

which it must either publish a consumer product safety rule addressing the risk of injury from fire and shock associated with miniature Christmas tree lights or withdraw by rule the applicable notice of proceeding. This period may be further extended for good cause shown.

Dated: MARCH 6, 1979.

SADYE E. DUNN,
Secretary, Consumer
Product Safety Commission.

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[4110-03-M]

**DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE**

Food and Drug Administration

[21 CFR Part 333]

[Docket No. 75N-0183]

**TOPICAL ANTIMICROBIAL PRODUCTS FOR
OVER-THE-COUNTER HUMAN USE**

Reopening of the Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Reopening of record on proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record of the proposed monograph establishing conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) topical antimicrobial drug products for human use, e.g., antibacterial soaps, surgical scrubs, skin cleanser, and first-aid preparations. By this action, the agency is granting 6 petitions that requested reopening this record and is deferring action on 11 requests for an oral hearing.

DATES: New or additional data, information, and comments by June 7, 1979. Reply comments by July 9, 1979.

ADDRESS: Written data, information, comments, and reply comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of September 13, 1974 (39 FR 33103), FDA issued a proposal, under the OTC drug review procedures in §330.10 (21 CFR §330.10), to establish a monograph for OTC topical antimicrobial drug products for repeated daily human use, to-

gether with the report of the Advisory Review Panel on OTC Topical Antimicrobial (I) Drug Products. Interested persons were invited to submit comments on the proposal within 60 days—on or before November 12, 1974. Reply comments in response to comments filed during the initial 60-day period were allowed until December 12, 1974. In response to numerous requests, the agency published a notice in the FEDERAL REGISTER of October 17, 1974 (39 FR 37066) granting an extension of the deadlines for comments until December 12, 1974 and for reply comments until January 13, 1975.

In response to the proposal of September 13, 1974, 86 comments and reply comments were received, several of which contained extensive additional data. After an extensive and time-consuming review of the Panel's report, the proposed monograph, and all comments and reply comments, FDA issued in the FEDERAL REGISTER of January 6, 1978 (43 FR 1210) a tentative final monograph on OTC topical antimicrobial products.

Interested persons were invited to submit objections or requests for an oral hearing on or before February 6, 1978. In response to numerous requests to extend the time period for submitting objections or requests for oral hearing, the agency issued a notice in the FEDERAL REGISTER of February 3, 1978 (43 FR 4637) granting an extension of the deadline to March 6, 1978.

During the period permitted for submitting objections or requests for an oral hearing, FDA received the following six petitions to reopen the administrative record. The Proctor & Gamble Co., Cincinnati, OH 45217 (CP 0002) submitted new data on the safety and effectiveness of triclocarban as an active antimicrobial ingredient. Ciba-Geigy Corp., Ardsley, NY 10502 (CP 0001) submitted new data bearing on the proliferation of use of triclosan. This problem was first discussed in the tentative final order; it was never considered by the Panel. The Soap and Detergent Association, New York, NY 10016 (SUP 00015) submitted new data on the safety of antimicrobial soaps in infants. Significant amounts of new and previously unconsidered data were submitted with each of the above petitions. The Colgate-Palmolive Co., New York, NY 10022 (LET 0003) petitioned the agency to evaluate previously submitted data on the safety and effectiveness of a combination deodorant bar soap containing triclosan and triclocarban. These data were not addressed in the January 6, 1978 tentative final order. A petition was also submitted by the Upjohn Co., Kalamazoo, MI 49001 (HER 0001) to consider previously submitted data (OTC Volume 020093) on

the safety and effectiveness of secondary amylicresols and ortho-hydroxyphenylmercuric chloride as active antimicrobial ingredients. No new data were submitted with this petition. Xtrium Laboratories, Chicago, IL 60609 (CP 0003) requested the agency to consider data on chlorhexidine gluconate, a new ingredient not previously reviewed or included in the tentative final order. Copies of all of these petitions are on file in the office of the Hearing Clerk, FDA.

Eleven requests for a hearing and many comments containing new data have also been received in response to the tentative final order. Much new data have been generated over the 4-year period since the original Panel report was published. These new data may materially affect and alter some of the agency's decisions presented in the January 6, 1978 tentative final order. In addition, some of the data upon which the original Panel report was based have been called into question as a result of the agency's current investigation of certain testing laboratories.

Thus, FDA has determined that it is in the public interest to defer action on the requests for a hearing, and to grant the six petitions to reopen the administrative record to allow interested persons to submit comments, reply comments, and any new or additional data. FDA will publish an updated tentative final order and monograph based on the review and evaluation of these submissions, and on a reevaluation of existing data. Persons who requested a hearing or submitted a petition will be notified by letter that FDA has reopened the administrative record. Data, information, and comments submitted in response to the September 13, 1974 or January 6, 1978 publications need not be resubmitted.

Interested persons are invited to submit their comments in writing (preferably four copies identified with the Hearing Clerk document number found in brackets in the heading of this document) on or before June 7, 1979. Such comments should be addressed to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be accompanied by a supporting memorandum or brief. Additional comments replying to any comment so filed may also be submitted on or before July 9, 1979. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: February 26, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6764 Filed 3-8-79; 8:45 am]

[4310-02-M]

DEPARTMENT OF INTERIOR

Bureau of Indian Affairs

[25 CFR Part 273]

**EDUCATION CONTRACTS UNDER JOHNSON-
O'MALLEY ACT**

Distribution Formula

AGENCY: Bureau of Indian Affairs,
Department of the Interior.

ACTION: Proposed Rule.

SUMMARY: Notice is hereby given that it is proposed to revise 25 CFR 273.31, distribution formula. Pub. L. 95-561 Section 1102(a) requires the Secretary of Interior to develop and publish alternative methods for the equitable distribution of supplemental program funds. The intended effect of the action is to determine a formula for the purpose of distribution of funds appropriated.

DATES: Comments must be received on or before May 7, 1979.

ADDRESS: Send comments to U.S. Department of the Interior, Office of the Assistant Secretary for Indian Affairs: Attention: Deputy Assistant Secretary Lavis, 18th & C Streets NW., Room 6352, Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT:

Jon C. Wade, Division of Educational Assistance, Office of Indian Education Programs, Post Office Box 1788, Albuquerque, New Mexico 87103, Area Code 505-766-2427.

SUPPLEMENTARY INFORMATION: This notice is published in exercise of authority delegated by the Secretary of Interior to the Assistant Secretary—Indian Affairs by 230 DM 2.

It is the policy of the Department of Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments, suggestions or objections regarding the proposed rule to the U.S. Department of the Interior, Office of the Assistant Secretary for Indian Affairs: Attention: Deputy Assistant Secretary Lavis, 18th & C Streets NW., Washington, D.C. 20240.

The current distribution formula is not a part of regulation. It is required by law that it be incorporated into regulation. Pub. L. 95-561, Sec. 1102(a) directs the Secretary to develop alter-

native methods for the equitable distribution of any supplemental program funds provided and to publish them in the FEDERAL REGISTER by March 1, 1979 for the purpose to allow for eligible tribes to comment by May 1, 1979. During this time, the Secretary of Interior will conduct field hearings for the purpose of collecting further comments. Approximately two days of field hearings will be scheduled during the period of March 26, 1979 through April 15, 1979 in Anchorage, Alaska; Minneapolis, Minnesota; Ft. Hall, Idaho; Albuquerque, New Mexico; Sulphur, Oklahoma; Nashville, Tennessee; and San Diego, California.

After May 7, 1979, the Secretary will revise, in accordance with all comments, such formula alternatives and submit them to a vote of the tribes.

Pub. L. 95-561, Section 1102(b) requires that the formula which receives 51 percent of the above vote will be published as a final rule in the FEDERAL REGISTER by July 1, 1979. This vote will be taken during the period of May 7, 1979 to June 7, 1979 and will be certified by the Secretary. It must be also understood that each tribe, as defined in 25 CFR, Part 273.2(g) will have one (1) vote each.

Section 273.31, Distribution formula, provides for the apportionment among contractors within each State so that each contractor will receive approximately the same amount for each eligible Indian student to be served under the contract. The formula receiving a majority of votes will be made a part of § 273.31 and will be used for computing the distribution.

The following distribution formulas have been developed and are published for the purpose to allow eligible tribes to comment by May 1, 1979:

(1) Option "A": Based on the number of eligible Indian students for whom funds are sought, multiplied by a national average per-pupil expenditure and a weighting factor which is intended to take into account the differences in education costs among the States. The weighting factor is the quotient obtained by dividing every State's cost of delivering educational services by the lowest State's cost; except that, for every State whose cost is below the national average, the national average will be used as that State's cost. (This method is the current distribution formula).

(2) Option "B": the weighting factor for this option is the quotient obtained by dividing every State's cost of delivering educational services by the lowest State's cost; except that, in considering a State's cost of delivering educational services, no State will be considered at a level less than 80 percent and more than 120 percent of the national average.

(3) Option "C": Each eligible student will receive 25 percent of their State's or the national average per-pupil cost whichever is greater.

(4) Option "D": Every eligible student will receive the same amount.

(5) Option "E": Seventy-five percent (75 percent) of the appropriated funds will be distributed equally, with each eligible student receiving a per capita share. Twenty-five percent (25 percent) of the appropriated funds will be distributed in accordance with Option "A".

(6) Option "F": Seventy-five percent (75 percent) of the appropriated funds will be distributed equally, with each eligible student receiving a per capita share. Twenty-five percent (25 percent) of the appropriated funds will be distributed in accordance with Option "B" above.

Tribes may recommend and comment on their own proposed formula as well.

The Department of Interior has determined that this document is not a significant rule and does not require a regulatory analysis under Executive Order 12044 and 43 CFR Part 14.

I have determined that these proposed regulations are not a major Federal action within the scope of the National Environmental Policy Act of 1969, 42 U.S.C. 4223(2)(c).

The primary authors of this document are Bill Riefenberry, Task Force Member, Bureau of Indian Affairs, Western Washington Agency, telephone number (FTS) 8-392-9320, Commercial (206) 258-2651 and Steering Committee Members Maxine Edmo, Bureau of Indian Affairs, Fort Hall, Idaho, telephone number (208) 237-0405, and Benny Atencio, Santo Domingo Pueblo, Santo Domingo Pueblo, New Mexico, telephone number (505) 465-2240.

It is proposed to amend Part 273, § 273.31, Subchapter Y of Chapter 1 of Title 25 of the Code of Federal Regulations to read as follows:

§ 273.31 Distribution formula.

(a) Reserved for formula.

(b) The Commissioner may make exceptions to the provisions of Paragraph (a) of this section based upon the special cultural, linguistic, social or educational needs of the communities involved.

Dated: March 2, 1979.

FORREST J. GERARD,
Assistant Secretary,
Indian Affairs.

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