DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 284

[Docket No. RM98–10–000]

Regulation of Short-Term Natural Gas Transportation Services, and Regulation of Interstate Natural Gas Transportation Services

June 29, 2000.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final Rule, Notice of Availability of Instruction Manual for Electronic Filing of the Index of Customers.

SUMMARY: On February 9, 2000, the Federal Energy Regulatory Commission issued a final rule in this proceeding adding new information requirements to the Index of Customers to be filed by natural gas companies with the Commission, and posted on the companies' Internet web sites on the first business day of each calendar quarter. This notice announces the availability of the revised Instruction Manual for Electronic Filing of the Index of Customers in the Commission's Public Reference Room and electronically on the Commission's Internet web page.

DATES: Natural gas companies must implement the new reporting requirements by September 1, 2000.

ADDRESSES: Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT:

Michael Goldenberg, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 208–2294.

Craig Hill, Office of Markets, Tariffs and Rates, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 208–0621.

SUPPLEMENTARY INFORMATION: On February 9, 2000, the Federal Energy Regulatory Commission (Commission) issued Order No. 637 amending its regulations in response to the development of more competitive markets for natural gas and the transportation of natural gas.[1] These changes included expanding reporting requirements for the Index of Customers in order to provide shippers with a more useful picture of the structure of the market for decisionmaking and monitoring purposes.

The Commission added the following new reporting requirements to the Index of Customers data collection: the receipt and delivery points held under the contract and the zones or segments in which the capacity is held; the common transaction point codes; the contract number; a shipper identification number, such as DUNS; an indication whether the contract includes negotiated rates; the names of any agents or asset managers that control capacity in a pipeline rate zone; and any affiliate relationship between the pipeline and the holder of capacity.[2]

The Commission issues an Instruction Manual for Electronic Filing of the Index of Customers explaining how pipelines are to report Index of Customer data. This Manual has been revised to incorporate the new reporting requirements.

The revised Instruction Manual for Electronic Filing of the Index of Customers is attached to this notice as an Appendix.[3] The revised manual can be found at the following electronic address: *http://www.ferc.fed.us/public/elec req.htm.* The manual also is available in the Commission's Public Reference Room and on CIPS and RIMs. As indicated in Order No. 637, pipelines are required to implement these new reporting requirements by September 1, 2000.

David P. Boergers,

Secretary.

[FR Doc. 00–16997 Filed 7–5–00; 8:45 am]

BILLING CODE 6717–01–M

[1] 65 FR 10156 (Feb. 25, 2000); III FERC Stats. & Regs. ¶ 31,091 (Feb. 9, 2000).

[2] 18 CFR 284.13(c).

[3] The Revised Instruction Manual (Appendix A) and a summary of the new reporting requirements for the Index of Customers and the revisions to the IOC electronic filing instruction manual (Appendix B) attached to this notice will not be published in the **Federal Register.**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 98C–0212]

Listing of Color Additives Exempt From Certification; Haematococcus Algae Meal

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 haematococcus algae meal 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 Cyanotech Corp.

DATES: This rule is effective August 8, 2000; except as to any provisions that may be stayed by the filing of proper objections. Submit written objections and requests for a hearing by August 7, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Aydin Orstan, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of April 16, 1998 (63 FR 18920), FDA announced that a color additive petition (CAP 8C0256) had been filed by Cyanotech Corp., <73–4460 Queen Kaahumanu Hwy., #102, Kailua-Kona, HI 96740. The petition proposed to amend the color additive regulations to provide for the safe use of haematococcus algae meal as a color additive in salmonid fish feeds.

II. Identity, Technical Effect, and Specifications

Haematococcus algae meal consists of the comminuted and dried cells of the alga *Haematococcus pluvialis* (also known as *H. lacustris*). The major components of haematococcus algae meal are proteins, carbohydrates, and lipids produced by the alga cells. The primary coloring substance in haematococcus algae meal is astaxanthin (3,3′-dihydroxy-β,β-carotene-4,4′-dione), which exists

primarily in esterified forms (Ref. 1). One published (Ref. 2) and several unpublished studies included in the petition showed that haematococcus algae meal satisfactorily pigmented the flesh of the fish when it was fed to salmonid fish.

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 (hereinafter referred to as the April 1995 final rule). In the preamble to that rule, the agency stated that the new regulation for astaxanthin did not specify the source of astaxanthin or the manufacturing process, because the agency had made its safety determination based on the chemical similarity of synthetic astaxanthin to astaxanthin from natural sources. The agency concluded that any source could be used to produce the color additive as long as the astaxanthin meets the identity, specifications, and stability requirements defined in § 73.35, and it is manufactured in accordance with good manufacturing practice. Furthermore, the agency stated in the astaxanthin rule that the specifications were listed to convey the fact that FDA had evaluated only a particular form of the color additive. The agency also stated that it was concerned that deleterious materials not found in the habitat of salmonids may be included in fish feed from biomass products that contain only a small amount of astaxanthin with the rest of the material being residues from the producing organisms. Thus, the agency said that interested parties should submit information in the form of a new color additive petition if they wish to market a biomass product containing astaxanthin.

Haematococcus algae meal is a biomass product that contains a relatively small amount of astaxanthin with the rest of the material being proteins, carbohydrates, and lipids. In addition, the agency determined that haematococcus algae meal would not meet the specifications in § 73.35(b) for solubility in chloroform, absorption maximum wavelength, and residue on ignition, because some of the algal components in haematococcus algae meal would interfere with the test methods. Furthermore, the petitioner specified the astaxanthin content of haematococcus algae meal to be not less than 1.5 percent, whereas the corresponding specification for astaxanthin in § 73.35(b) is not less than 96 percent. Therefore, the agency concludes that a new regulation is necessary to list haematococcus algae meal.

In the April 1995 final rule, the agency concluded that 80 milligrams per kilogram (mg/kg) of astaxanthin in fish 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. However, the agency now notes that astaxanthin in the feed of farm-raised salmonid fish may come not only from the color additive astaxanthin meeting the specifications of § 73.35, but also from the color additive haematococcus algae meal and other color additives that are sources of astaxanthin the agency may list in the future. Therefore, new § 73.185(c)(2) requires that the quantity of astaxanthin in finished feed, from haematococcus algae meal when used alone or in combination with other astaxanthin color additive sources listed in part 73 (21 CFR part 73), shall not exceed 80 mg/kg (72 grams per ton) of finished feed.

III. Safety Evaluation

In evaluating the safety of the use of haematococcus algae meal in fish feed, the agency considered: (1) The safety of astaxanthin in haematococcus algae meal to humans and fish; and (2) the safety of the other components in haematococcus algae meal to humans and fish.

A. Safety of Astaxanthin

Astaxanthin is the principal pigment that imparts the pink or red coloring characteristic of the flesh of wild salmonids. These fish obtain astaxanthin from the crustaceans that constitute a significant portion of their diet (Ref. 3). A similar flesh color may be obtained in aquacultured salmonids by feeding them a diet supplemented with astaxanthin. In the April 1995 final rule, the agency concluded that astaxanthin was safe for use in the feed of salmonid fish. This conclusion was based on the following facts: (1) The petitioned use of astaxanthin would result in deposition of a very small amount of astaxanthin in salmonid flesh; (2) astaxanthin that was the subject of the April 1995 final rule, differed from astaxanthin present in the flesh of wild salmon only in its optical isomeric distribution; (3) human exposure to astaxanthin from consumption of aquacultured salmon fed synthetic astaxanthin is comparable to the exposure to astaxanthin from wild salmon. In addition, the results of the toxicity studies submitted by the petitioner supported the conclusion that there was reasonable certainty of no harm from the petitioned use of astaxanthin.

The facts upon which the agency concluded, in the April 1995 final rule, that astaxanthin was safe for use in the feed of salmonid fish, are similar to the facts upon which the agency is basing its conclusion that astaxanthin from the petitioned use of haematococcus algae meal is safe for use in the feed of salmonid fish. During the review of the present petition, the agency determined that in both crustaceans and *H. pluvialis*, astaxanthin is mainly in esterified forms that are converted to free astaxanthin during digestion and deposited as such in fish flesh (Ref. 4). The agency also determined that free astaxanthin from *H. pluvialis* differed from astaxanthin present in the flesh of wild salmon only in its optical isomeric distribution and that the petitioned use of astaxanthin would result in deposition of a very small amount of astaxanthin in salmonid flesh. Furthermore, the agency determined that the astaxanthin from haematococcus algae meal will substitute for the fish feed uses of astaxanthin listed in § 73.35, and that the petitioned use of haematococcus algae meal will not increase the estimated daily intake of astaxanthin in humans, which is comparable to the exposure to astaxanthin from wild salmon. Therefore, the agency concludes that astaxanthin from the petitioned use of haematococcus algae meal is safe for use in the feed of salmonid fish.

B. Safety of the Producing Organism

Based on the data in the petition and other relevant material, the agency determined that: (1) Consumers will not be directly exposed to haematococcus algae meal, but to astaxanthin remaining in fish that have consumed the yeast in their diet; (2) there is no evidence that any constituents other than astaxanthin will accumulate in fish maintained on diets supplemented with haematococcus algae meal; (3) the results of studies during which rats and salmon were fed haematococcus algae meal and bacterial mutagenicity tests did not reveal any adverse effects, indicating the absence of toxic impurities in the algae; (4) a literature search uncovered no reports of pathogenicity or toxicogenicity of *H. pluvialis*; and (5) algae are commonly used as feed components in fish aquaculture with no deleterious effects on fish health. Based on this information, FDA concludes that the petitioned use of haematococcus algae meal is safe (Ref. 5).

IV. Stability of Astaxanthin in Haematococcus Algae Meal

Based on the results of stability studies of haematococcus algae meal submitted by the petitioner, FDA concludes that to minimize chemical changes that would result in loss of color of astaxanthin, haematococcus algae meal must be added to fish feed only in the form of a stabilized color additive mixture. Therefore, new § 73.185(a)(2) requires that haematococcus algae meal be added to fish feed only as a component of a stabilized color additive mixture.

V. Labeling Requirements

All color additives, in accordance with § 70.25 (21 CFR 70.25), require 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. Therefore, the labeling of the color additive, haematococcus algae meal, 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 haematococcus algae meal, 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 act (21 U.S.C. 321(n) and 343(a)(1)) because 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 that may result from the use of the color additive. The use of haematococcus algae meal requires the declaration of expiration dates because astaxanthin in haematococcus algae meal can decompose to products that would not be coloring agents and thus would not affect the color of salmonid flesh.

In addition to the requirements for labeling the color additive or color additive mixture, the ingredient list on fish feed, to which haematococcus algae meal is added, must identify the presence of the color additive under § 501.4 (21 CFR 501.4). New § 73.185(d)(2) references § 501.4 to ensure that the presence of haematococcus algae meal 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 haematococcus algae meal 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 haematococcus algae meal, 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 must be declared on any bulk container of food containing a color additive that is held at a retail establishment under the provisions in § 101.100(a)(2) (21 CFR 101.100(a)(2)). The ingredient label would prevent economic fraud in salmonid fish containing added haematococcus algae meal because the ingredient label would notify the consumer that the fish is artificially colored. Without such ingredient labeling, food comprising salmonid fish with added haematococcus algae meal 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 containing haematococcus algae meal is required to declare the presence of the color additive or color additive mixture. New § 73.185(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 haematococcus algae meal 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.

In the future, the agency also intends to propose to amend § 73.35(d)(3) to include references to § 101.22(b) and (c).

VI. Conclusion

Based on the data in the petition and other relevant material, FDA concludes that the petitioned use of haematococcus algae meal as a color additive in fish feed to color the flesh of salmonid fish is safe, the additive will achieve its intended technical effect, and therefore, part 73 should be amended as set forth below. In addition, based upon the factors listed in 21 CFR 71.20(b), the agency concludes that certification of haematococcus algae meal is not necessary for the protection of the public health.

VII. Inspection of Documents

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 are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. 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.

VIII. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for CAP 8C0256. 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.

IX. Paperwork Reduction Act of 1995

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

X. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by August 7, 2000. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

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

1. Renstrom, B., G. Borch, O. M. Skulberg, and S. Liaaen-Jensen, ''Optical Purity of (3S,3′S)-Astaxanthin from *Haematococcus pluvialis*,'' *Phytochemistry*, 20:2561–2564, 1981.

2. Sommer, T. R., W. T. Potts, and N. M. Morrissy, ''Utilization of Microalgal Astaxanthin by Rainbow Trout (*Oncorhynchus mykiss*),'' *Aquaculture*, 94:79–88, 1991.

3. Kitahara, T., ''Carotenoids in the Pacific Salmon During the Marine Period,'' *Comprehensive Biochemistry and Physiology*, 78B:859–862, 1984.

4. Mori, T., K. Makabe, K. Yamaguchi, S. Konosu, and S. Arai, ''Comparison Between Krill Astaxanthin Diester and Synthesized Free Astaxanthin Supplemented to Diets in Their Absorption and Deposition by Juvenile Coho Salmon (*Oncorhynchus kisutch*),'' *Comprehensive Biochemistry and Physiology*, 93B:255–258, 1989.

5. Johnson, C. B., Memorandum entitled ''*Haematococcus pluvialis* Algae Meal for Use in Feed for Salmonids: Final Toxicology Review'' from the Division of Health Effects Evaluation (HFS–225) to the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, FDA, August 12, 1999.

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, 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 73.185 is added to subpart A to read as follows:

§ 73.185 Haematococcus algae meal.

(a) *Identity.* (1) The color additive haematococcus algae meal consists of the comminuted and dried cells of the alga *Haematococcus pluvialis*.

(2) Haematococcus algae meal may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with haematococcus algae meal 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.* Haematococcus algae meal 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:

Physical state, solid.

Lead, not more than 5 parts per million.

Arsenic, not more than 2 parts per million.

Mercury, not more than 1 part per million.

Heavy metals (as Pb), not more than 10 parts per million.

Astaxanthin, not less than 1.5 percent.

(c) *Uses and restrictions.* Haematococcus algae meal 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 haematococcus algae meal when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 milligrams per kilogram (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 haematococcus algae meal 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: June 27, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–17018 Filed 7–5–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 97C–0466]

Listing of Color Additives Exempt From Certification; Phaffia Yeast

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 phaffia yeast 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 Archer Daniels Midland Co.

DATES: This rule is effective August 8, 2000; except as to any provisions that may be stayed by the filing of proper objections. Submit written objections and requests for a hearing by August 7, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aydin Orstan, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of November 19, 1997 (62 FR 61823), FDA announced that a color additive petition (CAP 8C0252) had been filed by Archer Daniels Midland Co., P.O. Box 1470, Decatur, IL 62525. The petition proposed to amend the color additive regulations to provide for the safe use of astaxanthin from *Phaffia*