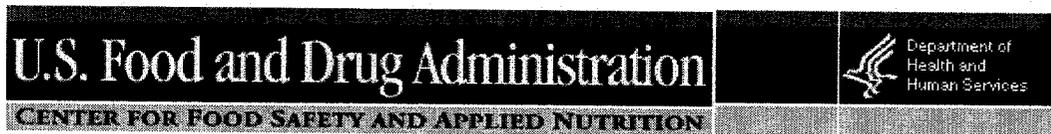


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CFSAN/Office of Food Additive Safety  
August 17, 2004

## Agency Response Letter GRAS Notice No. GRN 000146

Dr. Edward Iorio  
Jedwards International  
10 Furnace Brook Parkway  
Quincy, MA 02169

Re: GRAS Notice No. GRN 000146

Dear Dr. Iorio:

The Food and Drug Administration (FDA) is responding to the notice, dated February 11, 2004, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on February 17, 2004, filed it on February 20, 2004, and designated it as GRAS Notice No. GRN 000146.

The subject of the notice is salmon oil. The notice informs FDA of the view of Jedwards International (Jedwards) that salmon oil is GRAS, through scientific procedures, for use as a direct food ingredient at the levels listed in Table 1 (below), when not combined or augmented with any other food ingredient containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). At this time, Jedwards intends for salmon oil to be used in the same food categories and at the same maximum use levels as those currently listed in 21 CFR 184.1472 (a)(3) for menhaden oil. These use levels are listed in Table 1 as "Current maximum proposed use levels." FDA recently issued a proposed rule (the menhaden oil proposal; 67 FR 8744, February 26, 2002) that would amend 21 CFR 184.1472(a)(3) by changing the maximum use levels and food categories in which menhaden oil may be used. Jedwards asks in their notice that the agency apply any changes in 21 CFR 184.1472(a)(3) to the intended use of salmon oil. These values are incorporated in the column labeled "Future maximum proposed use levels" in Table 1. FDA has issued a tentative final rule amending 21 CFR 184.1472 (69 FR 2313; January 15, 2004).

As with the use of menhaden oil, the maximum use levels of Jedwards' salmon oil are designed to assure that the combined daily intake of two fatty acids that are components of salmon oil (i.e., EPA and DHA) would not exceed 3 grams/person/day (g/p/d). FDA has affirmed the GRAS status of menhaden oil (21 CFR 184.1472 (a)(3)) provided that the combined daily intake of EPA and DHA from consumption of menhaden oil does not exceed 3 g/p/d. Similarly, Jedwards concludes that salmon oil is safe for use as a direct ingredient provided that the combined daily intake of EPA and DHA from consumption of salmon oil-containing foods does not exceed 3 g/p/d and salmon oil is added as the sole source of EPA and DHA in any given food category.

As part of its notice, Jedwards evaluated the data and information that are the basis for its GRAS determination. Jedwards discusses the source and chemical composition of salmon oil, the GRAS affirmed status of menhaden oil (21 CFR 184.1472), and the scientific literature on fish oils. According to Jedwards, salmon oil is manufactured in the same manner as menhaden oil and is virtually chemically identical in composition; hence salmon oil is a safe substitute for menhaden oil in various food categories listed in 21 CFR 184.1472 (a)(3) and subsequently updated in FDA's tentative final rule for menhaden oil (69 FR 2313; January 15, 2004).

**Table 1**  
**Current and Future Maximum Proposed Use Levels of Salmon Oil in Various Food Categories**

| Food Category                         | Current maximum proposed<br>use levels<br>(%) | Future maximum proposed<br>use levels<br>(%) |
|---------------------------------------|---|--|
| Baked goods and baking mixes (1)      | n/a   | 5.0  |
| Breads and Rolls (white and dark) (1) | 1.0   | n/a**  |
| Cookies, Crackers (1)                 | 5.0   | n/a**  |
| Fruit pies, custard pies (1)          | 7.0   | n/a**  |
| Cakes (1)                             | 1.0   | n/a**  |
| Nonalcoholic Beverages (3)            | n/a   | 0.5  |
| Cereals (4)                           | 4.0   | 4.0  |
| Cheese products (5)                   | 5.0   | 5.0  |

|   |      |        |
|---|------|--------|
| Chewing Gum (6)                                   | n/a  | 3.0    |
| Condiments (8)                                    | 5.0  | 5.0    |
| Confections and Frosting (9)                      | n/a  | 5.0    |
| Dairy Product Analogs (10)                        | n/a  | 5.0    |
| Egg Products (11)                                 | 5.0  | 5.0    |
| Fats and Oils (not including infant formula) (12) | 20.0 | 12.0   |
| Fish Products (13)                                | 20.0 | 5.0    |
| Frozen dairy products/desserts (20)               | 5.0  | 5.0    |
| Gelatins and Puddings (22)                        | n/a  | 1.0    |
| Pastas (23)                                       | n/a  | 2.0    |
| Gravies, sauces (24)                              | 5.0  | 5.0    |
| Hard Candy (25)                                   | n/a  | 10.0   |
| Jams and Jellies (28)                             | n/a  | 7.0    |
| Meat Products (29)                                | 10.0 | 5.0    |
| Milk Products (31)                                | n/a  | 5.0    |
| Yogurt (31)                                       | 4.0  | n/a*** |
| Nut Products (32)                                 | 5.0  | 5.0    |

|   |     |      |
|---|-----|------|
| Plant Protein Products (33)   | n/a | 5.0  |
| Poultry Products (34)   | n/a | 3.0  |
| Processed Fruit Juices (35)   | n/a | 1.0  |
| Processed Vegetable Juices (36)   | n/a | 1.0  |
| Snack foods (37)  | 5.0 | 5.0  |
| Soft Candy (38)   | n/a | 4.0  |
| Soup Mixes (40)   | 3.0 | 3.0  |
| White Granulated Sugar (41)   | n/a | 4.0  |
| Sugar Substitutes (42)  | n/a | 10.0 |
| Sweet Sauces, Toppings, and Syrups (43)   | n/a | 5.0  |
| <p>* The food categories correspond to those listed in 21 CFR 170.3 (n). The number in parenthesis following each food category is the paragraph listing of that food category in 21 CFR 170.3 (n).<br/> ** Subsumed by "baked goods and baking mixes."<br/> *** Subsumed by "milk products."</p> |     |      |

Jedwards describes generally available information about the identity and composition of salmon oil. Salmon oil is a complex mixture of glycerides, fatty acids, unsaponifiables, and phospholipids from the body of salmon, primarily *Salmo salar*. Salmon oil consists mainly of a mixture of triglycerides of various long chain (14-22 carbons) fatty acids, with small amounts of mono- and diglycerides. Jedwards notes that salmon oil, like menhaden oil, contains approximately 20 percent by weight of omega-3 fatty acids. According to Jedwards, the relative proportions of EPA and DHA, expressed on a weight percent basis, are typically 12 percent EPA and 8 percent DHA for menhaden oil and 8 percent EPA and 12 percent DHA for salmon oil. Jedwards provides analytical results to show the EPA and DHA content of the salmon oil as well as the typical distributions of saturated (22%), monounsaturated (39%), and polyunsaturated (35%) fatty acids in the salmon oil ingredient. According to Jedwards, individual lots of salmon oil typically differ in the proportions of EPA and DHA, but lots are blended to achieve a standardized amount of 8 percent EPA and 12 percent DHA.

Jedwards states that salmon oil is processed according to standardized procedures for fish oils. Fish are cooked and pressed, with the oil separated from the expressed liquor. The oil is further processed in accordance with current good manufacturing practice using standard refining methods employed in the processing of edible oils that include winterization, neutralization, bleaching, and deodorizing. Jedwards briefly describes two purification processes used in the method of manufacture to remove persistent organochlorine pollutants and other contaminants potentially present in fish tissue. Salmon oil is filtered through clay to remove heavy metal contaminants and through activated charcoal to remove organic contaminants. Jedwards provides specifications for maximum levels of environmental contaminants in salmon oil.

Jedwards acknowledges that FDA raised concerns about the consumption of high levels of EPA and DHA, which may increase bleeding time, increase levels of low-density lipoprotein cholesterol, and have an effect on glycemic control in non-insulin dependent diabetics (menhaden oil final rule; 62 FR 30751; June 5, 1997). In affirming the GRAS status of menhaden oil, FDA concluded that the use of menhaden oil as a direct food ingredient is GRAS, provided that the combined daily intake of EPA and DHA from consumption of menhaden oil does not exceed 3 g/p/d. To assure that the combined exposure to EPA and DHA would not exceed 3 g/p/d, FDA established maximum levels of use of menhaden oil that would be permitted in specified food categories (21 CFR 184.1472(a)(3)). Jedwards states that, in accordance with the menhaden oil limitations, the proposed use of salmon oil would correspond with a dietary intake of EPA plus DHA that does not exceed 3 g/p/d. Further, salmon oil is not to be combined or augmented with any other food ingredient containing EPA and DHA.

Based on the information provided by Jedwards, as well as other information available to FDA, the agency has no questions at this time regarding Jedwards' conclusion that salmon oil is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of salmon oil. As always, it is the continuing responsibility of Jedwards to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

During its evaluation of GRN 000146, FDA consulted with the Labeling and Consumer Protection Staff of the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA). Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS is responsible for determining the efficacy and suitability of food ingredients and additives in meat and poultry products as well as prescribing safe conditions of use. Suitability relates to the effectiveness of the ingredient in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product, or one that misleads consumers. FSIS requested that FDA advise Jedwards to seek regulatory guidance from FSIS, Labeling and Consumer Protection Staff, about the use of salmon oil in meat and poultry products. Jedwards should direct such an inquiry to Dr. Robert Post, Director, Labeling and Consumer Protection Staff, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, 1400 Independence Ave., S.W., Suite 602, Annex, Washington, DC 20250-3700. The telephone number for his office is (202) 205-0279 and the telefax number is (202) 205-3625.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at <http://www.cfsan.fda.gov/~lrd/foodadd.html>).

Sincerely,

/s/

Laura M. Tarantino, Ph.D.

Director

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition

cc: Dr. Robert Post, Director  
Labeling and Consumer Protection Staff  
Office of Policy, Program Development and Evaluation  
Food Safety and Inspection Service  
300 12th Street, SW, Room 602  
Washington, DC 20250-3700

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