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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2007–C–0456] (formerly Docket No. 2007–C–0245)

Listing of Color Additives Exempt From Certification; Paracoccus Pigment

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 paracoccus pigment 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 Nippon Oil Corp.

DATES: This rule is effective December 17, 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 16, 2009. See section X of this document for information on the filing of objections.

ADDRESSES: You may submit electronic or written objections and requests for a hearing identified by Docket No. FDA–2007–C–0456, 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 number 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: Mical E. Honigfort, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1278.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of July 9, 2007 (72 FR 37243), FDA announced that a color additive petition (CAP 7C0283) had been filed by Nippon Oil Corp., c/o Beckloff Associates, 7400 West 110th St. suite 300, Overland Park, KS 66210. The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73) to provide for the safe use of *Paracoccus carotinifaciens (P. carotinifaciens)* granules as a color additive in the feed of salmonid fish to enhance the color of their flesh. This color additive is commonly known as paracoccus pigment. Therefore, the agency is establishing paracoccus pigment as the common or usual name for this color additive.

II. Identity, Technical Effect, and Specifications

Paracoccus pigment consists of cells of the bacterium *P. carotinifaciens* that are produced by fermentation, and then killed by heat. The major components of the dried cells are proteins, carbohydrates, and lipids. The cells may be mixed with calcium carbonate added as necessary to yield a granular solid that contains at least 1.75 percent (weight/weight) astaxanthin and lesser amounts of other carotenoids as coloring agents. Calcium carbonate is added to adjust the astaxanthin content to the appropriate level in the final pigment. The primary coloring substance in paracoccus pigment is astaxanthin, which is typically present in the color additive at an average concentration of 2.18 percent, and represents approximately 51 percent of the total carotenoids present. The approximate levels of other carotenoids present in paracoccus pigment at lower levels that contribute to the color of the salmonid flesh are adonirubin (30 percent), canthaxanthin (10 percent), adonixanthin (4 percent), and asteroidenone (2 percent). When fed to salmonid fish, the petitioned use of paracoccus pigment results in deposition of very small amounts of carotenoids in the flesh of the fish. Studies included in the petition showed that paracoccus pigment at the intended level of use satisfactorily pigmented the flesh of the fish to levels comparable to that in wild salmonids.

In the **Federal Register** of April 13, 1995 (60 FR 18736), the agency published a final rule that listed astaxanthin in § 73.35 (21 CFR 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 salmonid fish. 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, the agency published final rules that listed haematococcus algae meal in § 73.185 (65 FR 41581) and phaffia yeast in § 73.355 (65 FR 41584) 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. Canthaxanthin also is listed for use as a color additive in salmonid fish feed with a limit of 80 mg/kg of finished feed (§ 73.75).

Consistent with these other listings, the petitioner proposes that the maximum amount of astaxanthin in finished feed from the use of paracoccus pigment not exceed 80 mg/kg and has requested that this level be specified in the listing regulation. 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 § 73.352(c)(2) requires that the quantity of astaxanthin in finished feed, from paracoccus pigment when used alone or in combination with other astaxanthin color additive sources listed in part 73, shall not exceed 80 mg/kg (72 grams per ton) of finished feed.

III. Evaluation of Safety

In evaluating the safety of the use of paracoccus pigment in fish feed, FDA considered the safety of the paracoccus pigment to humans and fish and the safety of the producing organism, *P. carotinifaciens*.

A. Safety of Paracoccus Pigment

Because consumers are not directly exposed to the paracoccus pigment, FDA focused its review on the safety of the carotenoids present in the pigment that are deposited in the fish. The agency considered the safety of astaxanthin and canthaxanthin, which are already approved for use in the feed of salmonid fish, as well as the safety of the other carotenoids in the pigment. Astaxanthin and canthaxanthin are two substances found in wild salmonids that are responsible for imparting the pink or red coloring to the flesh of these fish. The agency has determined that the astaxanthin and canthaxanthin from paracoccus pigment, which account for approximately 60 percent of the total carotenoids in paracoccus pigment, will substitute for the fish feed uses of other approved color additive sources of these carotenoids. Additionally, the agency considers the intake of astaxanthin and canthaxanthin from the consumption of wild salmon and the intake of astaxanthin and canthaxanthin from consumption of farm-raised salmonid fish that have been fed approved color additive sources of these carotenoids to be comparable. Therefore, the agency concludes that the petitioned use of paracoccus pigment will not increase the estimated daily intake of astaxanthin and canthaxanthin, and that these two carotenoids are safe as components of the paracoccus pigment in the feed of salmonid fish.

To support the safety of the petitioned use of the subject color additive, including the carotenoids adonirubin, adonixanthin, and asteroidenone, the petitioner provided data from studies in which sea bream and rainbow trout were fed feed containing paracoccus pigment at levels up to 5 percent in the feed. The studies did not reveal any toxicity to the target fish species. Therefore, FDA concludes that the petitioned use of paracoccus pigment is safe to salmonid fish. The petitioner also provided results from toxicity studies in which rats were fed paracoccus pigment. These studies did not reveal any adverse effects from exposure to paracoccus pigment. Importantly, consumers will not be directly exposed to paracoccus pigment, but to carotenoids remaining in the fish that have consumed the color additive in their diet. Therefore, based on the exposure estimates for the individual carotenoids, the results from the fish and rat toxicity studies and genetic toxicity tests, as well as previous safety determinations regarding the use of astaxanthin and canthaxanthin in salmonid fish feed, FDA concludes that there is a reasonable certainty of no harm to consumers from the petitioned use of paracoccus pigment.

B. Safety of the Producing Organism, P. carotinifaciens

FDA reviewed the pathogenicity, toxigenic potential, and antimicrobial activity of the producing organism, *P. carotinifaciens*. The heat treatment during production of paracoccus pigment ensures that no viable *P. carotinifaciens* cells will be in the final product and ensures that there is no pathogenic or toxigenic potential of *P. carotinifaciens* in the production of paracoccus pigment. In addition, as a condition of safe use, FDA is requiring that only a nonpathogenic and nontoxicogenic strain of the bacterium *P. carotinifaciens* be used in the production of paracoccus pigment. FDA also reviewed a study that provided evidence that the strain of *P. carotinifaciens* used to produce paracoccus pigment is not capable of producing antibiotics. Based on this information and the fact that consumers will not be directly exposed to paracoccus pigment, but to carotenoids remaining in the fish that have consumed the pigment, FDA concludes that the petitioned use of *P. carotinifaciens* in the production of paracoccus pigment 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, paracoccus pigment, 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 in paracoccus pigment, an expiration date must be stated on the label of sealed and open containers, in accordance with § 70.25(a)(4). FDA also finds that declaration of the expiration date constitutes a material fact that must be disclosed on the label of the color additive mixture under sections 201(n) and 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n) and 343(a)(1)). Failure to disclose the material fact on the label of the color additive mixture would constitute a failure to reveal facts that are: (1) Material in light of the representations made on the label and (2) material with respect to consequences which may result from the use of the color additive. The use of paracoccus pigment requires the declaration of expiration dates because astaxanthin in paracoccus pigment 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 paracoccus pigment is added, must identify the presence of the color additive under § 501.4 (21 CFR 501.4). New § 73.352(d)(2) references § 501.4 to ensure that the presence of paracoccus pigment 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, containing added paracoccus pigment 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 paracoccus pigment, to bear labeling even though such food is not in package form. Section 101.22(c) (21 CFR 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 comprising salmonid fish with added paracoccus pigment would be deemed to be misbranded under section 403(k) of the Federal Food, Drug, and Cosmetic 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 containing paracoccus pigment is required to declare the presence of the color additive or color additive mixture. New § 73.352(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 paracoccus pigment 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 paracoccus pigment 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 § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of paracoccus pigment 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 (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 7C0283 (72 FR 37243). 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 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) through (4) applies. In our review of this petition, FDA did not consider whether section 301(ll) or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll). Furthermore, this language is now included in all color additive final rules for food use and therefore should not be construed to be a statement of the likelihood that section 301(ll) 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 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, 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 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 73.352 is added to subpart A to read as follows:

§ 73.352 Paracoccus pigment.

(a) *Identity.* (1) The color additive paracoccus pigment consists of the heat-killed, dried cells of a nonpathogenic and nontoxicogenic strain of the bacterium *Paracoccus carotinifaciens* and may contain added calcium carbonate to adjust the astaxanthin level.

(2) Color additive mixtures for fish feed use made with paracoccus pigment 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.* Paracoccus pigment 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) Lead, not more than 5 milligrams per kilogram (mg/kg) (5 parts per million (ppm)).

(3) Arsenic, not more than 2 mg/kg (2 ppm).

(4) Mercury, not more than 1 mg/kg (1 ppm).

(5) Heavy metals (as Pb), not more than 10 mg/kg (10 ppm).

(6) Astaxanthin, not less than 1.75 percent.

(c) *Uses and restrictions.* Paracoccus pigment 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 in finished feed, from paracoccus pigment when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 mg/kg (72 grams per ton) of finished feed.

(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 paracoccus pigment 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: November 5, 2009.

Leslye M. Fraser,

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

[FR Doc. E9–27394 Filed 11–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 239

[DOD–2009–OS–0090]

RIN 0790–AI58

Homeowners Assistance Program—Application Processing

AGENCY: Under Secretary of Defense for Acquisition, Technology, and Logistics, Office of the Deputy Under Secretary of Defense (Installations and Environment), DoD.

ACTION: Interim final rule; extension of comment period.

SUMMARY: On September 30, 2009, DoD published an interim final rule implementing the Homeowners Assistance Program (HAP), with an effective date of September 30, 2009 (74 FR 50109–50115). This notice is being published to invite additional public comment on the interim final rule. Any timely public comments received will be considered and any changes to the final rule will be published in the **Federal Register.** The public comment period is being extended for 60 days.

DATES: The effective date of the HAP interim final rule remains September 30, 2009. Additional comments must be received on or before January 15, 2010.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by either of the following methods:

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

Mail: Federal Docket Management System Office, 1160 Defense Pentagon, Room 3C843, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Deanna Buchner, (703) 602–4353.

Dated: November 9, 2009.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E9–27373 Filed 11–13–09; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Marine Corps Base Hawaii, Kaneohe Bay, Island of Oahu, HI

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The U.S. Army Corps of Engineers is amending the regulations at 33 CFR 334.1380 for the existing danger zone in the vicinity of Kaneohe Bay, Hawaii. The amendment reflects the current operational and safety procedures at the Ulupau Crater Weapons Training Range and highlights a change in the hours that weapons firing may occur. The amendment also expands the boundaries of the existing danger zone. These regulations are necessary to protect the public from potentially hazardous conditions which may exist as a result from use of the areas by the United States Marine Corps.

DATES: *Effective date:* December 16, 2009.

FOR FURTHER INFORMATION CONTACT: Mr. David B. Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922 or by e-mail at *david.b.olson@usace.army.mil*, or Ms. Susan A. Meyer, Corps of Engineers, Honolulu District, Regulatory Branch, at 808–438–2137 or by e-mail at *susan.a.meyer@usace.army.mil.*

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps is amending the danger zone regulations at