Regulatory Flexibility Act

We certify that these rules will not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96–354, the Regulatory Flexibility Act, is not required.

(Catalog of Federal Domestic Assistance Program No. 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: May 27, 1997.

John J. Callahan,

Acting Commissioner of Social Security.

Subpart D of part 416 of chapter III of title 20 of the Code of Federal Regulations is amended as follows:

PART 416—[AMENDED]

1. The authority citation for subpart D of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611(a), (b), (c), and (e), 1612, 1617, and 1631 of the Social Security Act (42 U.S.C. 902(a)(5), 1382(a), (b), (c), and (e), 1382a, 1382f, and 1383).

2. Section 416.420 is amended by revising paragraph (a) and redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c) to read as follows:

§ 416.420 Determination of benefits; general.

* * * * *

(a) *General rule.* We use the amount of your countable income in the second month prior to the current month to determine how much your benefit amount will be for the current month. We have determined that no reliable information exists which is currently available to compute benefits on a current basis as is explained in paragraph (c) of this section. However, if you have been receiving an SSI benefit and receiving a Social Security insurance benefit and the latter is increased on the basis of the cost-of-living adjustment or because your benefit is recomputed, we will compute the amount of your SSI benefit for January, the month of an SSI benefit increase, by including in your income the amount by which your Social Security benefit in January exceeds the amount of your Social Security benefit in November. Similarly, we will compute the amount of your SSI benefit for February by including in your income the amount by which your Social Security benefit in February exceeds the amount of your Social Security benefit in December.

Example 1. Mrs. X's benefit amount is being determined for September (the current month). Mrs. X's countable income in July is used to determine the benefit amount for September.

Example 2. Mr. Y's SSI benefit amount is being determined for January (the current month). Mr. Y has Social Security income of $100 in November, $100 in December, and $105 in January. We find the amount by which his Social Security income in January exceeds his Social Security income in November ($5) and add that to his income in November to determine the SSI benefit amount for January.

* * * * *

(c) *Reliable information which is currently available for determining benefits.* The Commissioner has determined that no reliable information exists which is currently available to use in determining benefit amounts.

(1) *Reliable information.* For purposes of this section ''reliable information'' means payment information that is maintained on a computer system of records by the government agency determining the payments (e.g., Department of Veterans Affairs, Office of Personnel Management for Federal civil service information and the Railroad Retirement Board).

(2) *Currently available information.* For purposes of this section ''currently available information'' means information that is available at such time that it permits us to compute and issue a correct benefit for the month the information is pertinent.

* * * * *

[FR Doc. 97–14614 Filed 6–4–97; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 86G–0289]

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 affirming that menhaden oil is generally recognized as safe (GRAS) as a direct human food ingredient with specific limitations. The agency is also affirming that partially hydrogenated menhaden oil with an iodine number between 86 and 119 is GRAS as a direct human food ingredient with no limitation other than current good manufacturing practice. These actions complete the agency's response to a petition filed by the National Fish Meal and Oil Association.

DATES: Effective June 5, 1997. The Director of the Office of the Federal Register approves the incorporation by reference, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, of certain publications in 21 CFR 184.1472(a)(2), effective June 5, 1997.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFS–206), 200 C St. SW., Washington, DC 20204, 202–418–3103.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 170.35, the National Fish Meal and Oil Association, 2000 M St. NW., suite 580, Washington, DC 20036 (current address: 1525 Wilson Blvd., suite 500, Arlington, VA 22209), submitted a petition (GRASP 6G0316) seeking affirmation that menhaden oil and partially hydrogenated menhaden oil are GRAS for use as direct human food ingredients. The petition included information about the identity of, and manufacturing processes for, menhaden oil and partially hydrogenated menhaden oil; final reports and published articles of long-term animal feeding studies with partially hydrogenated menhaden oil; information about the history of human food use of partially hydrogenated menhaden oil; and the results of an extensive search of the published scientific literature (encompassing over 2,600 articles) with respect to the safety of fish oils in general.

FDA published a notice of filing of this petition in the **Federal Register** of July 31, 1986 (51 FR 27461), and gave interested persons an opportunity to submit comments to FDA's Dockets Management Branch. FDA received three comments, two from manufacturers and one from a government agency. All of the comments supported the affirmation of GRAS status for use of the oils in food.

FDA affirmed that partially hydrogenated menhaden oil (with an iodine number not more than 85) and fully hydrogenated menhaden oil are GRAS in the **Federal Register** of September 15, 1989 (54 FR 38219). These oils were affirmed as GRAS based on the chemical similarity between these oils and partially hydrogenated common edible vegetable oils, and on the established history of use in Europe

of these oils in margarine and shortening (54 FR 38219 at 38222).

Pending further evaluation, the agency deferred its decision on menhaden oil that has not been hydrogenated, because this oil contains high levels of the *omega-3* polyunsaturated fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which are known to have physiologic effects, for example, effects on blood clotting (54 FR 38219). The agency's evaluation is now complete.

I. Basis for GRAS Status

Under section 201(s) of the act (21 U.S.C. 321(s)) and § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances added to food. The basis of such views may be either: (1) Scientific procedures or, (2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). The petitioner relies upon scientific procedures to establish that menhaden oil is GRAS, because the oil has no history of common use as a food ingredient prior to 1958.

II. Identity

Menhaden oil is a refined marine oil that is derived from menhaden fish (*Brevoortia* species). It consists primarily of triglycerides, with small amounts of monoglycerides and diglycerides. The triglycerides are esters of glycerol and fatty acids with chains of 14 to 22 carbon atoms. Menhaden oil differs from edible vegetable oils and animal fats in its high proportion of polyunsaturated fatty acids with 4, 5 and 6 double bonds (about 25 percent). The mean percentages for these polyunsaturated fatty acids in menhaden oil are C18:4 (2.3 percent), C20:4 (2.0 percent), C20:5 (13.1 percent), C22:5 (2.5 percent) and C22:6 (6.7 percent).[1] C20:5 and C22:6 are EPA and DHA, respectively, and are the major source of *omega*-3 fatty acids from fish oil. (*Omega*-3 fatty acids refer to fatty acids with the first double bond occurring at the third carbon from the methyl (or omega) end of the fatty acid.) Menhaden oil also contains about 33 percent saturated fatty acids and about 31 percent monounsaturated fatty acids.

[1] The first number refers to the total number of carbon atoms in the fatty acid; the second number refers to the total number of double bonds.

III. Manufacturing Process

Menhaden, a plankton-feeding fish, is harvested commercially from the Gulf of Mexico and northward along the Atlantic coast of the United States. The fish is less than 12 inches long and less than a pound in weight. To produce menhaden oil, the fish is cooked whole at about 96 °C for 8 to 10 minutes to coagulate the protein and rupture the fat cells. The cooked fish is then pressed and the liquid is centrifuged to separate the oil and aqueous phases. Crude oil is then shipped to food companies for further processing, which may include storage (winterization), degumming, neutralization, bleaching, deodorization, and hydrogenation.

IV. Previous Evaluations

Data in the petition indicate that ingestion of EPA and DHA from fish oils can have a significant effect on bleeding time (the time taken for bleeding from a standardized skin wound to cease) and other physiological effects, as discussed below. Because of the potential safety concerns raised by these effects, and because there are no food oils in the food supply containing significant amounts of EPA and DHA, the agency contracted with the Mitre Corp. to perform an independent analysis of the scientific literature on the safety of menhaden oil. The Mitre Corp. issued, in April 1989, a report entitled, ''Health Effects of Refined Menhaden Oil.'' (Copies are available from the National Technical Information Service, Order No. PB89–182398, price code A08.)

The report stated that:

> [a]n increase in bleeding time is the only prominent health effect observed in humans that has been firmly established as a consequence of fish oil ingestion. This effect has been reported anecdotally in the Eskimo population and consistently observed in studies of healthy human subjects with a daily intake of 3 g [grams] of omega-3 fatty acids. The magnitude of the effect at this low dose is not a cause for alarm, but a lack of systematic dose-response data precludes prediction of the severity of the effect at higher daily intakes.

(Pages 7–1 and 7–2 of the report.)

In addition, the Nutrition Labeling and Education Act of 1990 required FDA to evaluate health claims for 10 nutrient-disease relationships, including the relationship of *omega*-3 fatty acids and heart disease. The agency evaluated the claim that consumption of *omega*-3 fatty acids is associated with a decreased risk of coronary heart disease under the standard set forth in section 403(r)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)): Whether, based on the totality of publicly available scientific evidence, there is significant scientific agreement, among experts qualified by scientific training and experience, that the claim for the diet-disease relationship is supported by the evidence. In the **Federal Register** of January 6, 1993 (58 FR 2682), FDA issued a final rule announcing its decision not to authorize a health claim relating to an association between *omega*-3 fatty acids and a decreased risk of coronary heart disease because it had concluded that there was not significant scientific agreement among experts that the totality of the scientific evidence supported the claim. Because the focus of that evaluation was a review of evidence concerning a possible beneficial effect of *omega*-3 fatty acids on the heart, a comprehensive review of the safety of *omega*-3 fatty acids from fish oils or other sources was not conducted. However, in the health claim final rule the agency did discuss, in addition to the potential health benefit, concerns over possible adverse effects of fish oils on bleeding time, glycemic control, and low-density lipoprotein (LDL) cholesterol. These issues are discussed below.

V. Safety Information

A. Bleeding Time

Increased bleeding time has been reported in many studies with humans whose diets were supplemented with fish oils. FDA stated in the health claim final rule that the importance of the increase in bleeding time reported in many studies with supplemental fish oils or with increased fish consumption is not clear (58 FR 2682 at 2699). Further, increases in bleeding time do not correlate with clinically significant bleeding, and there are debates regarding the clinical significance of the increase in bleeding time (Ref. 1). However, FDA considers excessive bleeding to be a safety concern, and has examined the scientific literature for evidence that consumption of fish oils may contribute to excessive bleeding.

There are more than 50 reports in the scientific literature on fish oils that include data on bleeding time. Several reports described the absence of changes in bleeding time, but did not provide data. A few studies involving substantial numbers of healthy human subjects indicated that there was no statistically significant increase in bleeding time after supplemental intakes of EPA and DHA from fish oils

in daily amounts of 3.0 g or less (Refs. 3 through 6). Other studies with fewer human subjects, but in which the total diet was carefully controlled, also revealed that daily intakes of 3.0 g or less of EPA and DHA in fish oils did not increase bleeding time (Refs. 7 and 8).

However, two studies described increases in bleeding time that were reported to be statistically significant. Subjects in the studies consumed about 3.0 g per person per day (/p/d) EPA and DHA from fish oils. Mortensen et al. (Ref. 9), in a crossover, double-blind, placebo-controlled study among 20 normal, healthy males, showed that consumption of slightly more than 3.0 g/d of EPA and DHA in fish oil capsules for 4 weeks produced a small but statistically significant increase (16 percent) in median bleeding time; however, both the mean and 75th percentile bleeding times were well within the normal range. Harris and Windsor (Ref. 10) reported that consumption of fish oil containing 2.2 g/d of EPA and DHA also produced a small (15 percent) but statistically significant increase in bleeding time, but this increase was also within the normal range.

Studies in which greater daily amounts (higher than 3.0 g/p/d) of fish oils were fed often reported statistically significant increases in bleeding time (Refs. 11 through 22). In some of those studies, use of fish oils resulted in substantial prolongation of bleeding time outside the normal range, as indicated by the standard deviations reported (Refs. 8, 12, 18, 21, and 22). However, the pre-treatment bleeding times in those studies were also beyond the normal range, making it difficult to evaluate the effect of fish oils on bleeding time. In other studies, the increase in bleeding time after daily intakes of more than 3.0 g of EPA and DHA is difficult to interpret meaningfully because of the small number of subjects tested (Refs. 23 through 27).

Studies have also been carried out with subjects who had evidence of coronary heart disease or risk factors for coronary heart disease. After intake of 3.2–6.0 g/p/d of EPA and DHA in fish oils, many of these subjects showed increased bleeding time (Refs. 20, and 28 through 33). However, none of the studies reported evidence that the prolonged bleeding time was clinically significant. In those cases where the effect of fish oils in angioplasty or bypass surgery patients (a total of 520 patients fed supplemental fish oil) was studied, excessive bleeding was not reported even though acetylsalicylic acid (aspirin), which itself greatly prolongs bleeding time, was used concurrently (Refs. 34 through 40). One large study that used a dose of 6 g/p/d EPA and DHA in fish oils did report four cases of increased bleeding in the fish oil group (of 124 treated) versus none in the placebo group, but the difference in rates of occurrences between the two groups was not statistically significant (Ref. 40).

In summary, the totality of the scientific evidence demonstrates that when consumption of fish oils is limited to 3 g/p/d or less of EPA and DHA, there is no significant risk for increased bleeding time beyond the normal range. A report from an industry-sponsored roundtable discussion on the topic of fish oils and bleeding time (Ref. 2) also supports the conclusion that EPA and DHA are safe at intake levels at or below 3 g/p/d. On the other hand, amounts of fish oils providing more than 3 g/d of EPA and DHA have generally been found to produce increases in bleeding time that are statistically significant. At this time, there are insufficient data to evaluate the clinical significance of this finding. Because of the lack of data and because of the potential risk of excessive bleeding in some individuals with intakes at higher levels, FDA concludes that the safety of menhaden oil is generally recognized only at levels that limit intake of EPA and DHA to 3 g/p/d.

B. Glycemic Control

Some studies on non-insulin-dependent diabetics have reported increased glucose levels when large amounts of fish oils (4.5 to 8.0 g/p/d) were used in the diet. In the health claim final rule, FDA discussed the possible adverse effects of fish oil consumption on glycemic control among diabetics and stated that such effects were a safety concern (58 FR 2682 at 2704 through 2705). FDA concluded in that document that the effects of fish oils on blood glucose appear to depend on the amount of fish oils fed, based on review of a number of studies (58 FR 2682 at 2705). One study found no change in fasting blood glucose levels among type-II [non-insulin-dependent] diabetics treated with 3.0 g/d EPA plus DHA for 2 weeks (Ref. 41). Two other studies that used 3 g/d EPA plus DHA for 6 weeks (Ref. 42) and 2.7 g/d EPA plus DHA for 8 weeks (Ref. 43) found only transient increases in blood glucose halfway through their respective supplementation periods. Another study (Ref. 44) that used 3.0 g/d EPA plus DHA for 3 weeks found comparable increases in fasting blood glucose when either fish oil or safflower oil was fed, so the increase cannot be attributed specifically to *omega*-3 fatty acids. A study that compared the effects of fish oil and olive oil (Ref. 45) fed 3 g/d of EPA plus DHA and did not find a difference in fasting glucose or glycosylated hemoglobin after fish oil supplementation compared to baseline; they did find a significant difference compared to the olive oil treatment, which produced changes in the opposite direction from fish oil. Studies on type II diabetics that reported increased glucose used higher amounts (4.5 to 8 g/d) of *omega*-3 fatty acids (Refs. 46 through 49).

Based on the available information, FDA concludes that consumption of EPA and DHA in fish oils at 3 g/p/d by diabetics has no clinically significant effect on glycemic control, although higher amounts of EPA and DHA (4.5 g/p/d and above) remain of concern. Therefore, FDA concludes that 3 g/p/d of EPA and DHA is a safe level with respect to glycemic control.

C. LDL Cholesterol

In the health claim final rule, FDA noted that many studies on hypertriglyceridemic or hypercholesterolemic subjects, and some studies on normal subjects, reported an increase in LDL cholesterol or apo B (apolipoprotein B, a principal component of LDL) following fish oil supplementation (58 FR 2682 at 2705). Because increases in LDL cholesterol predict increased risk of coronary heart disease, FDA recently reevaluated those studies, as well as newer studies published since the health claim final rule, to address the question of whether 3 g/p/d of EPA and DHA derived from menhaden oil is generally recognized as a safe level with respect to its effect on LDL cholesterol. The agency considered the reported effects of fish oil on LDL cholesterol levels in healthy persons with normal cholesterol levels, as well as in persons with diabetes mellitus, hypertension, abnormal blood lipid levels, and cardiovascular disease.

As a result of its reevaluation, FDA found that although reported study results are variable, there appears to be a trend toward increased LDL cholesterol values with increased fish oil consumption in all population subgroups, with the magnitude of the increase appearing greater and more consistent in populations with abnormal blood lipid levels, hypertension, diabetes, and cardiovascular disease.

In the health claims final rule, FDA noted that because most reports of increased LDL were in studies where large amounts of fish oils were given (i.e., 5 g or more per day of EPA plus DHA), any safety concern relating to

changes in LDL cholesterol might be suitably addressed by restricting the intake of DHA and EPA (58 FR 2682 at 2705). As discussed below, the petitioner has suggested maximum use levels of menhaden oil for each food category in which menhaden oil can be used. Based on these levels, FDA has determined that the mean intake of menhaden oil, if menhaden oil were to be used at the maximum allowable level in all permitted food categories, would be less than 3 g of DHA and EPA per day. Further, menhaden oil would substitute for other dietary fats, some of which have similar effects on LDL cholesterol. Based on its evaluation, the agency concludes that the petitioned levels of menhaden oil are safe with respect to the effect on LDL cholesterol.

VI. Consumer Exposure

In September 1993, the petitioner amended the petition to include maximum use levels for menhaden oil in various food categories. Based on these levels, FDA estimated that the mean exposure to EPA and DHA from the use of menhaden oil in all food categories would be 2.8 g/p/d (Ref. 50). Although the petition originally included all potential food uses of menhaden oil, the petitioner subsequently requested that the use of menhaden oil in infant formula be withdrawn from consideration. Therefore, the exposure estimate does not include this potential use of menhaden oil.

VII. Iodine Numbers of Oils from Menhaden

When FDA affirmed hydrogenated and partially hydrogenated menhaden oils as GRAS based on their pre-1958 history of safe use in food, the agency included in the regulation a specification that the iodine number for partially hydrogenated menhaden oil be no more than 85. (Iodine number is a measure of the unsaturation of fats and oils, expressed in terms of centigrams of iodine absorbed per gram of sample.) The iodine number limit of 85 was chosen then because menhaden oil with an iodine number greater than 85 is not considered hardened, and only hardened oil had a documented history of common use in food before 1958 (54 FR 38219 at 38222). Moreover, corroborative toxicological studies submitted in the petition used oil with an iodine number no more than 85 (54 FR 38219 at 38222). The iodine number limit of 85 also ensured that the partially hydrogenated menhaden oil affirmed as GRAS at that time would contain no more than traces of EPA and DHA, and thus would not significantly increase the dietary intake of these substances, pending completion of the agency's evaluation of the safety of DHA and EPA as part of its review of the GRAS status of menhaden oil. By specifying this upper limit, the agency deferred its decision on the GRAS status of partially hydrogenated menhaden oil with an iodine number above 85.

The agency now concludes (as stated below), based on scientific procedures, that menhaden oil is GRAS, provided that daily intakes of EPA and DHA from menhaden oil do not exceed 3 g/p/d. The petitioner has provided information demonstrating that partially hydrogenated menhaden oil may have an iodine number up to 119. The agency finds that the use of partially hydrogenated menhaden oil with an iodine number up to 119 under conditions specified in current 21 CFR 184.1472 will not cause the total exposure to EPA and DHA from all types of menhaden oil to exceed 3 g/p/d (Ref. 50). Therefore, FDA concludes that partially hydrogenated menhaden oil with an iodine number between 86 and 119 is GRAS based on scientific procedures, and is raising the iodine number limit in the regulation for partially hydrogenated menhaden oil to 119. With this change, the iodine number range for partially hydrogenated menhaden oil will be 11 through 119 instead of 11 through 85.

The effect of the change in the iodine number range for partially hydrogenated menhaden oil will be to affirm as GRAS a substance that was not previously affirmed as GRAS (i.e., partially hydrogenated menhaden oil with an iodine number between 86 and 119), rather than to amend the specifications for a substance already affirmed as GRAS. Even if the change in the iodine number range is characterized as an amendment, however, the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) permits an agency to amend a regulation without notice and comment procedures when the agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest. Because notice of the filing of a petition seeking GRAS affirmation of menhaden oil and partially hydrogenated menhaden oil was given (51 FR 27461), and an opportunity for public comment on all issues relating to the petition, including iodine number ranges, was provided at that time, FDA finds that separate, additional notice and comment procedures on the specific issue of the iodine number range for partially hydrogenated menhaden oil are unnecessary. Therefore, the agency finds that there is good cause to proceed to final action without an opportunity for additional public comment on this issue.

VIII. Conclusions

FDA has evaluated the information in the petition and many published articles in scientific journals, along with other relevant information. Based on this evaluation, the agency finds that the use of menhaden oil as a direct food ingredient is safe, provided that daily intakes of EPA and DHA from menhaden oil do not exceed 3 g/p/d. As noted in section VI of this document, the petitioned uses of menhaden oil incorporate maximum use levels for menhaden oil in specific food categories to ensure that daily intakes of EPA and DHA from menhaden oil do not exceed 3 g/p/d. FDA has further determined that the many pertinent published human clinical studies provide an adequate basis to conclude that the safety of the petitioned uses of menhaden oil is generally recognized among the community of experts qualified by scientific training and experience to evaluate the safety of food ingredients. Therefore, the agency is affirming that the use of menhaden oil as a direct human food ingredient is GRAS with specific limitations (21 CFR 184.1(b)(2)). This GRAS affirmation is based on scientific procedures (21 CFR 170.30(b)). To ensure that only food-grade menhaden oil is used in food, FDA is including appropriate specifications in the regulation.

FDA further concludes, based on scientific procedures, that partially hydrogenated menhaden oil with an iodine number between 86 and 119 is GRAS with no limitation other than current good manufacturing practice. Therefore, the agency is increasing the iodine number limit for partially hydrogenated menhaden oil to 119.

IX. Environmental Impact

The agency is affirming that menhaden oil is generally recognized as safe (GRAS) as a direct human food ingredient with specific limitations. The agency is also affirming that partially hydrogenated menhaden oil with an iodine number between 86 and 119 is GRAS as a direct human food ingredient with no limitation other than current good manufacturing practice.

The agency has carefully considered the potential environmental effects of these actions. FDA has concluded that these actions will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an

environmental assessment, may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

X. Analysis of Impacts

FDA has examined the economic implications of the final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic impact of that rule on small entities.

FDA finds that this final rule is not a significant rule as defined by Executive Order 12866. This final rule recognizes the applicability of a statutory exemption. The impact of the rule is to remove uncertainty about the regulatory status of the petitioned substance. Accordingly, under the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities (Ref. 51).

XI. Effective Date

As this rule recognizes an exemption from the food additive definition in the Federal Food, Drug, and Cosmetic Act, and from the approval requirements applicable to food additives, no delay in effective date is required by the Administrative Procedure Act (5 U.S.C. 553(d)). The rule will therefore be effective immediately (5 U.S.C. 553(d)(1)).

XII. References

The following information has been placed on display with 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. Rodgers, R. P. C., and J. Levin, ''A Critical Reappraisal of the Bleeding Time,'' *Seminars in Thrombosis and Hemostasis*, 16:1–20, 1990.

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4. Blonk, M. C., H. J. G. Bilo, J. J. P. Nauta, C. Popp-Snijders, C. Mulder, and A. J. M. Donker, ''Dose Response Effects of Fish Oil Supplement in Healthy Volunteers,''*American Journal of Clinical Nutrition*, 52:120–127, 1990.

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6. Rogers, S., K. S. James, B. K. Butland, M. D. Etherington, J. R. O'Brien, and J. G. Jones, ''Effects of Fish Oil Supplement on Serum Lipids, Blood Pressure, Haemostasis and Rheological Variables,'' *Atherosclerosis*, 67:137–143, 1987.

7. Nelson, G. J., P. C. Schmidt, and L. Corash, ''The Effect of a Salmon Diet on Blood Clotting, Platelet Aggregation, and Fatty Acids in Normal Adult Men,''*Lipids*, 26:87–96, 1991.

8. Wander, R. C., and B. D Patton, ''Comparison of Three Species of Fish Consumed as a Part of a Western Diet: Effects on Platelet Fatty Acids and Function, Hemostasis, and Production of Thromboxane,''*American Journal of Clinical Nutrition*, 54:326–333, 1991.

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11. Sanders, T. A. B., V. Marquerite, and A. P. Haines, ''Effect on Blood Lipids and Haemostasis of a Supplement of Cod Liver Oil, Rich in Eicosapentaenoic and Docosahexaenoic Acids, in Healthy Young Men,'' *Clinical Science*, 61:317–324, 1981.

12. Goodnight, S. H., W. S. Harris, and W. E. Connor, ''The Effects of Dietary ω-3 Fatty Acids on Platelet Composition and Function in Man: A Prospective, Controlled Study,'' *Blood*, 58:880–885, 1981.

13. Fischer, S., and P. C. Weber, ''Prostaglandin I_3 is Formed *in vivo* in Man After Dietary Eicosapentaenoic Acid,'' *Nature*, 307:165–168, 1984.

14. Knapp, H. R., I. A. G. Reilly, P. Alessandrini, and G. A. FitzGerald, ''In vivo Indexes of Platelet and Vascular Function During Fish-oil Administration in Patients with Atherosclerosis,'' *New England Journal of Medicine*, 314:937–942, 1986.

15. Sanders, T. A. B., and F. Roshanai, ''The Influence of Different Types of ω-3 Polyunsaturated Fatty Acids on Blood Lipids and Platelet Function in Healthy Volunteers,'' *Clinical Science*, 64:91–99, 1983.

16. Schmidt, E. B., K. Varming, E. Ernst, P. Madsen, and J. Dyerberg, ''Dose-Response Studies on the Effect of n-3 Polyunsaturated Fatty Acids on Lipids and Haemostasis,'' *Thrombosis and Haemostasis*, 63:1–5, 1990.

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50. Memorandum, October 19, 1993, Michael DiNovi, FDA, Washington, DC to Lawrence Lin, FDA, Washington, DC.

51. Memorandum, May 16, 1997, William Hubbard, Associate Commissioner for Policy Coordination, FDA, Rockville, MD to Lawrence Lin, FDA, Washington, DC.

List of Subjects in 21 CFR Part 184

Food additives, Food ingredients, Incorporation by reference.

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: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. Section 184.1472 is revised to read as follows:

§ 184.1472 Menhaden oil.

(a) *Menhaden oil.* (1) Menhaden oil is prepared from fish of the genus *Brevoortia*, commonly known as menhaden, by cooking and pressing. The resulting crude oil is then refined using the following steps: Storage (winterization), degumming (optional), neutralization, bleaching, and deodorization. Winterization may separate the oil and produce a solid fraction.

(2) Menhaden oil meets the following specifications:

(i) *Color and state.* Yellow liquid to white solid.

(ii) *Odor.* Odorless to slightly fishy.

(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 Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(iv) *Iodine number.* Not less than 120 as determined by the American Oil Chemists' Society Recommended Practice Cd 1d–92—''Iodine Value of Fats and Oils, Cyclohexane—Acetic Acid Method,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a) (2) (iii) of this section.

(v) *Unsaponifiable matter.* Not more than 1.5 percent as determined by the American Oil Chemists' Society Official Method Ca 6b–53—''Unsaponifiable Matter'' (reapproved 1989), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a) (2) (iii) of this section.

(vi) *Free fatty acids.* Not more than 0.1 percent as determined by the American Oil Chemists' Society Official Method Ca 5a–40—''Free Fatty Acids''

(reapproved 1989), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a) (2) (iii) of this section.

(vii) *Peroxide value*. Not more than 5 milliequivalents per kilogram of oil as determined by the American Oil Chemists' Society Official Method Cd 8–53—''Peroxide Value, Acetic Acid—Chloroform Method'' (updated 1992) or Recommended Practice Cd 8b–90—''Peroxide Value, Acetic Acid—Isooctane Method'' (updated 1992), which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(viii) *Lead*. Not more than 0.1 part per million as determined by the American Oil Chemists' Society Official Method Ca 18c–91—''Determination of Lead by Direct Graphite Furnace Atomic Absorption Spectrometry'' (revised 1992), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(ix) *Mercury*. Not more than 0.5 part per million as determined by the method entitled ''Biomedical Test Materials Program: Analytical Methods for the Quality Assurance of Fish Oil,'' published in the ''NOAA Technical Memorandum NMFS–SEFC–211,'' F. M. Van Dolah and S. B. Galloway, editors, National Marine Fisheries Service, U. S. Department of Commerce, pages 71–88, November, 1988, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(3) In accordance with § 184.1(b)(2), the ingredient may be used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)
Cookies, crackers, § 170.3(n)(1) of this chapter.	5.0 percent
Breads, rolls (white & dark), § 170.3(n)(1) of this chapter.	1.0 percent
Fruit pies, custard pies, § 170.3(n)(1) of this chapter.	7.0 percent
Cakes, § 170.3(n)(1) of this chapter.	10.0 percent
Cereals, § 170.3(n)(4) of this chapter.	4.0 percent
Fats, oils, § 170.3(n)(12) of this chapter, but not in infant formula.	20.0 percent
Yogurt, § 170.3(n)(31) of this chapter.	4.0 percent
Cheese products, § 170.3(n)(5) of this chapter.	5.0 percent
Frozen dairy products, § 170.3(n)(20) of this chapter.	5.0 percent
Meat products, § 170.3(n)(29) of this chapter.	10.0 percent
Egg products, § 170.3(n)(11) of this chapter.	5.0 percent
Fish products, § 170.3(n)(13) of this chapter.	20.0 percent
Condiments, § 170.3(n)(8) of this chapter.	5.0 percent
Soup mixes, § 170.3(n)(40) of this chapter.	3.0 percent
Snack foods, § 170.3(n)(37) of this chapter.	5.0 percent
Nut products, § 170.3(n)(32) of this chapter.	5.0 percent
Gravies, sauces, § 170.3(n)(24) of this chapter.	5.0 percent

(b) *Hydrogenated and partially hydrogenated menhaden oils*. (1) Partially hydrogenated and hydrogenated menhaden oils are prepared by feeding hydrogen gas under pressure to a converter containing crude menhaden oil and a nickel catalyst. The reaction is begun at 150 to 160 °C and after 1 hour the temperature is raised to 180 °C until the desired degree of hydrogenation is reached. Hydrogenated menhaden oil is fully hydrogenated.

(2) Partially hydrogenated and hydrogenated menhaden oils meet the following specifications:

(i) *Color*. Opaque white solid.

(ii) *Odor*. Odorless.

(iii) *Saponification value*. Between 180 and 200.

(iv) *Iodine number*. Not more than 119 for partially hydrogenated menhaden oil and not more than 10 for fully hydrogenated menhaden oil.

(v) *Unsaponifiable matter*. Not more than 1.5 percent.

(vi) *Free fatty acids*. Not more than 0.1 percent.

(vii) *Peroxide value*. Not more than 5 milliequivalents per kilogram of oil.

(viii) *Nickel*. Not more than 0.5 part per million.

(ix) *Mercury*. Not more than 0.5 part per million.

(x) *Arsenic* (*as As*). Not more than 0.1 part per million.

(xi) *Lead*. Not more than 0.1 part per million.

(3) Partially hydrogenated and hydrogenated menhaden oils are used as edible fats or oils, as defined in § 170.3(n)(12) of this chapter, in food at levels not to exceed current good manufacturing practice.

(4) If the fat or oil is fully hydrogenated, the name to be used on the label of a product containing it shall include the term ''hydrogenated,'' or if it is partially hydrogenated, the name shall include the term ''partially hydrogenated,'' in accordance with § 101.4(b)(14) of this chapter.

Dated: May 22, 1997.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 658

[FHWA Docket No. 96–12]

RIN 2125–AEO4

Truck Size and Weight; National Network; North Carolina

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA has modified the National Network for commercial motor vehicles by adding a route in North Carolina. The National Network was