§ 126.805 What are the procedures for appeals of HUBZone status determinations?

(a) *Who may appeal.* The protested HUBZone SBC, the protestor, or the CO may file appeals of protest determinations with the ADA/GC&BD.

(b) *Timeliness of appeal.* The ADA/GC&BD must receive the appeal no later than five business days after the date of receipt of the protest determination. SBA will dismiss any appeal received after the five-day period.

* * * * *

(h) *Decision.* The ADA/GC&BD will make a decision within five business days of receipt of the appeal, if practicable, and will base his or her decision only on the information and documentation in the protest record as supplemented by the appeal. SBA will provide a copy of the decision to the CO, the protestor, and the protested HUBZone SBC, consistent with law. The ADA/GC&BD's decision is the final agency decision.

■ 52. Revise paragraph § 126.900(b) to read as follows:

§ 126.900 What penalties may be imposed under this part?

* * * * *

(b) *Civil penalties.* Persons or concerns are subject to civil penalties under the False Claims Act, 31 U.S.C. 3729–3733, and under the Program Fraud Civil Remedies Act, 31 U.S.C. 3801–3812, and any other applicable laws.

Dated: May 14, 2004.

Hector V. Barreto,

Administrator.

[FR Doc. 04–11579 Filed 5–21–04; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N–0276]

RIN 0910–AC40

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) published an interim final rule in the **Federal Register** of October 10, 2003 (68 FR 58894). The interim final rule requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States, to register with FDA by December 12, 2003. Due to several errors in §§ 1.231 and 1.232 (21 CFR 1.231 and 1.232), the interim final rule contains some incorrect information. This document corrects those errors.

DATES: Effective May 24, 2004.

FOR FURTHER INFORMATION CONTACT: Melissa S. Scales, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1720.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 10, 2003 (68 FR 58894), FDA published an interim final rule on Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Since that time, FDA has discovered that the interim final rule contains several errors.

First, FDA is correcting the phone number to which registration form requests and other technical questions should be directed. The appropriate phone numbers are 1–800–216–7331 or 301–575–0156.

Second, § 1.232 of the interim final rule contains several editorial errors. Section 1.232(d) currently states that each foreign facility must submit ''the name, address, phone number, and emergency contact phone number of its U.S. agent (if there is no other emergency contact designated under § 1.233(c)).'' To improve the clarity of this provision, FDA is also revising § 1.232(d). The reference to § 1.233(c) in this sentence is incorrect; the proper reference is to § 1.233(e). Also, the reference in § 1.232(g) to § 1.233(e) is incorrect; the proper reference is to § 1.233(j).

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, 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 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.231 is amended by revising paragraph (b)(1) to read as follows:

§ 1.231 How and where do you register?

* * * * *

(b) * * *

(1) You must register using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS–681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting a copy of this form by phone at 1–800–216–7331 or 301–575–0156.

* * * * *

■ 3. Section 1.232 is amended by revising paragraphs (d) and (g) to read as follows:

§ 1.232 What information is required in the registration?

* * * * *

(d) For a foreign facility, the name, address, phone number, and, if no emergency contact is designated under § 1.233(e), the emergency contact phone number of the foreign facility's U.S. agent;

* * * * *

(g) Applicable food product categories as identified in § 170.3 of this chapter, unless you check either ''most/all human food product categories,'' according to § 1.233(j), or ''none of the above mandatory categories'' because your facility manufactures/processes, packs, or holds a food that is not identified in § 170.3 of this chapter;

* * * * *

Dated: May 10, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–11598 Filed 5–21–04; 8:45 am]

BILLING CODE 4160–01–S

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 May 24, 2004; submit written or electronic objections and requests for a hearing by June 23, 2004. 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 May 24, 2004.

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*.

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, 202–418–3299.

SUPPLEMENTARY INFORMATION:

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I. Subject of Petition

In a notice published in the **Federal Register** of April 6, 1999 (64 FR 16742), FDA announced that an FAP (FAP 9A4652) 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-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-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

[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.

[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.

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 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.

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.[6]

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.[7] 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 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

[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.

[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).

[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 Farenheit (190 degrees Celsius), with wet filter paper and during shallow frying for 14 minutes at 375 degrees Farenheit (190 degrees Celsius), with inclusion of a wet filter paper to simulate heat sink and hydrolysis conditions.

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 (FAP 7A3997) 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.

[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).

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 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__of__federal__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.

* * * * *

Dated: May 12, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–11502 Filed 5–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

RIN 1010–AD04

Federal Oil Valuation

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule—technical amendment.

SUMMARY: The July 6, 2004, effective date of the final rule originally published May 5, 2004, entitled ''Federal Oil Valuation,'' is changed to August 1, 2004, to correct an inadvertent clerical error.

DATES: The correct effective date of the rule published on May 5, 2004, at 69 FR 24959, is August 1, 2004.

FOR FURTHER INFORMATION CONTACT: Sharron L. Gebhardt, Lead Regulatory Specialist, Chief of Staff Denver Office, Minerals Revenue Management, MMS at (303) 231–3211. E-mail: *Sharron.Gebhardt@mms.gov.* Address: P.O. Box 25165, MS 320B2, Denver, Colorado 80225–0165.

SUPPLEMENTARY INFORMATION: The MMS published a final rule entitled ''Federal Oil Valuation'' in the **Federal Register** on May 5, 2004 (69 FR 24959). The May 2004 final rule amended the existing regulations governing the valuation of crude oil produced from Federal leases for royalty purposes, and related provisions governing the reporting thereof. The amendments primarily affect which published market prices are most appropriate to value crude oil not sold at arm's length and what transportation deductions should be allowed. The effective date for the May 2004 final rule as originally published is July 6, 2004.

The original intent in publishing the May 2004 final rule was to make the rule become effective on the first day of the calendar month that is more than 60 days following the date of publication in the **Federal Register**. Through an inadvertent clerical error, just prior to publication, the effective date was changed to 60 days following the date of publication in the **Federal Register**. Consequently, the rule was published with an effective date of July 6, 2004. If left unchanged, Federal lessees would have to apply the existing rule to oil produced from July 1 through July 5, 2004, and then apply the May 2004 final rule to oil produced from July 6 to July 31, 2004. It was not MMS's intent to require Federal lessees to value oil produced during a particular production month (in this case, July 2004) using two different valuation rules. The MMS recognizes that to do so would be both administratively burdensome and costly to Federal lessees and MMS. Therefore, MMS is changing the effective date of the May 2004 final rule from July 6, 2004, to August 1, 2004.

This change does not require public comment under 5 U.S.C. 553(b)(3)(B). Public comment is unnecessary for the reasons explained above. Under 5 U.S.C. 553(d), MMS, for good cause, finds that this final rule—technical amendment, should be immediately final upon publication to correct MMS's inadvertent clerical error regarding the May 2004 final rule's effective date.

Dated: May 17, 2004.

Rebecca W. Watson,

Assistant Secretary for Land and Minerals Management.

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