

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 1999F-0719]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to allow for the safe use of olestra as a replacement for fats and oils in prepackaged, unpopped popcorn kernels that are ready-to-heat. This action is in response to a food additive petition (FAP) filed by the Procter and Gamble Co.

DATES: This rule is effective *[insert date of publication in the Federal Register]*; submit written or electronic objections and requests for a hearing by *[insert date 30 days after date of publication in the Federal Register]*. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 172.867 (21 CFR 172.867) as of *[insert date of publication in the Federal Register]*.

ADDRESSES: Submit written objections to the Division of Dockets Management (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Submit electronic objections to <http://www.fda.gov/dockets/ecomments>.

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FOR FURTHER INFORMATION CONTACT: Jason K. Dietz, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202418-3299.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Subject of Petition

11. Background

111. Use of Olestra in Microwave Popcorn

A. Effect on Estimated Consumption of Olestra

B. Effect of Microwave Popcorn Preparation on Vitamins A, D, E, and K

1. Temperatures Reached During Popcorn Preparation

2. Degradation of Fat-soluble Vitamins

3. Safety of Fat-soluble Vitamin Degradation Products

4. Nutritional Implications of Fat-soluble Vitamin Degradation

C. Response to Comment

D. Conclusions About the Use of Olestra in Microwave Popcorn

IV. Amendment of § 172.867(b) and (c)

V. Deletion of § 172.867(f)

VI. Summary

VII. Environmental Impact

VIII. Paperwork Reduction Act of 1995

IX. Inspection of Documents

X. Objections

XI. References

I. Subject of Petition

In a notice published in the **Federal Register** of April 6, 1999 (64 FR 16742), FDA announced that an FAP (FAP9A4652) was filed by the Procter

& Gamble Co., 6071 Center Hill Ave., Cincinnati, OH 45224 (P&G, the petitioner) proposing that the food additive regulations be amended in § 172.867 *Olestra* to provide for the safe use of olestra in place of fats and oils in prepackaged, unpopped popcorn kernels that are ready-to-heat. In this document, such prepackaged popcorn kernels will be referred to as “microwave popcorn.”¹

Although not noted in the FAP (64 FR 16742), the petitioner also requested two editorial changes in the regulation that would have no effect on the substance of the regulation. Because the identity and specifications for olestra are now listed in the *Food Chemicals Codex* (FCC), the petitioner requested that the regulation incorporate by reference the specifications for olestra provided in the FCC, consistent with other regulations. The petitioner also requested that FDA update § 172.867(f) because it is “out-of-date.” Section 172.867(f) requires FDA to hold a Food Advisory Committee (FAC) meeting on olestra within 30 months of olestra’s January 30, 1996, approval.

II. Background

In the **Federal Register** of January 30, 1996 (61 FR 3118, “the 1996 final rule”), FDA announced the approval of olestra for use as a replacement for fats and oils in prepackaged ready-to-eat savory (i.e., salty or piquant but not sweet) snacks (§ 172.867). As part of the 1996 final rule, FDA concluded that olestra inhibits the absorption of the fat-soluble components of the diet when these components are present in the gastrointestinal (GI) tract simultaneously with olestra (61 FR 3118 at 3132 to 3147). Such components include the fat-

¹ Two basic types of prepackaged, unpopped popcorn kernels exist in the market: Popcorn kernels in microwavable bags with heat susceptors for heat transfer and popcorn kernels in aluminum foil packages for stovetop heating. Although the petitioned use includes retail products that would be heated on the stovetop as well as those heated in microwave ovens, for simplicity FDA refers to these products as “microwave popcorn” throughout this document.

soluble vitamins A, D, E, and K. Based on data from nutritional studies conducted prior to the **1996** approval, FDA concluded that addition of the four fat-soluble vitamins (A, D, E, and K) to savory snacks containing olestra would compensate for any decreased absorption of these vitamins due to the action of olestra, thus ensuring that consumption of an olestra-containing savory snack would not alter the amount of vitamin available for absorption (**61 FR 3118 at 3144 to 3147**). As part of its **1996** final rule approving the use of olestra in savory snacks, FDA required that specified amounts of vitamins A, D, E, and K be added to olestra-containing savory snacks (§ 172.867(d)).

The **1996** final rule allowed the use of olestra in savory snacks that are ready-to-eat. Ready-to-eat savory snacks, including olestra-containing ready-to-eat savory snacks and their added fat-soluble vitamins, do not require preparation (i.e., heat treatment) by the consumer prior to consumption. Therefore, in such olestra-containing savory snacks, the levels of added fat-soluble vitamins are unlikely to change between manufacturing and consumption by the consumer. In contrast, the current petition requests approval for a use of olestra in which the olestra-containing savory snack (microwave popcorn), including the added fat-soluble vitamins, must be heated by the consumer prior to consumption.² This heat treatment may cause degradation of the added fat-soluble vitamins, resulting in the levels of fat-soluble vitamins present after heat preparation being less than those added by the manufacturer. This is not the case for ready-to-eat savory snacks which are not normally heated by consumers prior to consumption. Therefore, in ruling on this petition, FDA must consider whether heat preparation of olestra-

² **In this case the product purchased by the consumer will be olestra mixed with unpopped popcorn kernels and vitamins A, D, E, and K in a container used to heat the unpopped popcorn kernels. Preparation of the kernels for consumption requires heating the kernels until they pop.**

containing microwave popcorn causes any nutritionally important effects in the levels of added fat-soluble vitamins. Additionally, FDA must consider whether any degradation products resulting from the heating of fat-soluble vitamins in olestra-containing microwave popcorn raise any safety concerns.

III. Use of Olestra in Microwave Popcorn

A. Effect on Estimated Consumption of Olestra

The use of olestra as a replacement for fats and oils in microwave popcorn will not change the estimated intake of olestra. In FDA's **1996** decision, FDA calculated the estimated daily intake (EDI) of olestra based on the conservative assumption that all of the fat used in all savory snacks would be replaced by olestra. This approach to calculating the EDI included the assumption that all popcorn, regardless of source, would be made with olestra. Because the agency has already included popcorn consumption from all sources in its estimate of olestra consumption, approval of the current petition would not change the EDI of olestra (Ref. 1).

B. Effect of Microwave Popcorn Preparation on Vitamins A, D, E, and K

As noted, the current petition requests the approval of the use of olestra in a savory snack that will be heated by consumers prior to consumption. Heat treatment may cause degradation of vitamins, including those fat-soluble vitamins that would be added to olestra-containing microwave popcorn. To address this concern, P&G studied the effect of heating on the degradation of fat-soluble vitamins A, D, E, and K.³ The petitioner chose to use microwave oven heating to study the thermal degradation of fat-soluble vitamins, asserting that: (1) Both stovetop-prepared and microwave oven-prepared products rely

³ Safety issues associated with the heating of olestra have previously been considered (61 FR 3118 at 3130). The current petition presents no new issues regarding the heating of olestra.

on lipids as a heat transfer medium to “fry” the kernels in either a foil package on a stovetop or in a bag in a microwave oven, (2) both the stovetop and microwave deliver similar amounts of heat during popcorn preparation, and (3) most consumers prepare popcorn at home in microwave ovens.

FDA agrees that microwave heating of popcorn kernels is adequate to study the degradation of fat-soluble vitamins during heat preparation of both popcorn kernels in microwavable bags with heat susceptors and popcorn kernels in aluminum foil packages intended for stovetop heating (Ref. 1).

1. Temperatures Reached During Popcorn Preparation

As part of its petition, P&G presents data about the temperatures reached during typical microwave heating of popcorn kernels by consumers.⁴ P&G demonstrates that the temperature inside bags of microwave popcorn increases from approximately 30 degrees Celsius at the start of heating to a maximum temperature of approximately 175 degrees Celsius. The petitioner reported that exposure to temperatures of 150–175 degrees Celsius occurs for only a fraction (30–60 seconds) of a typical 3.5 minute popping cycle.⁵ For comparison, P&G points out that it is not uncommon to fry foods for 2 to 5 minutes at similar temperatures (150–200 degrees Celsius), including foods that serve as dietary sources of fat-soluble vitamins. Thus, fat-soluble vitamins added to microwave popcorn and heated in the home will not experience heating temperatures or times greater than those currently used in common food preparation practices.

⁴ P&G heated bags of microwave popcorn in a 1,000 Watt household microwave oven on high power until the popping frequency slowed to about 2–3 seconds between pops. Popping was usually “complete” in about 3.5 minutes. The temperature inside the bag during popping was recorded every 15 seconds by four thermocouples inserted into the bag. After popping, the bags were opened within 30 seconds after completion of popping and the popcorn transferred to a serving bowl, reflective of typical habit and practice for microwave popcorn consumers.

⁵ FDA notes that data in the petition show that during typical microwave popcorn preparation temperatures greater than 150 degrees Celsius are achieved for approximately 90 seconds of the 3.5 minute popping cycle (Ref. 2).

2. Degradation of Fat-soluble Vitamins

To assess the effect of microwave popcorn preparation on fat-soluble vitamin degradation the petitioner analyzed samples from olestra-containing microwave popcorn prepared using a microwave oven. This analysis shows that 44 percent of vitamin A, 4.3 percent of vitamin D, and 24.4 percent of vitamin K are lost during microwave popcorn preparation?

With respect to vitamin E, P&G states that loss of this vitamin was considered during FDA's review of the use of olestra in prepackaged, ready-to-eat savory snacks. Vitamin E loss was reported to be only 3–4 percent (as a-tocopherol) under frying conditions (including time and temperature) that exceed those encountered during microwave popcorn preparation? Thus, vitamin E loss resulting from microwave popcorn preparation is unlikely to exceed 3–4 percent.

3. Safety of Fat-soluble Vitamin Degradation Products

The petitioner considered the safety of degradation products resulting from the heating of fat-soluble vitamins. The petitioner stated that exposure to fat-soluble vitamin degradation products is not a new or unusual dietary experience because the chemical pathways producing fat-soluble vitamin degradation products in microwave popcorn and other heated foods are the same. Degradation products from vitamins A, D, E, and K are a natural consequence of cooking, and these degradation products are commonly eaten.

P&G also states that the amount of fat-soluble vitamin degradation products

⁶ FDA notes that the scientific literature shows a vitamin A loss similar to that observed in the study conducted by P&G for microwave popcorn. In particular, vitamin A loss was reported to be 40 percent in meat fried at 200 degrees Celsius for 5 minutes (Refs. 2 and 3).

⁷ P&G determined the amount of vitamin E degraded during five deep fries each for 10 minutes at 375 degrees Fahrenheit (190 degrees Celsius), with wet filter paper and during shallow frying for 14 minutes at 375 degrees Fahrenheit (190 degrees Celsius), with inclusion of a wet filter paper to simulate heat sink and hydrolysis conditions.

in a serving of microwave popcorn is comparable to the amount found in servings of other fried/heated foods. P&G concludes that the exposure to fat-soluble vitamin degradation products formed during the heating of microwave popcorn does not result in an increased safety risk relative to the exposure to degradation products arising from the frying of other foods commonly found in the diet. P&G states that microwave popcorn would just be another source of such degradation products.

FDA considered that the exposure to fat-soluble vitamin degradation products from this use of olestra would be similar to, or less than, that from other foods fried in oils, or otherwise cooked (Ref. 1). Based on its safety review, FDA concludes that exposure to fat-soluble vitamin degradation products from this use of olestra would be safe (Ref. 2).

4. Nutritional Implications of Fat-soluble Vitamin Degradation

P&G states that the nutritional impact of fat-soluble vitamin degradation during microwave popcorn preparation can be assessed by examining the likelihood of these losses having a nutritionally significant effect on the overall vitamin status of microwave popcorn consumers. P&G asserts that a nutritionally significant impact on microwave popcorn consumers cannot occur if olestra's potential to interact with dietary sources of fat-soluble vitamins is limited or infrequent. The current petition includes data from the Snack Food Association's **1996** Consumer Snacking Behavior Report. These data demonstrate that microwave popcorn is eaten an average of two eating occasions in **14** days among popcorn eaters and is rarely eaten with meals. (Popcorn is eaten with only about 0.4 percent of all meals.) Microwave popcorn is consumed alone 45 percent of the time and rarely with other foods that are significant sources of fat-soluble vitamins. When other foods are consumed

with microwave popcorn, a beverage is the preferred choice (42 percent of popcorn eating occasions). Based on these data, P&G asserts that there is little potential for the use of olestra in microwave popcorn to have an effect on the fat-soluble vitamin status of microwave popcorn consumers. Therefore, the petitioner concluded that the levels of vitamins A, D, E, and K currently required to be added to olestra-containing savory snacks under § 172.867(d) are sufficient for addition to microwave popcorn.

FDA agrees with the petitioner that the levels of vitamins A, D, E, and K required to be added to microwave popcorn should be those specified in § 172.867(d). FDA reached this conclusion because olestra-containing microwave popcorn is not likely to be consumed concurrently with dietary sources of fat-soluble vitamins. Therefore, it is unlikely that a person's daily intake of fat-soluble vitamins would be affected by the consumption of microwave popcorn that contains olestra. Moreover, the levels of vitamins D and E that are degraded during the heating process amount to such a small quantity (approximately 4 percent) that the systemic levels of these vitamins would not be affected by the small amounts degraded (Ref. 2).

C. Response to Comment

Although section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) establishes no comment period for FAPs, and the agency generally does not solicit comments in notices announcing the filing of an FAP, it is FDA's practice to consider any relevant comments timely submitted. FDA received one comment on the use of olestra in microwave popcorn. The comment and the agency's response follow.

A comment from an individual consumer requested that FDA deny the current petition. The comment expressed concern about the amount of iron

added to foods and the potential effects on infants of excess folic acid in their mother's diet. The comment states that the public does not know about the amounts of excess vitamins and iron added to their diets. The comment also requested that FDA allow each individual to add their own vitamins as needed.

The regulation that is the subject of this petition does not require that either iron or folic acid be added to olestra-containing products. Thus, issues surrounding excess levels of these nutrients in the diet are outside the scope of this petition.

D. Conclusions About the Use of Olestra in Microwave Popcorn

Based on a fair evaluation of the data and information in the current FAP, as well as data and information in the original FAP (FAP7A3997) that resulted in the establishment of § 172.867, FDA has concluded that there is a reasonable certainty that no harm will result from the use of olestra as a replacement for fats and oils in microwave popcorn. FDA is requiring that vitamins A, D, E, and K be added to microwave popcorn at levels specified in § 172.867(d).

IV. Amendment of § 172.867(b) and (c)

In its petition, P&G requested that § 172.867(b), which contains specifications for food-grade olestra, be amended to reference the specifications for food-grade olestra set forth in the FCC, fourth edition, first supplement. P&G observes that the specifications set out in the FCC monograph for olestra are identical to those currently provided in § 172.867(b) (Ref. 1).

In establishing food additive approval regulations, **FDA** generally incorporates by reference FCC specifications where such specifications have been issued and are consistent with FDA's safety evaluation. As noted, the FCC specifications are the same as those issued by FDA and thus, this change is simply editorial. In addition, manufacturers generally look to the FCC for

food grade specifications. Accordingly, FDA agrees that current § 172.867(b) should be amended to remove the current specifications in this paragraph and in their place to incorporate by reference the FCC specifications for food-grade olestra. FDA has concluded that the use of olestra as a replacement for fats and oils in microwave popcorn is safe. Accordingly, the agency is amending § 172.867(c) to include this use of the additive.

V. Deletion of § 172.867(f)

In its petition, P&G also noted that § 172.867(f) is obsolete. In the 1996 final rule, FDA committed to review and evaluate all data and information bearing on the safety of olestra received by the agency after the effective date of the regulation (January 30, 1996) and present such data, information, and evaluation to the agency's Food Advisory Committee (FAC) within 30 months of the approval of olestra (61 FR 3118 at 3168–3169; § 172.867(f)). Consistent with its obligation under § 172.867(f), FDA convened a meeting of its FAC on June 15–17, 1998, fulfilling its obligation under § 172.867(f).⁸ Thus, FDA has concluded that § 172.867(f) no longer serves a function and should be deleted.

VI. Summary

FDA has concluded that there is reasonable certainty that no harm will result from the use of olestra in microwave popcorn (21 CFR 170.3(i)). FDA is requiring that vitamins A, D, E, and K be added to microwave popcorn at levels currently specified in § 172.867(d). FDA has also concluded that § 172.867 should be updated by revising § 172.867(b) to incorporate by

⁸ At an open public meeting, held June 15–17, 1998, new data and information concerning olestra, obtained since the 1996 approval were presented. The complete set of transcripts of the June 15–17, 1998, FAC meeting is publicly available through FDA's Division of Dockets Management and through FDA's Internet site. The Internet site is located at <http://www.fda.gov/ohrms/dockets/ac/cfsan98t.htm#Food Advisory Committee> (choose June 15, 16, and 17).

reference the food-grade specifications for olestra set forth in the FCC, fourth edition, first supplement and by deleting § 172.867(f).

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Inspection of Documents

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (see **ADDRESSES**) by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

X. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections (see **DATES**). Each objection shall be separately numbered, and each

numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

The following references have been placed on display in the Division of Dockets Management and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from M. DiNovi, FDA to M. Ditto, FDA, **August** 10, 1999.
2. Memorandum from T. P. Twaroski, FDA to M. Ditto, FDA, May 17, 2002.
3. Burger, I. H. and Walters, C. L., "The Effect of Processing on the Nutritive Value of Flesh Foods," *Proceedings of the Nutrition Society*, 32:1-8, 1973.
4. Memorandum from M. DiNovi, FDA to M. Ditto, FDA, May 6, 2002.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Section 172.867 is amended by revising paragraphs (b) and (c) and by removing paragraph (f) to read as follows:

§ 172.867 Olestra.

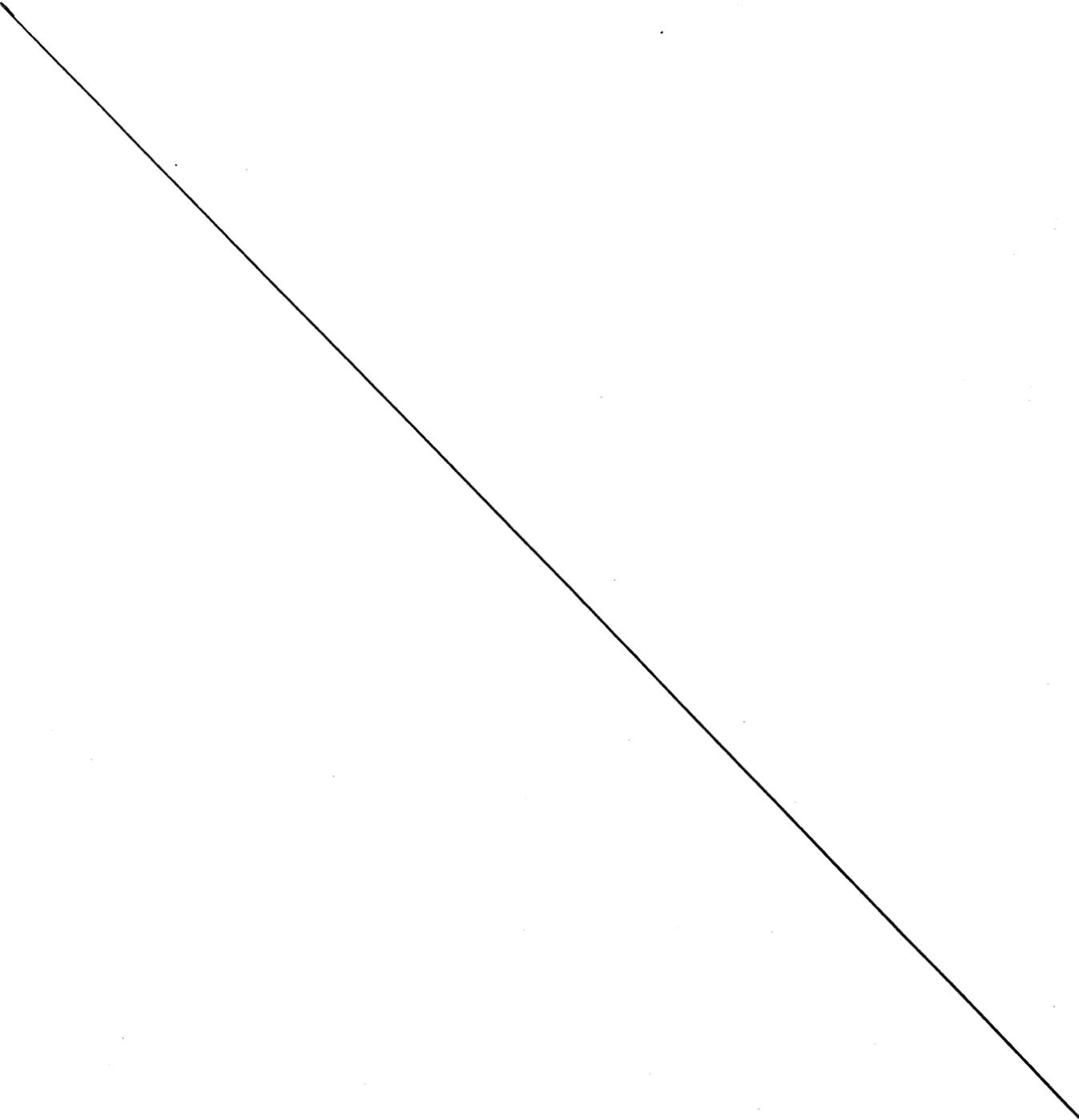
* * * * *

(b) Olestra meets the specifications of the *Food Chemicals Codex*, 4th edition, 1st supplement (1997), pp. 33–35, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418 (Internet address <http://www.nap.edu>). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal__register/code—offederal—regulations/ibr__locations.html.

(c) Olestra may be used in place of fats and oils in prepackaged ready-to-eat savory (i.e., salty or piquant but not sweet) snacks and prepackaged,

unpopped popcorn kernels that are ready-to-heat. In such foods, the additive may be used in place of fats and oils for frying or baking, in dough conditioners, in sprays, in filling ingredients, or in flavors.

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Dated: May 12, 2004
May 12, 2004.

William K. Hubbard

William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 04-????? Filed ??-??-048:45 am]

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