proposed rules

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 989]

RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

Proposed Preliminary Free and Reserve Percentages for 1975–76 Crop Year

Notice is given of a proposal to designate for natural Thompson Seedless and Dipped Seedless raisins for the 1975–76 crop year, beginning September 1, 1975, preliminary free tonnage percentages of 52 percent and 53 percent, respectively, and preliminary reserve tonnage percentages of 48 percent and 47 percent, respectively. These designations would be under § 989.55 of the marketing agreement, as amended, and Order No. 989, as amended (7 CFR Part 989), regulating the handling of raisins produced from grapes grown in California. The proposal would also revise § 989.224 (40 FR 46299) to delete the designation of a desirable free tonnage for the 1975–76 crop year of 2,850 tons of Zante Currant raisins contained in that section. The amended marketing agreement and order, hereinafter referred to collectively as the "order", are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). This proposal with respect to designation of free and reserve tonnage percentages was unanimously recommended under § 989.54(b) by the Raisin Administrative Committee established under the order.

Production of natural Thompson Seedless and Dipped Seedless raisins for the 1975–76 crop year has been estimated to be 240,000 tons and 9,000 tons, respectively, by the Committee. The Committee determined that a field price for natural Thompson Seedless and Dipped Seedless raisins is firmly established. Under § 989.54(b) of the order, the Committee is required to recommend to the Secretary a preliminary free tonnage percentage which when applied to the estimated production of a varietal type would release 85 percent of the desirable free tonnage for that varietal type. A desirable free tonnage for natural Thompson Seedless and Dipped Seedless raisins of 148,000 tons and 5,620 tons, respectively, was designated by the Secretary on October 7, 1975 (40 FR 46299).

Eighty-five percent of the desirable free tonnage for natural Thompson Seedless raisins would be 125,800 tons. Dividing 125,800 tons by the estimated production (240,000 tons) and rounding to the nearest full percent results in a preliminary free percentage of 52 percent. Eighty-five percent of the desirable free tonnage for Dipped Seedless raisins would be 4,777 tons. Dividing 4,777 tons by the estimated production (9,000 tons) and rounding to the nearest full percent results in a preliminary free percentage of 53 percent.

Section 989.54(b) also provides that any difference between the preliminary or final free tonnage percentage and 100 percent shall be the reserve percentage. Thus, the preliminary reserve percentages for natural Thompson Seedless and Dipped Seedless raisins would be 48 percent and 47 percent, respectively.

A desirable free tonnage, for the 1975–76 crop year, of 2,850 tons for Zante Currant raisins was designated on October 7, 1975 (40 FR 46299), and is contained in § 989.224. The Committee's October 3, 1975, estimate of production of these raisins for the 1975–76 crop year was 2,850 tons. Thus, no volume regulation is needed for this varietal type of raisin and all of the 1975–76 production of Zante Currant raisins should be free tonnage. Therefore, the Committee recommended that § 989.224 be revised to delete the desirable free tonnage designated for these raisins in that section.

Consideration will be given to any written data, views, or arguments pertaining to the proposal which are received by the Hearing Clerk, U.S. Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, not later than October 31, 1975. All written submissions made regarding this notice should be in quadruplicate and will be made available for public inspection at the office of the Hearing Clerk during regular hours of business (7 CFR 1.27 (b)).

The proposal is as follows:

1. Section 989.224 is revised to read:

§ 989.224 Desirable free tonnage.

The desirable free tonnage designated for natural Thompson Seedless and Dipped Seedless raisins for the 1975–76 crop year are 148,000 tons and 5,620 tons, respectively.

2. A new § 989.231 is added reading as follows:

§ 989.231 Free and reserve percentages for the 1975–76 crop year.

The preliminary percentages of standard natural Thompson Seedless and Dipped Seedless raisins acquired by handlers during the crop year beginning September 1, 1975, which shall be free tonnage and reserve tonnage, respectively, are designated as follows:

	Free percentage	Reserve percentage
Natural Thompson Seedless	52	48
Dipped Seedless	53	47

NOTE.—It is hereby certified that the economic and inflationary impacts of this proposed regulation have been carefully evaluated in accordance with OMB Circular A–107.

Dated: October 14, 1975.

CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.75–28277 Filed 10–20–75;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 330]

[Docket No. 75N–0039]

OVER-THE-COUNTER DRUGS

Testing of Category III Active Ingredients

The Commissioner of Food and Drugs is proposing to amend § 330.10 (21 CFR 330.10), the procedural regulations governing the over-the-counter (OTC) drug review project, to establish the conditions under which an OTC drug classified in category III (insufficient data to permit final classification at this time) may continue to be marketed pending development of data to support approval of the ingredient, labeling, or other condition as safe, effective, and not misbranded, through amendment of the applicable OTC drug monograph or approval of a new drug application (NDA). Comments on this proposal will be accepted until December 22, 1975.

The Commissioner proposed in the FEDERAL REGISTER of January 5, 1972 (37 FR 85) and promulgated in the FEDERAL REGISTER of May 11, 1972 (37 FR 9464), procedures governing the review and classification of OTC drug products. These procedures provide for initial classification of the ingredients, labeling claims, and other conditions reviewed as generally recognized as safe and effective and not misbranded (category I), not generally recognized as safe and effective or misbranded (category II), and insufficient data to permit final classification at this time (category III).

The Commissioner has provided in § 330.10(a)(6) that a reasonable period of time will be specified within which category III conditions may be continued in marketed products while the

data necessary to support their use are being obtained for submission to and evaluation by the Food and Drug Administration. Section 330.10(a)(12) then provides that the Commissioner may propose to amend or repeal a monograph on his own initiative or on the petition of any interested person, and that an NDA may be submitted in lieu of, or in addition to, a petition to amend a monograph.

The Food and Drug Administration has received numerous requests for clarification of the conditions under which drug products with category III conditions may continue to be promoted and marketed pending further testing, and the circumstances under which the Food and Drug Administration will require that the monograph be amended rather than permitting approval of a category III condition through submission of an NDA. These issues were thoroughly considered by the Commissioner in promulgating the final monograph on OTC antacid drug products in the FEDERAL REGISTER of June 4, 1974 (39 FR 19862). The Commissioner concludes that the decisions made at that time have broad applicability to all OTC drug products subject to this review. Accordingly, the Commissioner has concluded that these matters should be resolved by this proposed amendment of § 330.10(a)(12).

Regarding the question of continued marketing of a drug product with a category III condition pending further testing, the Commissioner advises that the provisions of § 330.10(a)(6) currently state that such marketing is lawful only if testing to obtain the data necessary to support the questioned condition is in fact conducted for the specific product involved. The Commissioner proposes to specify in the regulations that because one manufacturer is conducting such testing does not mean that other manufacturers may continue to market their product without such testing. However, a trade association or other group could conduct appropriate testing on behalf of a number of manufacturers and thereby satisfy the requirement that testing has been conducted on their behalf. Similarly, a chemical manufacturer may conduct testing of a category III ingredient on behalf of all his customers. Therefore, a manufacturer or distributor may market an OTC drug with a category III condition only if he is conducting the testing himself or is supporting such testing, or such testing is otherwise conducted on his behalf.

The Commissioner further proposes that such testing must be initiated prior to the date on which drug products with category II conditions can no longer be shipped in interstate commerce. The failure to initiate testing by that time would subject a category III condition to the same regulatory sanctions as a category II condition.

The submission of test protocols or periodic reports or other information with respect to such testing is optional, not mandatory. However, the Commissioner may require some proof that such testing has been undertaken in compliance with the requirements of the regulations. Any manufacturer who wishes to submit information on such testing may do so by sending it to the Assistant Director for Implementation, Division of OTC Drug Evaluation, HFD-510, Food and Drug Administration, Rm. 16-85, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20852.

Section 330.10(a)(12) of the regulations provides that approval of a category III condition may be obtained either by amendment of the applicable monograph or by an NDA. There have been many questions about whether an NDA may be submitted if a category III condition is continued in use during the testing period permitted by the final regulation. The Commissioner recognizes that the intended application of this provision is unclear, and proposes to clarify it herein.

As proposed, a petition to amend the monograph would have to be submitted prior to 60 days before the end of the time period for testing of category III conditions, which is specified in the promulgation of the final monograph. If a petition is received within this time period, marketing on an interim basis may continue thereafter, unless and until the Food and Drug Administration denies the petition.

The Commissioner proposes that a manufacturer may submit an NDA, rather than a petition to amend the monograph, only if the drug product with the condition involved has not been marketed on an interim basis while the supporting data have been gathered. If the product with that condition, e.g., an ingredient or claim placed in category III, has been marketed during the interim period, it could only have been so marketed lawfully on the basis of a conclusion by the manufacturer that the product is not a new drug by reason of that condition, and accordingly, the proper procedure for permanent approval of the condition would be through an old drug monograph rather than through an NDA. Only if the product with that condition is not marketed during that interim period, and thus if any clinical testing has been conducted pursuant to an IND plan, may the manufacturer properly obtain approval for the condition involved through an NDA.

The Commissioner notes that there is no provision in section 505 of the act for marketing a new drug prior to approval of an NDA. Marketing of a new drug prior to such approval constitutes a violation of the act. Thus, any manufacturer who desires to request approval of a category III condition through an NDA must conduct all clinical testing pursuant to an IND plan and may not market a product with that condition on an interim basis prior to approval of the NDA.

If an NDA is submitted to request approval of a category III condition and the Commissioner concludes that an NDA is inappropriate because the applicant has marketed a product with that condition during the interim testing period, the Commissioner proposes that the NDA be handled as a petition to amend the monograph. However, the Commissioner may not otherwise utilize safety and effectiveness data and information contained in an NDA, which have not previously been disclosed to the public, to determine that the condition involved is generally recognized as safe and effective and thus that the monograph should be amended. Of course, if one manufacturer chooses to obtain amendment of the monograph and another chooses to obtain approval of an NDA for the same category III condition, once the monograph is amended to include the condition involved, the NDA will no longer be operative and, in accordance with the agency's public information regulations, the safety and effectiveness data contained in that NDA will be available for public disclosure.

The Commissioner is of the opinion that these provisions are reasonable and fully reflect the requirements of the law. By requiring that a petition to amend a monograph be submitted prior to 60 days before the end of the testing period specified for a category III condition, the Food and Drug Administration will have a reasonable opportunity to determine whether the petition contains adequate supporting data and information before that time period expires. Manufacturers need not be concerned about possible difficulties in the time taken to process a petition for amendment of a monograph since it is only necessary that such petition, containing all data and information obtained for the testing, be filed prior to 60 days before the cut-off date set for category III testing, not that it be approved by the Food and Drug Administration by that final cut-off date. If further time is necessary for processing the petition, which will be the case where a proposal to amend the monograph is published for comment, marketing may continue until the matter is resolved. If the petition is denied, marketing must cease.

It is possible that the Food and Drug Administration will conclude that a petition to amend a monograph establishes safety and effectiveness but not general recognition of safety and effectiveness, and thus that an NDA for the product is approvable even though the monograph cannot properly be amended. The Commissioner proposes that, under these circumstances, the petition for amendment of the monograph be treated by the Food and Drug Administration as an NDA, and thus that approval of an NDA can be granted without first requiring disapproval of the petition and cessation of marketing.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701(a), 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055 (U.S.C. 321, 352, 355, 371(a))) and under the authority delegated to him (21 CFR 2.120), the Commissioner proposes to revise § 330.10(a)(12) to read as follows:

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and as not misbranded, and for establishing monographs.

* * * * *

(a) * * *

(12) *Amendment of monographs.* (i) The Commissioner may amend or revoke any monograph established pursuant to this section on his own initiative or on the petition of any interested person, pursuant to the provisions of Part 2 of this chapter.

(ii) Any person who wishes to continue marketing a product with a condition subject to paragraph (a)(6)(iii) (category III) of this section shall undertake, or have undertaken on his behalf, testing adequate and appropriate to obtain the data necessary to resolve the issues which resulted in such classification. Such testing shall be initiated prior to the date after which a product with a condition subject to paragraph (a)(6)(ii) (category II) of this section may no longer be shipped in interstate commerce. The failure to initiate such testing within such time period shall result in imposition of the sanctions applicable under paragraph (b) of this section. Upon request, the manufacturer shall furnish to the Food and Drug Administration adequate proof that such testing has been initiated within the time period specified.

(iii) A new drug application may be submitted in lieu of a petition to amend the monograph only if the drug product with the condition which is the subject of the NDA has not been marketed on an interim basis pursuant to the provisions of paragraph (a)(6)(iii) (category III) of this section, all clinical testing has been conducted pursuant to an IND plan, and no marketing is undertaken prior to approval of the NDA. The Food and Drug Administration shall handle an NDA as a petition for amendment of a monograph, and shall review it on that basis, if the provisions of this paragraph preclude approval of an NDA but permit the granting of such a petition.

(iv) A petition to amend the applicable monograph shall be submitted prior to 60 days before the expiration date for a condition subject to the provisions of paragraph (a)(6)(iii) (category III) of this section in order to justify continued marketing of a product with a condition subject to that paragraph. Marketing may thereafter be continued unless and until the petition is disapproved. The Food and Drug Administration shall handle a petition for amendment of a monograph as a new drug application, and shall review it on that basis, if the provisions of this paragraph preclude granting such a petition but permit approval of a new drug application. However, until the Agency determines whether or not an approved NDA can issue, the data submitted will be considered as a petition for amendment of a monograph and marketing may be continued.

* * * * *

Interested persons may, on or before December 22, 1975 submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: October 10, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-28226 Filed 10-20-75;8:45 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Insurance Administration

[24 CFR Part 1917]

[Docket No. FI-733]

CITY OF KINGFISHER, OKLAHOMA

Proposed Flood Elevation Determinations

The Federal Insurance Administrator, in accordance with Section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added Section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR Part 1917 (§ 1917.4(a)), hereby gives notice of his proposed determinations of flood elevations for the City of Kingfisher.

Under these Acts, the Administrator, to whom the Secretary has delegated the statutory authority, must develop criteria for flood plain management in identified flood hazard areas. In order to participate in the National Flood Insurance Program, the City must adopt flood plain management measures that are consistent with the flood elevations determined by the Secretary.

Proposed flood elevations (100-year flood) are listed below for selected locations. Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations are available for review at City Hall, 119 W. Miles Street, Kingfisher, Oklahoma 73750.

Any person having knowledge, information, or wishing to make a comment on these determinations should immediately notify Mr. Vernie Snow, City Superintendent. The period for comment will be ninety days following the second publication of this notice in a newspaper of local circulation in the above-named community or ninety days from the publication of this notice in the FEDERAL REGISTER, whichever is the later.

The proposed 100-year Flood Elevations are:

Source of flooding	Location	Elevation in feet above mean sea level	Width from shoreline or bank of stream (facing downstream) to 100-yr flood boundary (in feet)	
			Right	Left
Kingfisher Creek	County road (13th St.)	1,048	[1] 2,250	[3]
	U.S. Highway 81	1,045	[2] 2,350	[3]
	Chicago, Rock Island and Pacific RR.	1,043	[1] 1,100	[3]
Uncle John's Creek	Oklahoma Ave.	1,048	[3]	[2] 550
	East Bowman Ave.	1,048	[3]	[2] 800
	Oklahoma Highway 33	1,044	[3]	[2] 950
	East Roberts Ave.	1,043	[3]	[1] 900

[1] Approximate distance in feet from corporate limits to boundary of 100-yr flood.
[2] Approximate distance in feet from bank of stream to boundary of 100-yr flood.
[3] Extends beyond corporate limits.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001-4128; and Secretary's delegation of authority to Federal Insurance Administrator 34 FR 2680, February 27, 1969, as amended by 39 FR 2787, January 24, 1974.)

Issued: September 30, 1975.

J. ROBERT HUNTER,
Acting Federal Insurance Administrator.

[FR Doc.75-28286 Filed 10-20-75;8:45 am]

[24 CFR Part 1917]

[Docket No. FI-732]

TOWN OF CRYSTAL BEACH, GALVESTON COUNTY, TEXAS

Proposed Flood Elevation Determination

The Federal Insurance Administrator, in accordance with Section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added Section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR Part 1917 (§ 1917.4(a)) hereby gives notice of his proposed determinations of flood elevations for the Town of Crystal Beach.

Under these Acts, the Administrator, to whom the Secretary has delegated the statutory authority, must develop criteria for flood plain management in identified flood hazard areas. In order to participate in the National Flood Insurance Program, the Town must adopt flood plain management measures that are consistent with the flood elevations determined by the Secretary.

Proposed flood elevations (100-year flood) are listed below for selected locations. Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations are available for review at the Town Hall, Crystal Beach Fire Department, Highway 87, Crystal Beach.

Any person having knowledge, information, or wishing to make a comment