This rulemaking is promulgated under the authority described in Subtitle VII, part A, subpart I, section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with issuing regulations to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority since it defines controlled airspace in the vicinity of the Palmer Metropolitan Airport to ensure the safety of aircraft operating near that airport and the efficient use of that airspace.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration amends part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[AMENDED]

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

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

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

§ 71.1 [Amended]

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

* * * * *

ANE MA E5 Palmer, MA [Removed]

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Issued in Jamaica, New York, on March 14, 2005.

John G. McCartney,

Acting Area Director, Eastern Terminal Operations.

[FR Doc. 05–5647 Filed 3–22–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 1999P–5332]

Substances Affirmed as Generally Recognized as Safe: Menhaden Oil

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations by reallocating the uses of menhaden oil in food that currently are established in the regulations, with the condition that when menhaden oil is added to food it is not used in combination with other added oils that are significant sources of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

DATES: This rule is effective March 23, 2005. Submit written or electronic objections and requests for a hearing by April 22, 2005.

ADDRESSES: You may submit written objections and requests for a hearing, identified by Docket No. 1999P–5332, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting objections.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting objections on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 1999P–5332 in the subject line of your e-mail message.
- 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.

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.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the paragraph pertaining to objections and requests for a hearing in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.fda.gov/ohrms/dockets/default.htm* 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: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1267.

SUPPLEMENTARY INFORMATION: In response to a petition (GRASP 6G0316) from the National Fish Meal and Oil Association (NFMOA), FDA issued a final rule on June 5, 1997 (62 FR 30751) (the June 1997 final rule) affirming menhaden oil as generally recognized as safe (GRAS) for use as a direct human food ingredient with limitations on the maximum use levels of menhaden oil in specific food categories. FDA concluded that these limitations are necessary to ensure that daily intakes of EPA and DHA from menhaden oil do not exceed 3.0 grams per person per day (g/p/d). As stated in the June 1997 final rule, the maximum limit of 3.0 g/p/d on the total daily intake of EPA and DHA is a safeguard against the possible adverse effects of these fatty acids on increased bleeding time (the time taken for bleeding from a standardized skin wound to cease), glycemic control in non-insulin dependent diabetics, and increased levels of low-density lipoprotein cholesterol.

On February 26, 2002 (the February 2002 proposed rule), FDA published a proposed rule in the **Federal Register** (67 FR 8744) in response to a petition from the NFMOA to amend § 184.1472 (21 CFR 184.1472) by reallocating the uses of menhaden oil in food that were previously affirmed as GRAS, while maintaining the total daily intake of EPA and DHA from menhaden oil at a level not exceeding 3.0 g/p/d. The reallocation is performed by the following three actions: (1) Reducing the maximum levels of use of menhaden oil in some of the currently listed food categories; (2) adding additional food categories along with assigning maximum levels of use in these new categories; and (3) eliminating the listing of subcategories, e.g., cookies and crackers, breads and rolls, fruit pies and custard pies, and cakes, and including them under broader food categories, e.g., baked goods and baking mixes.

Because of developing interest in food ingredients that are significant sources of EPA and DHA, especially other fish oils, FDA believed that it was necessary to state explicitly in the regulation that when menhaden oil is added as an

ingredient in foods, it may not be used in combination with any other added oil that is a significant source of EPA and DHA. Without this restriction, the intake of DHA and EPA could exceed 3.0 g/p/d. Therefore, FDA published a tentative final rule in the **Federal Register** of January 15, 2004 (69 FR 2313) (the January 2004 tentative final rule), in which FDA tentatively concluded that the reallocated uses of menhaden oil are GRAS, but only when the menhaden oil is not used in combination with any other added oil that is a significant source of EPA and DHA. Because the February 2002 proposed rule did not include a condition of use for other added oils, FDA issued this final rule as tentative to give interested persons an opportunity (75 days) to comment on this use limitation.

FDA received two comments on the tentative final rule. One comment expressed general support for the proposed action. The other comment expressed opposition to it because of labeling issues and environmental concerns. Labeling issues pertaining to menhaden oil are outside the scope of the proposed rule and will not be discussed further. With regard to environmental concerns, the comment asserts that the menhaden fish population is in short supply and that the regional fish commissions responsible for monitoring the menhaden population are biased organizations and controlled by the fishing industry. This assertion is not supported by factual information and addresses an issue outside FDA jurisdiction. Furthermore, the comment does not provide the agency with any information that affects the agency's previous determination that reallocating the foods to which menhaden oil can be added will not have a significant impact on the human environment and that an environmental impact statement is not required. In addition to labeling and environmental concerns, the comment also asserts that FDA's conclusion that there are no safety concerns from food uses of menhaden oil due to possible bioaccumulation of lipophilic chemical contaminants in the source fish is unsupported because FDA does not identify the data that it evaluated. FDA responded in the January 2004 tentative final rule to comments that were received pertaining to concerns about the potential for lipophilic chemical contaminants in menhaden oil. FDA's response to these concerns referred to data that were evaluated by FDA on levels of various chemical contaminants in menhaden oil. The data referred to by FDA in its response are part of the administrative record and are in the docket (Docket No. 1999P–5332). In addition, a copy of FDA's evaluation of these data was placed in the docket when the tentative final rule published. Therefore, FDA's conclusion regarding the potential for lipophilic chemical contaminants in menhaden oil is fully supported by data in the administrative record. FDA did not receive any comments on the limitation that when menhaden oil is added to food it is not to be used in combination with any other added oil that is a significant source of EPA and DHA. The agency is therefore issuing this final rule based on the tentative final rule and is amending § 184.1472 as set forth below.

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections by (see **DATES**). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents 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.

List of Subjects in 21 CFR Part 184

Food additives.

■ 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 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

■ 2. Section 184.1472 is amended by revising paragraphs (a)(2)(iii) and (a)(3) and adding paragraph (a)(4) to read as follows:

§ 184.1472 Menhaden oil.

(a) * * *

(2) * * *

(iii) *Saponification value.* Between 180 and 200 as determined by the American Oil Chemists' Society Official Method Cd 3–25—''Saponification Value'' (reapproved 1989), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.

* * * * *

(3) In accordance with § 184.1(b)(2), the ingredient may be used in food only within the following specific limitations to ensure that total intake of eicosapentaenoic acid or docosahexaenoic acid does not exceed 3.0 grams/person/day:

Category of food	Maximum level of use in food (as served)
Baked goods, baking mixes, § 170.3(n)(1) of this chapter.	5.0 percent
Cereals, § 170.3(n)(4) of this chapter.	4.0 percent

Category of food	Maximum level of use in food (as served)
Cheese products, § 170.3(n)(5) of this chapter.	5.0 percent
Chewing gum, § 170.3(n)(6) of this chapter.	3.0 percent
Condiments, § 170.3(n)(8) of this chapter.	5.0 percent
Confections, frostings, § 170.3(n)(9) of this chapter.	5.0 percent
Dairy product analogs, § 170.3(n)(10) of this chapter.	5.0 percent
Egg products, § 170.3(n)(11) of this chapter.	5.0 percent
Fats, oils, § 170.3(n)(12) of this chapter, but not in infant formula.	12.0 percent
Fish products, § 170.3(n)(13) of this chapter.	5.0 percent
Frozen dairy desserts, § 170.3(n)(20) of this chapter.	5.0 percent
Gelatins, puddings, § 170.3(n)(22) of this chapter.	1.0 percent
Gravies, sauces, § 170.3(n)(24) of this chapter.	5.0 percent
Hard candy, § 170.3(n)(25) of this chapter.	10.0 percent
Jams, jellies, § 170.3(n)(28) of this chapter.	7.0 percent
Meat products, § 170.3(n)(29) of this chapter.	5.0 percent
Milk products, § 170.3(n)(31) of this chapter.	5.0 percent
Nonalcoholic beverages, § 170.3(n)(3) of this chapter.	0.5 percent
Nut products, § 170.3(n)(32) of this chapter.	5.0 percent
Pastas, § 170.3(n)(23) of this chapter.	2.0 percent
Plant protein products, § 170.3(n)(33) of this chapter.	5.0 percent
Poultry products, § 170.3(n)(34) of this chapter.	3.0 percent
Processed fruit juices, § 170.3(n)(35) of this chapter.	1.0 percent
Processed vegetable juices, § 170.3(n)(36) of this chapter.	1.0 percent
Snack foods, § 170.3(n)(37) of this chapter.	5.0 percent
Soft candy, § 170.3(n)(38) of this chapter.	4.0 percent
Soup mixes, § 170.3(n)(40) of this chapter.	3.0 percent
Sugar substitutes, § 170.3(n)(42) of this chapter.	10.0 percent
Sweet sauces, toppings, syrups, § 170.3(n)(43) of this chapter.	5.0 percent
White granulated sugar, § 170.3(n)(41) of this chapter.	4.0 percent

(4) To ensure safe use of the substance, menhaden oil shall not be used in combination with any other added oil that is a significant source of eicosapentaenoic acid or docosahexaenoic acid.

* * * * *

Dated: March 14, 2005.

Leslye M. Fraser,

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

[FR Doc. 05–5641 Filed 3–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2005N–0081]

Medical Devices; Immunology and Microbiology Devices; Classification of the Automated Fluorescence in situ Hybridization Enumeration Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying automated fluorescence in situ hybridization (FISH) enumeration systems into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Automated Fluorescence *in situ* Hybridization (FISH) Enumeration Systems.'' The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety