IV. Environmental Analysis

10. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the quality of the human environment.[4] Issuance of this Final Rule does not represent a major Federal action having a significant adverse effect on the quality of the human environment under the Commission's regulations implementing the National Environmental Policy Act. Part 380 of the Commission's regulations lists exemptions to the requirement to draft an Environmental Analysis or Environmental Impact Statement. Included is an exemption for procedural, ministerial or internal administrative actions.[5] This rulemaking is exempt under that provision.

V. Regulatory Flexibility Act

11. The Regulatory Flexibility Act of 1980 (RFA)[6] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. This Final Rule concerns matters of internal agency procedure. The Commission therefore certifies that it will not have such an impact. An analysis under the RFA is not required.

VI. Document Availability

12. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

13. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

14. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or e-mail at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. E-mail the Public Reference Room at *public.referenceroom@ferc.gov.*

VII. Effective Date and Congressional Notification

15. These regulations are effective immediately upon publication in the **Federal Register**. In accordance with 5 U.S.C. 553(d)(3), the Commission finds that good cause exists to make this Final Rule effective immediately. It makes minor revisions to matters of internal operations and is unlikely to affect the rights of persons appearing before the Commission. There is therefore no reason to make this rule effective at a later time.

16. The provisions of 5 U.S.C. 801 regarding Congressional review of Final Rules do not apply to this Final Rule, because this Final Rule concerns agency procedure and practice and will not substantially affect the rights of non-agency parties.

17. The Commission is issuing this as a Final Rule without a period for public comment. Under 5 U.S.C. 553(b), notice and comment procedures are unnecessary where a rulemaking concerns only agency procedure and practice, or where the agency finds that notice and comment is unnecessary. This rule concerns only matters of internal agency procedure and will not significantly affect regulated entities or the general public.

List of Subjects in 18 CFR Part 375

Authority delegations (Government agencies), Seals and insignia, Sunshine Act.

By the Commission.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

■ In consideration of the foregoing, the Commission amends Part 375, Chapter I, Title 18, Code of Federal Regulations, as follows.

PART 375—THE COMMISSION

■ 1. The authority citation for Part 375 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791–825r, 2601–2645; 42 U.S.C. 7101–7352, 16451–16463.

■ 2. Section 375.302 is amended by adding paragraph (aa) as follows:

§ 375.302 Delegations to the Secretary.

* * * * *

(aa) Issue a notice that the Commission will not further review on its own motion a Notice of Penalty filed under Section 215(e) of the Federal Power Act.

■ 3. Section 375.311 is amended by adding paragraphs (u) and (v) as follows:

§ 375.311 Delegations to the Director of the Office of Enforcement.

* * * * *

(u) Direct the Electric Reliability Organization or the applicable Regional Entity to provide such information as is necessary to implement Section 215(e)(2) of the Federal Power Act (16 U.S.C. 824o(e)(2)) pursuant to § 39.2 and Part 40 of this chapter.

(v) Issue an order extending the period of time for consideration of a Notice of Penalty filed under Section 215(e) of the Federal Power Act for the purpose of directing the Electric Reliability Organization or the applicable Regional Entity to provide such information as is necessary to implement Section 215(e)(2) of the Federal Power Act (16 U.S.C. 824o(e)(2)) pursuant to § 39.2 and Part 40 of this chapter.

[FR Doc. E9–26635 Filed 11–4–09; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2007–C–0044] (formerly Docket No. 2007C–0474)

Listing of Color Additives Exempt From Certification; Astaxanthin Dimethyldisuccinate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of astaxanthin dimethyldisuccinate as a color additive in the feed of salmonid fish to enhance the color of their flesh. This action is in response to a petition filed by DSM Nutritional Products, Inc.

DATES: This rule is effective December 8, 2009, except as to any provisions that may be stayed by the filing of proper objections. Submit electronic or written objections and requests for a hearing by December 7, 2009. See section X of this document for information on the filing of objections.

---

[4] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987).

[5] 18 CFR 380.4(1) and (5).

[6] 5 U.S.C. 601–612.

ADDRESSES: You may submit electronic or written objections and requests for a hearing, identified by Docket No. FDA–2007–C–0044, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal, as described previously in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Felicia M. Ellison, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1264.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of December 4, 2007 (72 FR 68166), with a correction of the docket number on December 26, 2007 (72 FR 73028), FDA announced that a color additive petition (CAP 7C0284) had been filed by DSM Nutritional Products, Inc., 45 Waterview Blvd., Parsippany, NJ 07054. The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73) to provide for the safe use of astaxanthin dimethyldisuccinate (hereinafter referred to as astaxanthin DMDS) as a color additive in the feed of salmonid fish to enhance the color of their flesh.

II. Identity, Technical Effect, and Specifications

Astaxanthin DMDS (3,3′-bis(4-methoxy-1,4-dioxobutoxy)-β,β-carotene-4,4′-dione) is a synthetic carotenoid with pink or red pigmenting properties. Astaxanthin DMDS is derived by esterification of astaxanthin, the principal pigment that imparts the characteristic pink or orange-red coloring of the flesh of wild salmonids, followed by several purification steps. The color additive contains not less than 96 percent astaxanthin DMDS, including trans, 9-cis, and 13-cis isomers, and minor amounts of astaxanthin monomethylsuccinate (MMS) and free astaxanthin. Other carotenoids (present at not more than 4 percent) are the esters of astaxanthin-related substances.

The stability studies of astaxanthin DMDS submitted by the petitioner show that astaxanthin DMDS is unstable on its own. Therefore, in order to minimize chemical changes that would result in loss of color of astaxanthin, astaxanthin DMDS may be added to fish feed only in the form of a stabilized color additive mixture. This requirement is reflected in new § 73.37(a)(2), which provides that astaxanthin DMDS be added to fish feed only as a component of a stabilized color additive mixture.

In the **Federal Register** of April 13, 1995 (60 FR 18736), the agency published a final rule that listed astaxanthin in § 73.35 for use in the feed of salmonid fish. In that final rule, the agency concluded that 80 milligrams (mg) of astaxanthin per (/) kilogram (kg) of finished feed would result in adequate pigmentation of the flesh of salmonids. Therefore, in § 73.35(c)(2), the agency limited the astaxanthin content of finished feed to not more than 80 mg/kg. In the **Federal Register** of July 6, 2000 (65 FR 41581 and 41584), the agency published final rules that listed haematococcus algae meal (§ 73.185) and phaffia yeast (§ 73.355) as additional sources of astaxanthin for use in the feed of salmonid fish. Both haematococcus algae meal and phaffia yeast may be used alone or in combination with other astaxanthin color additive sources, provided that the quantity of astaxanthin in the finished feed does not exceed 80 mg/kg.

Consistent with these other listings, the petitioner proposes that the maximum amount of astaxanthin in finished feed from the use of astaxanthin DMDS not exceed 110 mg/kg, which corresponds to an astaxanthin equivalent of 80 mg/kg (72 grams (g) per ton) in the finished feed. Because of the other listed sources of astaxanthin and other color additives that are sources of astaxanthin the agency may list in the future, new § 73.37(c)(2) requires that the quantity of astaxanthin in finished feed, from astaxanthin DMDS when used alone or in combination with other astaxanthin color additive sources listed in part 73, shall not exceed 80 mg/kg (72 g per ton) of finished feed.

III. Evaluation of Safety

Data provided by the petitioner demonstrate that the color additive is safe for the fish at the proposed use levels, and that astaxanthin DMDS is converted to free astaxanthin during digestion and deposited as such in the flesh of the fish. There also is no evidence that any constituents of the color additive, other than astaxanthin, will accumulate in fish maintained on diets supplemented with astaxanthin DMDS. Consequently, consumers will not be directly exposed to astaxanthin DMDS, but to the astaxanthin in the flesh of the fish that have consumed the color additive. The safety of astaxanthin has been previously established (see 65 FR 41581 and 41584).

FDA has determined that the astaxanthin from the subject color additive will substitute for the fish feed uses of other approved color additive sources of astaxanthin. Additionally, the agency considers the intake of astaxanthin from the consumption of wild salmon and the intake of astaxanthin from consumption of farm-raised salmonid fish that have been fed approved color additive sources of astaxanthin to be comparable. Therefore, the agency concludes that the petitioned use of the subject color additive will not increase the current cumulative estimated daily intake of astaxanthin. Based on this information, as well as other relevant material provided by the petitioner, FDA concludes that the petitioned use of astaxanthin DMDS is safe.

IV. Labeling Requirements

All color additives, in accordance with § 70.25 (21 CFR 70.25), are required to be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by the agency in other applicable regulations. The labeling of the color additive,

astaxanthin DMDS, and any mixture prepared therefrom, is subject to the requirements of § 70.25.

According to § 70.25(a)(4), an expiration date for a color additive must be stated on its label if stability data require it. FDA finds that because of the instability of astaxanthin DMDS, expiration dates must be stated on the label of the sealed and open containers, in accordance with § 70.25(a)(4). FDA also finds that declaration of the expiration dates constitutes a material fact that must be disclosed on the label of the stabilized mixture formulated with astaxanthin DMDS because under sections 201(n) and 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(n) and 343(a)(1)), failure to do so would constitute a failure to reveal facts material in light of the representations made on the label and material with respect to consequences which may result from the use of the color additive. The use of astaxanthin DMDS requires the declaration of expiration dates because the astaxanthin component of astaxanthin DMDS is unstable and can decompose, thereby affecting the efficacy of the color.

In addition to the requirements for labeling the color additive or color additive mixture, the ingredient list on fish feed to which astaxanthin DMDS is added must identify the presence of the color additive under § 501.4 (21 CFR 501.4). New § 73.37(d)(2) references § 501.4 to ensure that the presence of astaxanthin DMDS as a color additive in the fish feed will be declared on the ingredient label. Finally, the presence of the color additive must be declared on the label of any food, including salmonid fish given feed containing astaxanthin DMDS and food containing such salmonid fish as an ingredient. Section 101.22(b) (21 CFR 101.22(b)) requires a food that bears or contains artificial coloring, such as salmon artificially colored with a source of astaxanthin, to bear labeling even though such food is not in package form. Section 101.22(c) requires that label statements of artificial coloring be ''likely to be read by the ordinary person under customary conditions of purchase and use of such food.''

Furthermore, § 101.22(k)(2) requires, in the statement of ingredients for a food to which any coloring has been added, and for which the coloring is not subject to certification, a declaration that makes it clear that a color additive has been used in the food. In addition, the presence of a color additive in a food received in a bulk container that is held at a retail establishment must be declared on the labeling of the bulk container or on a counter card or other similar device under the provisions in § 101.100(a)(2) (21 CFR 101.100(a)(2)). The ingredient label would alert the consumer that the fish is artificially colored. Without such ingredient labeling, food containing salmonid fish previously given feed containing astaxanthin DMDS would be deemed to be misbranded under section 403(k) of the act, which states that a food shall be deemed to be misbranded ''if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact.''

Therefore, in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2), labeling on any salmonid fish given feed containing astaxanthin DMDS is required to declare the presence of the color additive. New § 73.37(d)(3) references §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) to ensure that, at the retail level, the presence of a source of astaxanthin as a color additive in the fish will be declared, and that the labeling of the bulk fish container, including a list of ingredients, will be displayed on the container or on a counter card with similar information.

V. Conclusion

FDA reviewed data in the petition and other available relevant material to evaluate the safety of the use of astaxanthin DMDS as a color additive in the feed of salmonid fish to enhance the color of their flesh. Based on this information, the agency concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect. Therefore, the regulations in part 73 should be amended as set forth in this document. In addition, based upon the factors listed in 21 CFR 71.20(b), the agency concludes that certification of astaxanthin DMDS is not necessary for the protection of the public health.

VI. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for CAP 7C0284 (72 FR 68166 and 72 FR 73028). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

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 (44 U.S.C. 3501–3520) is not required.

IX. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

FDA's review of this petition was limited to section 721 of the act (21 U.S.C. 379e). This final rule is not a statement regarding compliance with other sections of the act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the act to, among other things, add section 301(ll). Section 301(ll) of the act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1)–(4) applies. In our review of this petition, FDA did not consider whether section 301(ll) of the act or any of its exemptions apply to food products containing this color additive. Accordingly, this final rule should not be construed to be a statement that a product containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the act. Furthermore, this language is included in all color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the act applies.

X. Objections

This rule is effective as shown in the **DATES** section of this document, except as to any provisions that may be stayed by the filing of proper objections. Any

person who will be adversely affected by this regulation may at any time file with the Division of Dockets Management (see **ADDRESSES**) electronic or written objections. 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 are to be submitted and are to 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. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Section 73.37 is added to subpart A to read as follows:

§ 73.37 Astaxanthin dimethyldisuccinate.

(a) *Identity.* (1) The color additive astaxanthin dimethyldisuccinate is 3,3′-bis(4-methoxy-1,4-dioxobutoxy)-β,β-carotene–4,4′-dione.

(2) Astaxanthin dimethyldisuccinate may be added to the fish feed only as a component of a stabilized mixture. Color additive mixtures for fish feed use made with astaxanthin dimethyldisuccinate may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Astaxanthin dimethyldisuccinate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

(1) Physical state, solid.

(2) 0.05 percent solution in chloroform, complete and clear.

(3) Absorption maximum wavelength 484–493 nanometers (in chloroform).

(4) Residue on ignition, not more than 0.1 percent.

(5) Total carotenoids other than astaxanthin dimethyldisuccinate, not more than 4 percent.

(6) Lead, not more than 5 milligrams per kilogram (mg/kg) (5 parts per million).

(7) Arsenic, not more than 2 mg/kg (2 parts per million).

(8) Mercury, not more than 1 mg/kg (1 part per million).

(9) Heavy metals, not more than 10 mg/kg (10 parts per million).

(10) Assay including astaxanthin dimethyldisuccinate, astaxanthin monomethylsuccinate, and astaxanthin, minimum 96 percent.

(c) *Uses and restrictions.* Astaxanthin dimethyldisuccinate may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin dimethyldisuccinate in the finished feed, when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 110 milligrams per kilogram (mg/kg), which is equivalent to 80 mg/kg astaxanthin (72 grams per ton).

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing astaxanthin dimethyldisuccinate shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Dated: October 21, 2009.

Leslye M. Fraser,

Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. E9–26524 Filed 11–04–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9465]

RIN 1545–BF71

Determination of Interest Expense Deduction of Foreign Corporations; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to final regulations (TD 9465) that were published in the **Federal Register** on Monday, September 28, 2009 (74 FR 49315) concerning the determination of the interest expense deduction of foreign corporations engaged in a trade or business within the United States. These final regulations conform the interest expense rules to recent U.S. Income Tax Treaty agreements and adopt other changes to improve compliance.

DATES: This correction is effective on November 5, 2009], and is applicable on September 28, 2009.

FOR FURTHER INFORMATION CONTACT: Anthony J. Marra, (202) 622–3870 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9465) that are the subject of this document are under sections 882 and 884 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9465) contain errors that may prove