivalent of at least two semesters, two trimesters, or three quarters at a institution that measures academic process in credit hours.

*Accreditation* means the certification of an institution of higher education by a sanctioned national or regional accrediting agency or association recognized by the Secretary of Education.

*BIA* means the Bureau of Indian Affairs.

*Campus-based aid* means the Federal financial aid programs (i.e., Supplemental Educational Opportunity Grants (SEOG), College Work-Study (CWS), and Perkins Loan) administered by the financial aid office.

*Certificate of Agreement* means a written agreement between a grant recipient and the higher education program describing how a recipient pays back grants when the recipient does not meet the requirements in 25 CFR 40.8 and 40.9.

*Continuing student* means a grant recipient who is currently enrolled in an

eligible institution and is maintaining satisfactory progress in his or her course of study according to the institution's standards of satisfactory progress.

*Director* means the Director, Office of Indian Education Programs, Bureau of Indian Affairs.

*Education Line Officer* means a Bureau of Indian Affairs official designated as an Agency Superintendent for Education or an Education Program Administrator.

*Eligible institution* means an institution of higher education that is accredited by a national or regional accrediting agency or is a candidate for accreditation, or is a tribally controlled community college.

*Financial aid office* means the office of an institution of higher education that has responsibility for institutionally administered financial aid.

*Financial aid package* means the institution's documents that identify the amounts and types of financial aid awarded by the institution and the amount of unmet need.

*Full time student* means an enrolled student who is carrying a full time academic work load (other than correspondence course) as determined by the eligible institution.

*Higher education grant package* means documents required to identify, eligibility for assistance obtainable through federally recognized tribal offices, or BIA offices. This package is available from tribal Higher Education Grant Programs local Office of Indian Education Programs.

*Higher Education Office* means a Bureau Education Line Office, tribal or tribal organization administering funds appropriated to the Bureau for higher education grants to eligible students.

*Indian* means a person who is a member of or is at least one-quarter degree Indian blood descendant of a member of an Indian tribe that is eligible for the special programs and services provided by the United States through the Bureau of Indian Affairs to Indians because of their status as Indians.

*Indian tribe* means any Indian Tribe, Band, Nation, Rancheria, Pueblo, Colony or Community, including any Alaska Native village, that is recognized by the United States Government, through the Secretary of the Interior, for special programs and services provided by the Secretary to Indians because of their status as Indians.

*Mitigating circumstances* means a circumstance, such as, a student's medical diagnosed condition impairing the ability to continue a course of study documented by his or her physician, or any other undue hardship that

significantly hinders a student's academic progress.

*Near reservation* means those areas or communities next to reservations that are designated by the Assistant Secretary—Indian Affairs upon recommendations of the local BIA Superintendent with input of the affected tribal governing body.

*Program plan* means an individualized course of study in which the student, in conjunction with the degree granting institution of higher education, outlines the required courses for the desired degree.

*Unmet need* means the difference between the student's cost of education and the resources available to defray those costs.

*You* means the grant applicant or potential applicant.

#### **§ 40.2 What is the purpose of this part?**

The BIA Grant Program for Higher Education, administered under the authority of the Snyder Act of November 2, 1921 (25 U.S.C. 13), provides financial assistance to eligible Indian students who have unmet financial needs as determined by the eligible institution's Financial Aid Office. All grants made under this part shall be subject to availability of appropriations.

#### **§ 40.3 Who is eligible for a higher education grant?**

To be eligible for a higher education grant:

(a) You must be a member of a federally recognized Indian tribe eligible for the programs provided to Indians by the BIA, or be a one-quarter degree blood descendant of such a member;

(b) You must be admitted to an institution of higher education that is accredited by national or regional accrediting agency, is a candidate for accreditation, or is an eligible institution;

(c) You must apply for all available campus-based aid by an established due date; and

(d) You must have unmet need (the difference between the cost of your education and your resources for defraying that cost) as determined by the eligible institution's financial aid office.

#### **§ 40.4 How do I apply for a higher education grant?**

(a) You must have the institution's financial aid office prepare and certify an application package for financial aid. The package must include:

(1) A letter of acceptance from your institution (required only if you are a new, transfer, or a previously suspended student);

(2) A completed BIA form for applying for a higher education grant;

(3) A Certificate of Indian Blood (CIB) from your tribe or from the BIA certifying that you are a member of a tribe or have documentation to support a claim to Indian descent by blood quantum;

(4) A high school transcript or General Education Development (GED) high school equivalency certificate;

(5) Grades, transcripts or progress reports from previous term/year of attendance (continuing students); and

(6) A statement agreeing to repay the grant if you fail to enroll, withdraw or are expelled, unless there are mitigating circumstances.

(b) This package must be submitted to the BIA or tribal organization administering the program for your tribe by the due date set by that organization. If your application arrives after the due date, your application will be considered only if funds remain available.

(c) You must submit a separate application for a summer school program.

#### **§ 40.5 How is my application reviewed?**

The BIA or tribal organization administering the program for your tribe reviews your application. The BIA or tribal organization will:

(a) Determine your unmet need, using information from your institution's financial aid office;

(b) Approve your eligibility for a grant according to your tribe's priority plan; and

(c) Within availability of funds, fund no more than your unmet need.

#### **§ 40.6 How will I be notified if I am awarded a grant?**

The BIA or tribal organization administering the program for your tribe will tell you and your institution's financial aid office in writing of its approval or denial.

#### **§ 40.7 How will I receive the grant?**

(a) The BIA or tribal organization administering the program will issue your grant to your institution's financial aid office.

(b) Your institution's financial aid office will distribute the grant money according to its policy on disbursement.

#### **§ 40.8 How long does my financial aid last?**

(a) If your undergraduate degree or Certificate program requires four or fewer academic years, you may take extra years to complete the program, but you must finish a degree in no more than five academic years.

(b) If your undergraduate degree or certificate program normally requires more than four academic years, you may take extra years to complete the program, but you must finish a degree in six academic years.

(c) The BIA or tribal organization administering the program may waive the time limits for hardship caused by special circumstances.

(d) To remain eligible for continued funding, you must submit a grade report or transcript for each term to the BIA or tribal organization administering the program.

#### § 40.9 What happens if I withdraw from school?

(a) You will be required to pay back any portion of the grant you receive if you, without mitigating circumstances, fail to enroll, withdraw or are expelled before the completion of a term.

(b) Within ten days of your failure to enroll or withdrawal or expulsion you will be required to submit to the BIA or tribal organization administering the program:

(1) The date of your failure to enroll, withdrawal or expulsion;

(2) A written statement with supporting documentation stating your reasons for a failure to enroll, withdrawal or expulsion including mitigating circumstances; and

(3) A copy of your request to the institution that all remaining grant funds be returned to the BIA.

(c) The Bureau of Indian Affairs or tribal organization administering the program will notify you in writing of arrangements to pay the balance of funds based upon a Certificate of Agreement between you and the organization awarding your grant or grant you a waiver from repayment based upon mitigating circumstances.

#### § 40.10 How do I appeal a grant decision?

You may appeal the decisions of any BIA official by following the procedures in 25 CFR part 2, Appeals from Administrative Actions.

#### § 40.11 What records are kept for the grant program?

(a) The Higher Education Office will maintain your files, a ledger of all costs, and related records necessary to identify all transactions involving expenditure of funds made available to you under this program. These records:

- (1) Identify your award and status;
- (2) Demonstrate your eligibility;
- (3) Document the amount of your award and the manner in which your unmet need was calculated and met;
- (4) Identify whether your enrollment was terminated;

(5) Identify collections based upon Certificates of Agreement; and

(6) Identify waivers from repayment.

(b) By November 1 of each year, the Education Line Officer will submit a Higher Education Grant Program Annual Report for the preceding academic year to the Director of the Office of Indian Education Programs.

#### § 40.12 How does a tribe estimate allowable administrative costs?

Tribes and tribal organizations that do not have a negotiated an indirect cost rate with the Federal Government may use no more than 15 percent of available program funds to pay for indirect program costs chargeable to the program.

#### § 40.13 May a tribe prioritize its higher education grant program?

Yes.

(a) A tribe operating a higher education program may set program priorities for categories of applicants. These priorities in order to be given effect must be set out in the application materials provided to grant applicants, and attached to the tribe's contract or annual funding agreement. This tribal program priority plan may include a listing of priorities, the reasons and supporting documentation.

(b) If a tribe desires to set a higher academic standard by increasing the minimum grade point average, designate academic hours needed in order to be classified as a full time student, set priorities to first serve students residing near or within the exterior boundaries of the reservation or on trust or restricted lands, the tribe may do so.

#### § 40.14 Are there requirements for information collection?

The information collection requirement contained in this part has been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(d), and assigned clearance number 1076-0106.

Dated: January 28, 1997.

Ada E. Deer,

*Assistant Secretary—Indian Affairs.*

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## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### 32 CFR Part 286

[DoD 5400.7-R]

### DoD Freedom of Information Act Program Regulation

AGENCY: Department of Defense

ACTION: Proposed rule.

**SUMMARY:** This proposed revision provides substantive and administrative changes to conform to the requirements of the Electronic Freedom of Information Act Amendments of 1996, 5 U.S.C. 552, as amended by Public Law 104-231. It also provides guidance to the Department of Defense on implementation of this amended law.

**DATES:** Comments must be received by April 21, 1997.

**ADDRESSES:** Forward copies to ASD(PA), Room 2C757, 1400 Defense Pentagon, Washington, DC 20301-1400

**FOR FURTHER INFORMATION CONTACT:** Mr. C. Talbott, 703-697-1171.

#### SUPPLEMENTARY INFORMATION:

Executive Order 12866, "Regulatory Planning and Review"

It has been determined that 32 CFR part 286 is not a significant regulatory action. The rule does not:

(1) Have an annual effect to the economy of \$100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

It has been certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule implements the Freedom of Information Act (5 U.S.C. 552), a statute concerning the release of Federal Government records, and does not economically