The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) modifies Class E airspace at Leesburg, FL, to accommodate a NDB RWY 31 SIAP and for IFR operations at the Leesburg Municipal Airport.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet above the surface of the earth.

* * * * *

ASO FL E5 Leesburg, FL [Revised]

Leesburg Municipal Airport
(Lat. 28°49′22″ N, long. 81°48′33″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Leesburg Municipal Airport.

* * * * *

Issued in College Park, Georgia, on October 20, 1995.

Benny L. McGlamery,

Acting Manager, Air Traffic Division, South Region.

[FR Doc. 95–26988 Filed 10–31–95; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 87C–0316]

Listing of Color Additives Exempt From Certification; Astaxanthin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objection and denial of the request for a hearing; removal of stay for certain provisions.

SUMMARY: The Food and Drug Administration (FDA) is responding to an objection and is denying the request that it has received for a hearing on the final rule that amended the color additive regulations to authorize the use of astaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh. The objection concerns a specification and the requirement for labeling of salmonid fish that have been fed feeds that contain the color additive. After reviewing the objection to the final rule, the agency has concluded that the objection does not raise issues of material fact that justify granting a hearing. The agency also is establishing a new effective date for these two provisions of this color additive regulation, which were stayed by a document that published on August 14, 1995.

EFFECTIVE DATE: 21 CFR 73.35(b) and (d)(3), previously stayed (60 FR 41805, August 14, 1995) because of an objection regarding a specification and a labeling requirement, respectively, are effective November 1, 1995.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3078.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the Federal Register of April 13, 1995 (60 FR 18736), FDA issued a final rule permitting the use of astaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh. This regulation, codified at 21 CFR 73.35, was issued in response to a color additive petition filed by Hoffmann-La Roche, Inc., in the Federal Register of December 2, 1987 (52 FR 45867). In the preamble to the final rule, FDA discussed the safety basis for the agency's decision to list this use of astaxanthin and responded to 21 letters containing comments to the petition.

II. Objections and Requests for a Hearing

A manufacturer filed a timely objection to two provisions of the regulation and requested a formal evidentiary hearing on the issues raised in its objection. The manufacturer sought to amend the specifications for astaxanthin, specifically requesting that the 4 percent specification for carotenoids other than astaxanthin be changed to 40 percent. The manufacturer also sought to amend the labeling requirements for astaxanthin by removal of the requirement to label the presence of the color additive, in accordance with §§ 101.22(k)(2) and 101.100(a)(2) (21 CFR 101.22(k)(2) and 101.100(a)(2)), in salmonid fish that were fed feeds containing astaxanthin. The agency announced the stay of the two affected paragraphs of the regulation, namely § 75.73(b) and (d)(3), in the Federal Register of August 14, 1995 (60 FR 41805). In that document the agency confirmed the effective date of May 16, 1995, for the remainder of the regulation.

III. Standards for Granting a Hearing

Sections 701(e)(2) and 721(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2) and 379e(d)) provide that, within 30 days after publication of an order relating to a color additive regulation, any person adversely affected by such an order may file objections, specifying with particularity the provisions of the order ''deemed objectionable, stating the grounds therefor,'' and requesting a public hearing based upon such objections. FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing *Community Nutrition Institute* v. *Young,* 773 F.2d 1356, 1364 (D.C. Cir. 1985), *cert. denied*, 475 U.S. 1123 (1986).

Specific criteria for determining whether a request for a hearing is justified are set forth in § 12.24(b) (21 CFR 12.24(b)). A hearing will be granted if the material submitted by the requester shows that:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought, * * *.

(5) The action requested is not inconsistent with any provision in the act or any regulation particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) The requirements in other applicable regulations, e.g., 21 CFR 10.20, 12.21, 12.22, 314.200, 314.300, 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for a hearing are met.

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing.'' *Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980) *reh. den.*, 445 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test. *Georgia Pacific Corp.* v. *U.S. E.P.A.*, 671 F.2d 1235, 1241 (9th Cir. 1982). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute, and a party is entitled to judgment as a matter of law. See Rule 56, *Federal Rules of Civil Procedure*. The same principle applies in administrative proceedings.

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held. *Pineapple Growers Association* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing. *Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959) *cert. denied*, 362 U.S. 911 (1960). FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information. See *United States* v. *Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971). In other words, a hearing is justified only if the objections are made in good faith and if they ''draw in question in a material way the underpinnings of the regulation at issue.'' *Pactra Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. See *Citizens for Allegan County, Inc.* v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958).

In sum, a hearing request should present sufficient credible evidence to raise a material issue of fact, and the evidence must be adequate to resolve the issue as requested and to justify the action requested.

IV. Analysis of Objections and Response to Hearing Requests

In its objection, the manufacturing company raised two specific issues concerning the agency's final rule for astaxanthin and requested hearings on each issue raised by the objection. In the preamble to the final rule (60 FR 18736), the agency specifically addressed each of the issues raised by this company.

The company's first objection is to the specification in the final rule for total carotenoids other than astaxanthin of 4 percent. The company stated that this particular specification is not necessary or appropriate to assure the identity or the safe use of astaxanthin, and that it is unreasonable when applied to astaxanthin made from natural sources such as the yeast *Phaffia rhodozyma*, krill, or crayfish shells. The company stated that at the hearing it would show that a specification of 40 percent or more for total carotenoids other than astaxanthin would be appropriate.

FDA is denying the company's request for a hearing on this objection under § 12.24(b)(5), in that the request is inconsistent with the act and FDA's regulations. Under section 721(d) of the act, a proceeding for the issuance of a color additive regulation is instituted by the filing of a petition. The petition that led to the issuance of § 73.35 (21 CFR 73.35) sought a specification for total carotenoids other that astaxanthin of 4 percent. FDA granted that aspect of the petition.

Under section 701(e)(2) of the act, a person who will be adversely affected by the agency's action on the petition may object thereto. However, there is nothing in the act or in FDA's regulations that suggests or implies that, or that authorizes, interested persons to use the opportunity to object as an opportunity to expand the authorized use beyond those sought in the petition. On the contrary, 21 CFR 70.19(i) requires that a request for an amendment of a color additive listing regulation be accompanied by a deposit of $1,800.00.

Thus, under the act and FDA's regulations, the scope of a proceeding for the listing of a color additive is limited to the terms and conditions of use set out in the petition. To the extent that a person seeks to extend the petitioned-for terms and conditions of use, the person must do so by separate petition, not by objection to the final rule. To attempt to do so by objection (or by comment on the notice of filing) is to attempt to act in a manner that is inconsistent with the act and FDA's regulations. Therefore, FDA is denying a hearing on this issue. The proper procedure, as stated in § 12.24(b)(5), is for the company to petition for amendment of § 73.35.

The company's second objection is to the requirement that the presence of the color additive be declared on the labels of salmonid fish that have been fed feeds containing the astaxanthin color additive. In support of its objection, the company states that the labeling requirement would be misleading and would place fish farming operations at an unfair disadvantage when competing with the produce of ocean or river fishing. The company contends that every salmon with pink flesh has eaten in its diet foods containing astaxanthin. The company also contends that both types of salmon, whether grown in aquaculture or harvested from the ocean, contain astaxanthin that colors their flesh pink. Thus, the company asserts that the FDA-required astaxanthin labeling of aquacultured fish containing astaxanthin will mislead the public into believing that these two types of fish are different, and that salmon from aquaculture contain a substance not present in normal salmon.

FDA is denying a hearing on this issue for two reasons. First, under its regulations, FDA will not grant a hearing on the basis of mere allegations (§ 12.24(b)(2)). Consistent with this regulation, the relevant case law provides that where a party requesting a hearing only offers allegations without

an adequate proffer to support them, the agency may properly disregard those allegations. *General Motors Corp.* v. *FERC*, 656 F.2d 791, 798 n.20 (D.C. Cir. 1981). The company failed to submit any evidence to support its assertion that requiring the label of salmonid fish fed feeds that contain astaxanthin to declare that color has been added will mislead the public or will cause consumers to believe that fish so labeled are somehow different from other fish. Thus, because it has not proffered support for its allegation, the company has not justified a hearing on this issue.

Second, under § 12.24(b)(4), this assertion would not justify a hearing even if the company had made a proper proffer because declaration of the color additive is required as a matter of law on the label of fish that have been colored with it. Under § 101.22(k), the label of a food to which any coloring has been added shall declare the presence of the coloring in the statement of ingredients. Section 101.22(k) incorporates the provisions of section 403(k) of the act (21 U.S.C. 343(k)) into FDA's regulations.

Under § 101.22(a)(4), a coloring is any ''color additive'' as defined in § 70.3(f) (21 CFR 70.3(f)). Under § 70.3(f), a legislative regulation that was adopted after notice and comment rulemaking (28 FR 6439, June 22, 1963), ''color additive'' includes an ingredient of an animal feed whose intended function is to impart, through the biological processes of the animal, a color to the meat, milk, or eggs of the animal. Thus, as matter of law, astaxanthin is a color additive whose presence in salmonid fish that have been fed feeds that contain this color additive must be declared in the label or labeling of the fish. (Sections 101.22(k)(2) and 101.100(a)(2) of FDA's regulations describe how this declaration is to be made). On this basis, FDA concludes that this objection has no legal merit and does not justify a hearing.

V. Summary and Conclusion

The agency is denying the objection and the request for a hearing on the following: (1) The specification for carotenoid content of astaxanthin under § 73.35(b) on the basis that the request is beyond the scope of the petitioned action for astaxanthin and is appropriately resolved through the submission of a petition (§ 12.24(b)(5)); and (2) the labeling requirement for astaxanthin under § 73.35(d)(3) on the basis that a hearing will not be granted based on mere allegations or general descriptions of positions and contentions (§ 12.24(b)(2)), and that, even if an appropriate proffer had been made, the objection is not determinative of the issue raised (§ 12.24(b)(4)).

The filing of the objection and request for hearings served to stay automatically the effectiveness of the two provisions of § 73.35 to which the objections were made. Section 701(e)(2) of the act states: ''Until final action upon such objections is taken by the Secretary * * *, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made.'' Section 701(e)(3) of the act further stipulates that ''As soon as practicable * * *, the Secretary shall by order act upon such objections and make such order public.''

The agency has completed its evaluation of the objection and the request for a hearing and concludes that a continuation of the stay of the two provisions of the regulation is not warranted.

In the absence of any other objections and requests for a hearing, the agency, therefore, further concludes that this document constitutes final action on the objection and request for hearings received in response to the regulation as prescribed in section 701(e)(2) of the act. Therefore, the agency is acting to end the stay of the two provisions of the regulation by establishing a new effective date of November 1, 1995, for these provisions of the regulation of April 13, 1995, listing astaxanthin for use as a color additive in the feed of salmonid fish to enhance the color of their flesh. As announced in the Federal Register of August 14, 1995 (60 FR 41805), the effective date of the rest of the regulation was May 16, 1995.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701 and 721 (21 U.S.C. 371 and 379e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that the objection and the request for a hearing filed in response to the final rule § 73.35 that was published on April 13, 1995 (60 FR 18736), do not form a basis for further stay of the effectiveness of the specified provisions of this final rule or require amendment of the regulations. Accordingly, the stay of §§ 73.35(b) and 73.35(d)(3) that FDA announced on August 14, 1995 (60 FR 41805), is removed effective November 1, 1995. As noted previously, all other provisions of § 73.35 became effective on May 16, 1995.

Dated: October 25, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–27033 Filed 10–31–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8–R]

RIN 0720–AA19

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Expanded Active Duty Dependents Dental Benefit Plan

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: The rule establishes an expanded dental program for dependents of active duty members of the Uniformed Services. The amendment specifically describes: the legislative authority for expansion of dental benefits outside the United States; the continuation of dental benefits for active duty survivors; eligibility for pre-adoptive wards; the enhanced benefit structure; enrollment and eligibility requirements; premium cost-sharing; and benefit payment levels. The provisions of this rule will provide military families with the high quality of care they desire at an affordable price.

EFFECTIVE DATE: This final rule is effective December 1, 1995.

FOR FURTHER INFORMATION CONTACT: David E. Bennett, Program Development Branch, OCHAMPUS, Aurora, Colorado 80045–6900, telephone (303) 361–1094.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 16, 1993 (58 FR 48473), The Office of the Secretary of Defense published for public comment a proposed rule establishing an expanded dental program for dependents of active duty members of the Uniformed Services.

Background

The Basic Active Duty Dependents Dental Benefit Plan, was implemented on August 1, 1987, allowing military personnel to voluntarily enroll their dependents in a dental health care program that included diagnostic and preventative benefits, as well as simple restorative services. Under this program, DoD shared the cost of the premium with the military sponsor. Although the program was viewed as a major step in benefit enhancement for military families, with enrollment levels reaching as high as 60 percent, there were still complaints that the enabling legislation was too restrictive in scope and that there should be expansion of services to better meet the dental needs of the military family.