U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
September 3, 2002

Agency Response Letter
GRAS Notice No. GRN 000102

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

Re: GRAS Notice No. GRN 000102

Dear Dr. Iorio:

The Food and Drug Administration (FDA) is responding to the notice, dated March 23, 2002, 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 March 25, 2002, filed it on April 4, 2002, and designated it as GRAS Notice No. GRN 000102.

The subject of the notice is small planktivorous pelagic fish body oil (SPPFBO). The notice informs FDA of the view of Jedwards International (Jedwards) that SPPFBO is GRAS, through scientific procedures, for use in the food categories listed in 21 CFR 184.1472(a)(3) (menhaden oil) at levels of use that are two thirds of the maximum levels of use specified in that regulation (see Table 2, below). Because FDA recently issued a proposed rule (the menhaden oil proposal; 67FR 8744, February 26, 2002) that would amend 21 CFR 184.1472(a)(3) by reallocating the uses of menhaden oil in a different set of food categories (each with a specified maximum level of use), Jedwards notes that any changes to the maximum levels of use specified in 21 CFR 184.1472(a)(3) would also apply to SPPFBO. In other words, the levels of use of SPPFBO would be two-thirds of whatever maximum levels of use are specified in 21 CFR 184.1472(a)(3)). As with the use of menhaden oil, the maximum levels of use of SPPFBO are designed to assure that the combined daily intake of two fatty acids that are components of SPPFBO (i.e., eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)) would not exceed 3 grams per person per day (g/p/d). In an amendment dated July 15, 2002, Jedwards notes that SPPFBO will be used as the sole added source of EPA and DHA in any given food category and is not to be combined or augmented with any other EPA/DHA-rich oil in making a food product.

Jedwards describes generally available information about the identity and composition of SPPFBO. SPPFBO is derived fro m small planktivorous pelagic fish, primarily sea-harvested sardine (*Sardina pilchardus*) and anchovy (*Cetengraulis mysticetus*). Jedwards compares sardine and anchovy with menhaden and concludes that they are all plankton-eating fish that vary mainly in size. Because sardines and anchovies are commonly consumed fish, Jedwards considers that SPPFBO is already part of the diet.

Jedwards describes SPPFBO as a complex mixture of glycerides, fatty acids, unsaponifiables and phospholipids. It is predominantly a mixture of triglycerides with small amounts of mono- and diglycerides. Like other fish oils,

SPPFBO differs from edible vegetable oils and animal fats in its relatively high proportions of polyunsaturated fatty acids, such as EPA (which has five double bonds) and DHA (which has six double bonds).

As shown in Table 1, Jedwards compares the fatty acid composition of SPPFBO to that of menhaden oil and contrasts the fatty acid compositions of these two fish oils with that of a vegetable oil (i.e., soybean oil).

Table 1
Fatty Acid Composition of Menhaden Oil, SPPFBO, and Soybean Oil

	Percent by Weight		
Fatty Acid (Chain Length : Number of Double Bonds)	**Menhaden Oil**	**SPPFBO**	**Soybean Oil**
14:0	9.0	6.5	0.2
16:0	19.0	15.5	10.7
18:0	3.8	2.9	3.9
16:1	13.3	8.3	0.3
18:1	15.5	10.1	22.8
22:1	0.7	1.3	0.0
18:2	2.0	1.2	50.8
18:3	1.0	0.7	6.8
20:5 (EPA)	12.5	18.0	0.0
22:6 (DHA)	7.9	12.0	0.0

Jedwards describes the method of manufacture of SPPFBO. The fish are cooked and pressed. The oil is separated from the expressed liquor and further processed using standard methods in accordance with current good manufacturing practice. The oil is refined by winterization, neutralization, bleaching, and deodorization. The methods and equipment used to process SPPFBO are standard in the processing of other edible oils and fats. Jedwards describes the manufacture of SPPFBO as similar to that of menhaden and other fish oils. Jedwards provides product specifications with limits on saponification value, iodine number, unsaponifiable matter, free fatty acids, peroxide value, lead, and mercury.

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)). Likewise, Jedwards concludes that there appear to be no risks associated with the consumption of SPPFBO, provided that consumption is limited to a combined total intake for EPA and DHA of 3 g/p/d, with SPPFBO as the sole source of added oils containing EPA and DHA. Because SPPFBO contains higher levels of

EPA and DHA than menhaden oil (see Table 1, above), Jedwards intends to use SPPFBO at maximum levels that are two thirds of the maximum levels of use described in the regulation for menhaden oil. Table 2 lists these levels of use.

Table 2
Maximum Levels of Use of SPPFBO in Food Proposed by Jedwards

Food Category	**Maximum level of use of SPPFBO under the current menhaden oil regulation (Percent by weight)**	**Maximum level of use of SPPFBO if and when the menhaden oil regulation is amended (Percent by weight)**
Cookies, crackers	3.3	n/a*
Breads, Rolls (white and dark)	0.7	n/a
Baked goods and baking mixes	n/a	3.3
Fruit pies, custard pies	4.7	n/a
Cakes	6.7	n/a
Cereals	2.7	2.7
Fats, oils (not including infant formulae)	13.3	8.0
Yogurt	2.7	n/a
Cheese products	3.3	3.3
Frozen dairy products/desserts	3.3	3.3
Meat products	6.7	3.3
Egg products	3.3	3.3

Fish products	13.3	3.3
Condiments	3.3	3.3
Soup mixes	2.0	2.0
Snack foods	3.3	3.3
Nut Products	3.3	3.3
Gravies, sauces	3.3	3.3
Milk products	n/a	3.3
Nonalcoholic beverages	n/a	0.3
Chewing gum	n/a	2.0
Confections and frosting	n/a	3.3
Dairy product analogs	n/a	3.3
Gelatins and puddings	n/a	0.7
Pastas	n/a	1.3
Hard candy	n/a	6.7
Jams and jellies	n/a	4.7
Plant protein products	n/a	3.3
Poultry products	n/a	2.0
Processed fruit juices	n/a	0.7

Processed vegetable juices	n/a	0.7
Soft candy	n/a	2.7
White granulated sugar	n/a	2.7
Sugar substitutes	n/a	6.7
Sweet sauces, toppings,and syrups	n/a	3.3
*n/a = not applicable		

Jedwards concludes that SPPFBO is GRAS because its manufacture, composition and intended use are similar to the manufacture, composition, and intended use of menhaden oil.

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 SPPFBO is GRAS under the intended conditions of use, provided that the levels of use do not exceed two thirds of the levels of use described in 21 CFR 184.1472 and that a combined intake of EPA and DHA from all added sources does not exceed 3 g/p/d. The agency has not, however, made its own determination regarding the GRAS status of the subject use of SPPFBO. 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.

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 the 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).

During its evaluation of GRN 102, 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. Because SPPFBO is an oil of fish origin, similar in composition to menhaden oil, FSIS has no objections regarding the use of SPPFBO in the production of meat products at the levels proposed by Jedwards.

Sincerely,

/s/

Alan M. Rulis, 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
Independence Ave., S.W., Suite 602, Annex
Washington, DC 20250-3700

Food Ingredients and Packaging | Summary of all GRAS Notices

Foods Home | FDA Home | Search/Subject Index | Disclaimers & Privacy Policy | Accessibility/Help

Content last updated by amd/rxm/pmg on 2002-OCT-10
Hypertext updated by amd/rxm/pmg on 2002-OCT-11