(2) Foreign country that is not a Party to the Agreement but is found by the United States Trade Representative, ("Trade Representative") to extend rights and privileges to the United States that are substantially the same as those that would be so extended if that foreign country were a Party to the Agreement, may make a representation to the Trade Representative alleging that a standards-related activity engaged in within the United States violates the obligations of the United States under the Agreement on Technical Barriers to Trade.

(b) All representations under section 422 of the Trade Agreements Act of 1979 ("section 422") shall be addressed to the United States Trade Representative, Office of the United States Trade Representative, 600 17th Street, NW., Washington, D.C. 20506. Alternatively, such a representation may be made by diplomatic correspondence and may be accepted by the Trade Representative.

(c) "The Agreement", a "Party to the Agreement" and "standards-related activity" are defined as in section 451 of the Act (19 U.S.C. 2561).

§ 2009.1 Information required in representation.

(a) Each representation submitted under section 422 should state clearly on the first page that the representation is a request for action with respect to the obligations of the United States under the Agreement, and should contain the following information:

(1) The foreign country making the representation, the division of the foreign country's government representing that country's interest, the person(s) within the division who is (are) coordinating the foreign country's representation.

(2) A description of the standards-related activity at issues, including, whenever possible, copies of the standards-related activity's provisions.

(3) Identification of the foreign goods or services affected by the standards-related activity at issue.

(4) A statement of how the standards-related activity concerned is alleged to violate the obligations of the United States under the Agreement. This statement shoud indicate with particularity which such obligations are alleged to be violated.

(5) Indication as to whether the foreign country has officially petitioned, filed or complained for relief concerning the same subject matter as this representation to any international forum.

(b) Each representation submitted under section 422 of the Act must contain information sufficient to provide a reasonable indication that the standards-related activity concerned is having a significant trade effect, including (but not limited to) the volume of trade in the goods concerned.

(c) Representations should be submitted in 10 copies.

[FR Doc. 82-30491 Filed 11-4-82; 8:45 am]

BILLING CODE 3190-01-M

FEDERAL TRADE COMMISSION

16 CFR Part 13

[Docket C-3097]

Association of Independent Dentists; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement requires a Colorado dental association to cease, among other things, inhibiting competition by restricting or advising member dentists against the truthful advertising of their services. The order bars the association and its members from coercing any third-party payer into altering the terms and conditions of any dental health care plan. Further, the association is required to timely repeal any provision of its by-laws which are inconsistent with the prohibitions contained in the order; mail a copy of the order together with a letter specifying the changes made to the by-laws to every member; and provide all future members with a copy of the order.

DATES: Complaint and order issued October 22, 1982.[1]

FOR FURTHER INFORMATION CONTACT: FTC/CS-8, Arthur Lerner, Washington, D.C. 20580. (202) 724-1303.

SUPPLEMENTARY INFORMATION: On Monday, August 16, 1982, there was published in the **Federal Register**, 47 FR 35519, a proposed consent agreement with analysis In the Matter of Association of Independent Dentists, a corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart—Coercing and Intimidating: Section 13.367 Members. Subpart—Combining or Conspiring: Section 13.384 combining or conspiring; § 13.395 To control marketing practices and conditions; § 13.430 To enhance, maintain or unify prices. Subpart—Corrective Actions and/or Requirements: Section 13.533 Corrective actions and/or requirements; 13.533-60 Release of general, specific or contractual constrictions, requirements or restraints.

List of Subjects in 16 CFR Part 13

Dentists, Dental health care services.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Carol M. Thomas,

Secretary.

[FR Doc. 82-30529 Filed 11-4-82; 8:45 am]

BILLING CODE 6750-01-M

16 CFR Part 13

[Docket C-3028]

Fred Meyer, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Modifying order.

SUMMARY: This order reopens the proceeding and modifies the Commission's order issued on July 23, 1980 (45 FR 28754), by modifying Paragraphs A and B of Section IV, so as to extend from 10 to 14 days the time in which customers have to come into the store to settle their account once their layaway period has expired. The modification also extends from 11 to 15 days the time the store will wait before returning layaway merchandise to stock.

DATES: Consent Order issued July 23, 1980. Modifying Order issued Oct. 14, 1982.

FOR FURTHER INFORMATION CONTACT: FTC/PC, Julio A. Castillo, Washington, D.C. 20580. (202) 376-2805.

SUPPLEMENTARY INFORMATION: In the Matter of Fred Meyer, Inc. Codification appearing at 45 FR 28754 remains unchanged.

[1] Copies of the Complaint and the Decision and Order filed with the original document.

List of Subjects in 16 CFR Part 13

Layaway merchandise, trade practices.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

The Order Modifying Cease and Desist Order Issued July 23, 1980 is as follows:

Before the Federal Trade Commission

COMMISSIONERS: James C. Miller III, Chairman, David A. Clanton, Michael Pertschuk, Patricia P. Bailey

In the matter of Fred Meyer, Inc., Docket No. C-3028.

Order Modifying Cease and Desist Order Issued July 23, 1980

The Federal Trade Commission having considered the July 19, 1982, petition of Fred Meyer, Inc., a Delaware corporation, successor to Fred Meyer, Inc., an Oregon corporation, to reopen this matter and modify the consent order to cease and desist issued by the Commission on July 23, 1980, and having determined that public interest warrants reopening and modification of the order

It is ordered that order Paragraph A and B of Section 4 be revised as follows:

Mail to each layaway customer:

1. within twenty (20) days after the end of the period designated in the layaway agreement to make full payment for the merchandise,

2. if the payments received by respondent have not been returned to the customer, and

3. if the merchandise has not been delivered to the customer, and

4. before the merchandise is returned to stock and before making any entries in the layaway account which would close out the account, the following disclosure clearly and conspicuously in twelve-point or larger type, entirely on one side of a single piece of paper, separated from any other written matter:

We Owe You Money

(Date of mailing to be inserted here)

You haven't fully paid for your recent layaway purchase at our (name of store) store. You can fully pay for your purchase within 14 days from the above date. Or you can get a refund from us for the amount you have paid (less 35 cents handling charge). If you want a refund, come to the department of the store where you have the layaway not later than (insert date 14 days from notice) and ask for your money. You also have the choice of getting a credit to purchase other merchandise. Please bring this notice with you. If you don't ask for a refund or a credit, we will send you a check automatically within 45 days if the amount we owe you is more than $1.

Respondent may insert in the above notice a different handling charge that is reasonable in comparison with a 35 cent charge.

B. Defer returning layaway merchandise to stock until 15 days after the mailing of the notice specified in IV. A. and allow completion of the layaway purchase within 14 days after the mailing of the notice.

By direction of the Commission.

Issued: October 14, 1982.

Carol M. Thomas,

Secretary.

[FR Doc. 82-30489 Filed 11-4-82; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 18

[T.D. 82-204]

Customs Regulations Amendments Relating to Customs Bonded Warehouses

Correction

In FR Doc. 82-29742, beginning at page 49355, in the issue of Monday, November 1, 1982, on page 49368, in the middle column, § 18.4 is corrected in the last line of the authority citation by changing "16461a" to "1646a".

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 75G-0117]

GRAS Status of Ozone

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that ozone is generally recognized as safe (GRAS), with specific limitations, for use as a disinfectant in bottled water. This action is based on an industry petition requesting such affirmation.

EFFECTIVE DATE: November 5, 1982.

FOR FURTHER INFORMATION CONTACT: Mary C. Custer, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: Under procedures described in § 170.35 (21 CFR 170.35), the American Bottled Water Association, 1141 W. Olympic Blvd., Los Angeles, CA 90015, submitted a petition (GRASP 4G0043) requesting affirmation that the use of ozone as a disinfectant in bottled water is GRAS. FDA published a notice of filing of this petition in the **Federal Register** of June 25, 1975 (40 FR 26723), and the agency gave interested persons an opportunity to review the petition and to submit comments to the Dockets Management Branch, Food and Drug Administration. No comments were received in response to the notice.

Ozone has the chemical formula O_3; is an unstable blue gas with a pungent, characteristic odor; and occurs at low levels (about 0.05 part per million (ppm) in air at sea level) in nature. It is generally encountered in dilute form in a mixture with air or oxygen. Ozone is formed photochemically in the Earth's stratosphere by the action of ultraviolet light of short wavelengths on oxygen. It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen. Ozone is a powerful oxidant having an oxidation potential of 2.07 volts. In aqueous solution, ozone is relatively unstable. The rate of decay of ozone in solution is dependent both on the termperature and the purity of the water.

Along with chlorine, ozone is generally recognized as one of the most potent germicidal agents used in the treatment of water. Chemical disinfectants kill or inactivate microorganisms by physical or chemical disruption of a critical cellular structure or function. In the case of ozone, a chemical reaction takes place that is oxidative in nature. Thus, the oxidative potential of ozone is an important factor with regard to its capabilities as a disinfectant. The chemical state of ozone that is germicidally active is not known, but it may be the $OH\cdot$. (hydroxyl radical) or the HO_2^- (hydroperoxyl radical). The presence of other species, such as O_3^- (ozonide radical), O_2^- (superoxide radical), and O^- (oxide radical), have been demonstrated, but their role in germicidal activity is not known. Most experimental data indicate that the efficiency of ozone as a disinfectant varies with pH, and that it is somewhat more efficient at a lower pH (6.0) than at a higher pH (10.0). This result is probably caused by the greater stability of ozone in water at lower pH's.

The petitioner has sought agency affirmation that the use of this ingredient as a disinfectant in bottled water is GRAS. Information supplied by the petitioner indicates that, under normal conditions, the ozone dosage applied is 0.5 to 2.0 ppm. The petitioner's quality control standard is a maximum level of 0.4 ppm at the time of bottling.

The petition provides information from the published literature verifying that ozone is toxic, particularly by inhalation, at relatively low levels. However, the petition also provides data from the published literature on the rate

of dissipation of ozone in water under a wide range of conditions. These data show that ozone dissipates rapidly when used in water, and that the rate of decay of residual ozone in water varies inversely with the amount of oxidizable materials present. The petition also includes unpublished data confirming the disappearance of ozone under the proposed conditions of use and under what must be considered worst case conditions—from distilled water.

The petition also provides published information indicating that ozone has been in continuous use for disinfecting municipal water for nearly 70 years in Europe, originally in France, extending to Germany, Holland, Switzerland, and other European countries. In addition, published reports indicate that a few municipalities in the United States have used it in their drinking water systems. There have been no reports of human toxicity from the use of ozone in municipal water supplies in the United States and Europe. This information corroborates the safety of the use of ozone as a disinfectant in bottled water.

In a 1968 opinion letter, FDA stated that ozone used to disinfect potable water is GRAS if it is used in accordance with current good manufacturing practice and with the recommendations of the United States Public Health Service. The agency reiterated this position in the preamble to the final rule establishing current good manufacturing practice for bottled water (40 FR 11566; March 12, 1975).

Ozone is also regulated in § 129.80 (21 CFR 129.80), at a level of 0.1 part per million in water, for use in sanitizing operations of product water-contact surfaces and any other critical areas.

After a comprehensive review of all data regarding the use of ozone as a disinfectant for bottled water, the agency has determined that:

1. Ozone is not eligible for GRAS status as a disinfectant in bottled water based on common use in the United States before January 1, 1958.

2. Ozone is GRAS for this limited use based on scientific procedures. The agency's conclusion is based upon published data demonstrating that although ozone may be toxic at relatively low levels, it dissipates rapidly in water. These data are supplemented by unpublished data that confirm the rapid dissipation of ozone in water under the intended conditions of use. This conclusion is corroborated by published information that ozone has been used for 70 years in Europe for disinfecting municipal drinking water, and that it has had a limited use for this purpose in the United States. No reports of safety problems have been associated with this use.

3. Ozone performs the functional effect claimed by the petitioner.

Therefore, the agency concludes that the use and level of use of ozone as set forth in the petition is GRAS. The agency also has considered the potential consumer exposure to oxidation products formed during the reaction of ozone with impurities found in water. To assure that the levels of any oxidation products formed are low and safe, the agency has included in § 184.1563 (21 CFR 184.1563) the requirement that the starting water, before ozonation, meet the microbiological, physical, chemical, and radiological quality standards for bottled water specified in § 103.35 (b) through (e) (21 CFR 103.35 (b) through (e)). The agency thus concludes that this limited approval for use of ozone in bottled water constitutes a specific limitation on its use in accordance with § 184.1(b)(2) (21 CFR 184.1(b)(2)).

FDA is affirming ozone as GRAS even though there are no applicable food-grade specifications. The agency has determined that the method of manufacture of commercial ozone assures a product with purity suitable for the requested use. Therefore, the agency concludes that ozone must be of a purity suitable for its intended use in accordance with 21 CFR 170.30(h)(1), and that further specifications are unnecessary.

The format of the regulation is different from that in previous GRAS affirmation regulations. The agency has modified the form in which the specific limitations on the use of the ingredient is presented. This change has no substantive effect but is made merely for clarity.

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment not an environmental impact statement is required.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this rule, and the agency has determined that the rule is not a major rule as defined by the Order.

List of Subjects in 21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 184 is amended by adding new § 184.1563, to read as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

§ 184.1563 Ozone.

(a) Ozone (O_3, CAS Reg. No. 10028–15–6) is an unstable blue gas with a pungent, characteristic odor, which occurs freely in nature, It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen.

(b) The ingredient must be of a purity suitable for its intended use in accordance with § 170.30(h)(1) of this chapter.

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Category of food	Maximum treatment level in food	Functional use
Bottled water that prior to ozonation meets the microbiological, physical, chemical, and radiological quality standards of § 103.35 (b) through (e) of this chapter.	Not to exceed current good manufacturing practice. Current good manufacturing practice results in a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water.	Antimicrobial agent, § 170.3 (o)(2) of this chapter.

Effective date. This regulation shall become effective November 5, 1982.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Dated: October 18, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-30180 Filed 11-4-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 601

Licensing; Reclassification Procedures To Determine That Licensed Biological Products Are Safe, Effective, and Not Misbranded Under Prescribed, Recommended or Suggested Conditions of Use

Correction

In FR Doc. 82–27314, beginning at page 44062, in the issue of Tuesday, October 5, 1982, make the following corrections: