Street, Kansas City, Missouri 64106, Telephone (816) 426–3408.

SUPPLEMENTARY INFORMATION:

History

On May 30, 1989, the FAA published a Notice of Proposed Rulemaking which would amend § 71.181 of part 71 of the Federal Aviation Regulations so as to designate a transition area at Winterset, Iowa (54 FR 22913). Interested persons were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No objections were received as a result of the Notice of Proposed Rulemaking. Section 71.181 of part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6E dated January 3, 1989.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (FAR) designates a 700-foot transition area at Winterset, Iowa. To enhance airport usage, a new VOR/DME–A instrument approach procedure is being developed for the Winterset-Madison County Airport, Winterset, Iowa, utilizing the Des Moines VORTAC as a navigational aid. This navigational aid will offer new navigational guidance for aircraft utilizing the airport. The establishment of a new instrument approach procedure based on this navigational aid entails designation of a transition area at Winterset, Iowa, at and above 700 feet above ground level within which aircraft are provided air traffic control service. Transition areas are designed to contain IFR operations in controlled airspace during portions of the terminal operation and while transiting between the terminal and en route environment. The intended effect of this action is to ensure segregation of aircraft using the approach procedure under instrument flight rules (IFR) from other aircraft operating under visual flight rules (VFR). This action will change the airport status from VFR to IFR.

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 "major rule" under Executive Order 12291; (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

Aviation Safety, Transition areas.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 71 of the FAR (14 CFR part 71) is amended as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

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

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); 14 CFR 11.69.

§ 71.181 [Amended]

2. By amending § 71.181 as follows:

Winterset, IA [Revised]

That airspace extending upward from 700 ft. above the surface within a 5-mile radius of the Winterset-Madison County Airport (lat. 41°21'50" N., long. 94°01'15" W.), and within 2.5 miles each side of the 253° bearing from Winterset-Madison County Airport extending from the 5-mile radius to 6.5 miles southwest of the airport; excluding that portion which overlies the Des Moines, Iowa, transition area.

This amendment becomes effective at 0901 u.t.c., January 11, 1990.

Issued in Kansas City, Missouri, on August 15, 1989.

Clarence E. Newbern,

Manager, Air Traffic Division.

[FR Doc. 89–21808 Filed 9–14–89; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 97

[Docket No. 26002; Amdt. No. 1408]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: *Effective:* An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference—approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located; or
3. The Flight Inspection Field Office which originated the SIAP.

For Purchase—

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS–420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) prescribes new, amended, suspended, or revoke Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FARs). The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4,

and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form document is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment to part 97 is effective on the date of publication and contains separate SIAPs which have compliance dates stated as effective dates based on related changes in the National Airspace System or the application of new or revised criteria. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs is unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

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 "major rule" under Executive Order 1229; (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. For the same reason, the FAA certifies that this amendment 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 97

Approaches, Standard instrument, Incorporation by reference.

Issued in Washington, DC on August 31, 1989.

Robert L. Goodrich,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 g.m.t. on the dates specified, as follows:

PART 97—[AMENDED]

1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 1348, 1354(a), 1421, and 1510; 49 U.S.C. 106(g) (revised, Pub. L. 97–449, January 12, 1983); and 14 CFR 11.49(b)(2).

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

* * * *Effective November 16, 1989*

Ormond Beach, FL—Ormond Beach Muni, VOR RWY 8, Amdt. 10
Thomson, GA—Thomson-McDuffie County, VOR/DMA–A, Amdt. 1
Litchfield, IL—Litchfield Muni, NDB RWY 9, Amdt. 3
Litchfield, IL—Litchfield Muni, NDB RWY 27, Amdt. 5
Richmond, IN—Richmond Muni, VOR RWY 33, Orig.
Monticello, KY—Wayne County, NDB RWY 21, Amdt. 1
Murray, KY—Murray/Kyle-Oakley Field, NDB RWY 23, Amdt. 5
Rutherfordton, NC—Rutherford County, VOR RWY 36, Amdt. 3
Wauseon, OH—Fulton County, NDB RWY 27, Amdt. 6
Norwalk, OH—Norwalk-Huron County, VOR–A, Amdt. 4
Zanesville, OH—Zanesville Muni, VOR RWY 4, Amdt. 5
Zanesville, OH—Zanesville Muni, VOR/DME RWY 4, Orig.
Zanesville, OH—Zanesville Muni, NDB RWY 4, Amdt. 11, CANCELLED
Zanesville, OH—Zanesville Muni, NDB–A, Orig.
Lawton, OK—Lawton Muni, ILS RWY 35, Amdt. 4
Lawton, OK—Lawton Muni, RADAR–1, Amdt. 1
Lawton, OK—Lawton Muni, RADAR–2, Orig.
Lebanon, TN—Lebanon Muni, VOR/DME–A, Amdt. 6
Lebanon, TN—Lebanon Muni, NDB RWY 18, Amdt. 1
Winchester, TN—Winchester Muni, NDB RWY 18, Amdt. 4
Robstown, TX—Nueces County, VOR/DME–A, Orig.

* * * *Effective October 19, 1989*

Miami, FL—Miami Intl, NDB RWY 09L, Orig.
Miami, FL—Miami Intl, NDB RWY 27L, Orig.
Rome, GA—Richard B. Russell, LOC/DME BC RWY 19, Orig.
Bloomington/Normal, IL—Bloomington/Normal, VOR RWY 11, Amdt. 12
Mount Vernon, IL—Mount Vernon/Outland, VOR RWY 5, Amdt. 14
Mount Vernon, IL—Mount Vernon/Outland, VOR RWY 23, Amdt. 14
Mount Vernon, IL—Mount Vernon/Outland, ILS RWY 23, Amdt. 9
Indianapolis, IN—Indianapolis Intl, VOR RWY 14, Amdt. 23
Indianapolis, IN—Indianapolis Intl, NDB RWY 5L, Amdt. 19
Indianapolis, IN—Indianapolis Intl, NDB RWY 32, Amdt. 13
Indianapolis, IN—Indianapolis Intl, ILS RWY 5L, Amdt. 22
Indianapolis, IN—Indianapolis Intl, ILS RWY 14, Amdt. 2
Indianapolis, IN—Indianapolis Intl, ILS RWY 23R, Amdt. 6
Indianapolis, IN—Indianapolis Intl, ILS RWY 32, Amdt. 16
Indianapolis, IN—Indianapolis Intl, RADAR–1, Amdt. 27
Alexandria, MN—Chandler Field, NDB RWY 31, Amdt. 3
Holly Springs, MS—Holly Springs–Marshall County, VOR/DME 18, Amdt. 6
Jefferson City, MO—Jefferson City Meml., NDB RWY 12, Orig.
Scottsbluff, NE—William B. Heilig Field, VOR/DME or TACAN RWY 05, Amdt. 2
Scottsbluff, NE—William B. Heilig Field, VOR or TACAN RWY 23, Amdt. 10
Scottsbluff, NE—William B. Heilig Field, LOC BC RWY 12, Amdt. 6
Scottsbluff, NE—William B. Heilig Field, NDB RWY 12, Amdt. 6
Scottsbluff, NE—William B. Heilig Field, ILS RWY 30, Amdt. 8
Scottsbluff, NE—William B. Heilig Field, RNAV RWY 12, Amdt. 2
Scottsbluff, NE—William B. Heilig Field, RNAV RWY 30, Amdt. 3
McMinnville, TN—Warren County Memorial, NDB RWY 5, Amdt. 4, Cancelled
McMinnville, TN—Warren County Memorial, NDB RWY 23, Amdt. 4, Cancelled
Blackstone, VA—Blackstone AAF-Allen C. Perkinson Muni, NDB–A, Amdt. 10

Fredericksburg, VA—Shannon, NDB RWY 23, Orig.
Orange, VA—Orange County, NDB RWY 7, Orig.

** * * Effective August 31, 1989*

Winchester, VA—Winchester Regional, LOC RWY 32, Amdt. 2

** * * Effective August 23, 1989*

Martinsburg, WV—Eastern WV Regional/Shepherd Field, LOC/DME BC RWY 8, Amdt. 5

** * * Effective August 21, 1989*

Kansas City, MO—Kansas City Intl, ILS RWY 1, Amdt. 10

[FR Doc. 89-21812 Filed 9-14-89; 8:45 am]

BILLING CODE 4910-13-M

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: Hydrogenated and Partially Hydrogenated Menhaden Oils

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that hydrogenated and partially hydrogenated menhaden oils are generally recognized as safe (GRAS) for use as direct human food ingredients. This action is a partial response to a petition filed by the National Fish Meal and Oil Association.

EFFECTIVE DATE: September 15, 1989.

ADDRESSES: Background information on the environmental and economic effects and the references are on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Petition

In accordance with 21 CFR 170.35, the National Fish Meal and Oil Association, 2000 M St. NW., Suite 580, Washington, DC 20036, submitted a petition (GRASP 6G0316) seeking affirmation that the use of menhaden oil and partially hydrogenated menhaden oil as direct human food ingredients is GRAS. The petition includes information about the identity of, and manufacturing processes for, menhaden oil and partially hydrogenated menhaden oil; information about the history of human food use outside the United States of partially hydrogenated menhaden oil; final reports and published articles of long-term animal feeding studies with partially hydrogenated menhaden oil; and an extensive search of the published scientific literature (over 2,600 articles are included) 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 the Dockets Management Branch (address above). FDA received three comments, two from manufacturers and one from a government agency. All of the comments supported affirmation of GRAS status for use of the oils. In addition, one of the comments stated that menhaden oil that is fully hydrogenated is chemically very closely related to partially hydrogenated menhaden oil, and that it should also be affirmed as GRAS.

This final rule responds only to the portion of the petition requesting GRAS affirmation of the use of partially hydrogenated menhaden oil as an edible fat or oil and not to the portion pertaining to refined menhaden oil. Issues relevant to the GRAS status of refined menhaden oil will be dealt with in a future **Federal Register** document.

While there are similarities between partially hydrogenated and fully hydrogenated menhaden oils, these oils are quite different from refined menhaden oil. Refined menhaden oil contains a high proportion of polyunsaturated fatty acids with four, five, and six double bonds (about 32 percent). Among these fatty acids are the so-called "Ω-3 fatty acids" which are known to have physiological activities (Ref. 5). The activities attributable to the Ω-3 fatty acids may have potential health effects, such as effects on the synthesis of eicosanoids, on membrane fluidity, and on hemostasis (Ref. 5). In contrast, partially hydrogenated menhaden oil and fully hydrogenated menhaden oil have no Ω-3 fatty acids. FDA is currently evaluating the physiological activities attributable to the Ω-3 fatty acids. The agency will announce its determination on the GRAS status of the use of refined menhaden oil in the future document.

B. Basis for GRAS Status

Pursuant to 21 U.S.C. 321(s) and to 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 directly or indirectly added to food. The basis for 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 of the substance in food. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence that is required to obtain approval of a food additive. It must ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data and information. General recognition of safety through experience based on common use in food prior to January 1, 1958, may be established without the quantity or quality of scientific evidence required for approval of a food additive regulation but must be based upon generally available data and information

In the **Federal Register** of May 10, 1988 (53 FR 16544), FDA published a final rule that revised its procedural regulations to establish that general recognition among qualified experts of the safety of the use of a substance that was commonly used for that purpose in food before 1958 may be based upon experience derived from use of the substance in food outside the United States. The agency revised the definition of "common use in food" in 21 CFR 170.3(f) so that it would no longer stipulate that the history of consumption must have occurred in the United States.

In the same final rule, FDA added new paragraph (c)(2) to 21 CFR 170.30. This paragraph specifies the information that is required to establish that a substance is GRAS based on a history of common use in food when the use has occurred outside the United States. New 21 CFR 170.30(c)(2) requires documentation and corroboration of the history of common use in food. It states that the information about the use must be generally available and must describe the circumstances in which the substance was used. The information must establish that the use of the substance is safe. FDA elaborated on these requirements in the preamble to the document in which it proposed to make these changes in its regulations, which was published in the **Federal Register** of July 2, 1985 (50 FR 27294).

II. Partially Hydrogenated Menhaden Oil

A. Identity

Partially hydrogenated menhaden oil is prepared by hydrogenating menhaden oil. The partially hydrogenated oil contains no, or only a small amount of, polyunsaturated fatty acids that have five and six double bonds. For example, menhaden oil that has been hydrogenated to an iodine value of 84.5 was found to contain no eicosapentaenoic acid or docosahexaenoic acid, i.e., no Ω–3 fatty acids (Ref. 3). Thus, unlike menhaden oil partially hydrogenated menhaden oil does not possess the physiological properties attributable to Ω–3 fatty acids.

B. Manufacturing Process

Menhaden are plankton-feeding fish harvested commercially from the Gulf of Mexico and northward along the Atlantic coast of the United States. Most menhaden are less than 12 inches long and under 1 pound in weight.

Whole fish are cooked at about 96 °C for 8 to 10 minutes to coagulate the protein and rupture the fat cells. The cooked fish are then pressed, and the liquor is centrifuged to separate the oil and aqueous phases. Crude oil is often shipped abroad to food companies for further processing. Further processing may include storage (winterization), degumming (optional), neutralization, bleaching, deodorization, and hydrogenation.

Partially hydrogenated and fully 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 achieved. The degree of hydrogenation is controlled to obtain the desired firmness of the fat for use in various food products. Thus, the iodine value for partially hydrogenated menhaden oil is in the range of 10 to 149, as compared to that for menhaden oil which may have a range of 150 to 200.

C. Consumer Exposure

FDA estimated probable human consumption of partially hydrogenated menhaden oil (Ref. 3) based on the use of the oil proposed by the petitioner and on food consumption data from the 1977–1978 Market Research Corp. of America (MRCA) survey (Menu Census VI). FDA obtained the following 14-day average estimated daily intake (EDI) values (total sample basis—eaters plus noneaters): 11 grams (g) per person per day (mean) and 22 g per person per day (90th percentile) for the 2- to 5-year age class, and 13 g per person per day (mean) and 28 g per person per day (90th percentile) for the 2-year and over (all ages) age class.

D. Determination of GRAS Status

As stated earlier, the petitioner requested affirmation that partially hydrogenated menhaden oil is GRAS for general use as an edible fat or oil in food. The factors that have led FDA to conclude that the general food use of the oil is GRAS are:

1. The fatty acid composition of the oil is comparable to partially hydrogenated soybean oil;
2. There is a history of use of this substance in margarine and shortening in Europe prior to 1958; and
3. Animal studies (published and unpublished) are available to corroborate safety. A discussion of each of these factors follows.

1. The Fatty Acid Composition of the Oil

Partially hydrogenated menhaden oil consists mostly of fatty acids with 0, 1, 2, or 3 double bonds (Refs. 8a and 8b). It does not contain the physiologically active Ω–3 fatty acids. The oil is qualitatively comparable to partially hydrogenated common edible vegetable oils, such as partially hydrogenated soybean oil, that have a long history of safe use in this country. In a 100 g sample, partially hydrogenated menhaden oil has 33.1 g of saturated fatty acids, 37.7 g of monounsaturated fatty acids, and 28.3 g of polyunsaturated fatty acids. A similarly sized sample of partially hydrogenated soybean oil contains 19.5 g saturated fatty acids, 58.3 g monounsaturated fatty acids, and 25.3 g polyunsaturated fatty acids (Ref. 9c, page 25). Moreover, animal feeding studies show that partially hydrogenated menhaden oil and partially hydrogenated vegetable oil are biologically comparable (Ref. 9c). Thus, the minor quantitative differences in fatty acid content between the two types of oils are insignificant.

When oils containing unsaturated fatty acids are partially hydrogenated, some of the unsaturated oils are converted into *trans* unsaturated fatty acids. In the past, some concern was expressed over the human consumption of *trans* unsaturated fatty acids. When agency scientists evaluated the data in the petition on partially hydrogenated menhaden oil, they found that this oil contains about 27 percent *trans* unsaturated fatty acids. Because this level of *trans* unsaturated fatty acids is comparable to that found in some partially hydrogenated edible oils (25 percent) (Ref. 3), the agency concludes that there is no basis for a safety concern. This conclusion is consistent with that rendered by a review panel of the Federation of American Societies for Experimental Biology. This panel was asked by FDA to review the safety of *trans* unsaturated fatty acids. Upon completion of its review, the panel stated that the available scientific information suggests little reason for concern about the safety of *trans* unsaturated fatty acids at their present and expected levels of consumption (Ref. 7).

2. The History of Use in Margarine and Shortening

Partially hydrogenated menhaden oil has not been used in food in the United States, but it has been used in the production of margarine and shortening in Europe, particularly in the United Kingdom, since at least the 1940's (Refs. 1 and 2). In Europe, it is the custom in making margarine to blend together four or more different kinds of oil possessing different degrees of hardness or hydrogenation (Ref. 1). Among them are hardened fish oils derived from pilchard oil, sardine oil, and menhaden oil. In 1945, for example, the British margarine industry produced 406,000 tons of margarine using arachis oil, palm kernel oil, and hardened fish oils (including partially hydrogenated menhaden oil and hydrogenated menhaden oil) as starting materials (Ref. 2).

The petition contains information concerning the amount of hardened menhaden oils used in Belgium, Holland, Sweden, the United Kingdom, and West Germany in 1956, 1958, 1960, 1971, 1981, and 1983. ("Hardened menhaden oils" refers to partially hydrogenated menhaden oil and hydrogenated menhaden oil.) The available information thus demonstrates that hardened menhaden oils have been used in Europe in margarine and shortening continuously from the 1940's to the present.

The use of the hardened fish oils in Europe for decades has produced no evidence of an associated hazard. Therefore, the published information about the use in Europe of hardened menhaden oils in margarine and shortening provides an appropriate basis to find that these uses of partially hydrogenated and hydrogenated menhaden oils are GRAS. Moreover, there is nothing in this history of common use that would lead an expert to question the safety of these substances for general use as a fat or oil.

3. Animal Studies

As stated above, food ingredients may be affirmed as GRAS on the basis of scientific procedures. Such an affirmation requires some of the safety information be published so that it is available to scientists capable of making an independent judgment about the GRAS status of the ingredient. The published information, however, may be corroborated by unpublished information.

Four animal feeding studies are available on the safety of the use of partially hydrogenated menhaden oil in food. In these studies, a common edible vegetable oil (soybean) was used for comparison of biological effects. Three articles have been published in scientific journals based on one of these studies (Refs. 9a, 9b, and 9c). The studies include:

(1) A two-generation reproduction study with teratology phase in rats (International Research and Development Corp. (IRDC) Study No. 477–022);

(2) A long-term dietary study in rats exposed in utero (IRDC Study No. 477–001);

(3) A lifetime feeding study entitled "A Comparison of Partially Hydrogenated Fish Oils, Partially Hydrogenated Soybean Oil and Rapeseed Oil, Included at High Levels in the Feed of Rats (*In Utero* Exposed) for a Lifespan Period (107 weeks), With Particular Reference to Cardiac Histology and Relative Longevity" (Refs. 9a, 9b, and 9c) (Life Science Research (LSR) Report No. 80/1AF002/394); and

(4) A 12-month dietary safety assessment study in dogs (IRDC Study No. 511–002).

These studies have been reviewed by the agency (Ref. 4) and are summarized as follows:

In the two-generation reproduction study (IRDC Study No. 477–022), before mating, parental male and female Sprague-Dawley rats were treated for 70 and 28 days, respectively, with either a semisynthetic diet containing 8 percent partially hydrogenated menhaden oil or 4 percent partially hydrogenated menhaden oil plus 4 percent partially hydrogenated soybean oil. Two control groups were used in this study. One control group was fed Purina Chow (5.5 percent corn oil), and the other was fed a semisynthetic diet with 8 percent partially hydrogenated soybean oil.

Animals from the first mating (F1a) were selected for a lifetime feeding study (IRDC Study No. 477–001), which is discussed below. Animals from the second mating (F1b) of the parental rats were weaned and at the appropriate age allowed to mate to produce the F2a litter, which provided representative animals for either histopathological or teratological examinations. A second mating of the F1b animals produced fetuses that were subjected to a complete teratologic evaluation.

The data from this study show that Sprague-Dawley rats that were fed partially hydrogenated soybean oil, partially hydrogenated menhaden oil, or a mixture of the two in the semisynthetic diets had reduced fertility in both generations when compared to the control rats that were fed Purina Chow only. These effects related to the oil content of the diets rather than to any particular oil. No differences were found between rats fed partially hydrogenated menhaden oil and those fed other food oils.

As stated above, Sprague-Dawley rats of the F1a generation of animals in IRDC Study No. 477–022 were used in the long-term dietary study with in utero exposure (IRDC Study 477–001). The diets fed to these animals were: (1) A Purina Chow control; (2) 16 percent partially hyrogenated soybean oil; (3) 8 percent partially hydrogenated menhaden oil plus 8 percent partially hydrogenated soybean oil; and (4) 16 percent partially hydrogenated menhaden oil. The fish oils were admixed in a semisynthetic purified diet that contained 4 percent corn oil, thereby giving a total oil content of 20 percent in the experimental diets.

There were no changes in hematology, biochemistry, urinalysis, or organ weights that indicated an effect caused by the feeding of the oil diet mixtures. Evaluation of cardiac tissues at day 4, after 6 months, and upon termination of the study showed that, when compared to Purina Chow controls, animals from all oil treatment groups had minor but insignificant changes in cardiac tissue status.

Histological evaluation of this study at termination showed a high incidence of myelogenous leukemia among male rats ingesting oil-supplemented diets when compared to those fed the Purina Chow diet. Only a few female rats were observed with this neoplasia. The agency's Cancer Assessment Committee requested clarification regarding both the diagnosis and frequency of this lesion from the sponsor. After reviewing this additional information, the committee concluded that the diagnostic criteria for myelogenous leukemia used by the testing laboratory pathologists were appropriate (Ref. 4).

The Cancer Assessment Committee further concluded that there was no difference in myelogenous leukemia rates between the group that received partially hydrogenated menhaden oil and the group that received partially hydrogenated soybean oil. Myelogenous leukemia was apparently related to the high fat content in the test diets.

Myelogenous leukemia is relatively uncommon in Sprague-Dawley rats under conditions employing a "typical" dietary regimen. While there has been no previous indication that diet alters the incidence of myelogenous leukemia in rats, there is evidence that high dietary fat or increased caloric intake can alter the spontaneous levels of neoplasia at other sites, such as the endocrine glands, pancreas, and liver, in some strains of rats (Ref. 6).

Since oils from some species of fish are high in C_{22} monoene fatty acid (cetoleic acid), the life-time feeding study (LSR Report No. 80/1AF002/394) was designed to test for possible cardiotoxic effects of fish oils and rapeseed oil containing different levels and types of C_{22} monoenes. The C_{22} monoene content of the oils used in this study was as follows:

1. A refined rapeseed oil—1 percent C_{22} monoene;

2. Partially hydrogenated soybean oil—0 percent C_{22} monoene;

3. Partially hydrogenated menhaden oil—4 percent C_{22} monoene;

4. Partially hydrogenated capelin oil—14 percent C_{22} monoene (selected because of the high cetoleic acid content of this fish oil); and

5. Partially hydrogenated fish oils—9 percent C_{22} monoene (a mixture of No. 3 and No. 4).

The Wistar rats used in this study were the offspring of parents who were fed the above-mentioned oils incorporated into a semipurified diet at 8 percent, along with a corn oil and linseed oil mixture (providing some essential fatty acids) at 4 percent. The total oil content of the parental diets was 12 percent.

The presence of 8 percent partially hydrogenated menhaden oil, partially hydrogenated capelin oil, or partially hydrogenated fish oils had no effect on the mating performance and fertility of Wistar rats when compared to rats fed 8 percent partially hydrogenated soybean oil or refined rapeseed oil.

Offspring were weaned and fed the same types of diets as were fed their parents with the exception that the total oil content of the diets was 20 percent (16 percent of the above-mentioned oils plus 4 percent of the corn oil and linseed oil mixture).

There was essentially no difference in food consumption, body weight, mortality, or hematology between the offspring fed partially hydrogenated fish

oils as compared to those fed vegetable oils. There was no evidence of cardiotoxic effects from the ingestion of partially hydrogenated menhaden oil when compared to controls. In addition, there were no long-term effects observed during this study.

In the 12-month dietary study (IRDC Study No. 511–002), male and female dogs were fed a special certified canine diet as one control and 16 percent partially hydrogenated soybean oil as another control. Treated animals were fed either 8 percent partially hydrogenated menhaden oil plus 8 percent partially hydrogenated soybean oil or 16 percent partially hydrogenated menhaden oil.

There was a slight increase in the frequency of mild lipid infiltration in the right ventricle of the heart of females in all groups that were fed partially hydrogenated menhaden oil or partially hydrogenated soybean oil. However, such increases of neutral fat are usually seen in well-nourished animals, and there was no basis to associate them with the source of oil fed in this study.

In summary, review of two chronic studies of rats exposed in utero, the two-generation reproduction study in rats, and the 12-month dog study revealed no toxic effects attributable to the ingestion of partially hydrogenated menhaden oil.

E. Specifications

The petitioner requested a specification for partially hydrogenated menhaden oil of an iodine number between 10 and 149. However, the agency has included in the regulation a specification that the iodine number be no more than 85. FDA has done so based on the fact that menhaden oil that has an iodine number greater than 85 would not be considered hardened. There is no basis to find that menhaden oil that is not hardened was in common use in Europe before 1958 (Refs. 1 and 2). Furthermore, the menhaden oil that was used in the toxicological studies submitted in the petition did not have an iodine number above 85 (Ref. 4).

The specifications for arsenic and lead suggested by the petitioner are significantly higher than those that FDA has included in the regulation. FDA has selected specifications that set lower limits for two reasons. First, these specifications are more comparable with similar specifications adopted for common edible oils such as soybean oil that are included in the "Food Chemicals Codex," 3d Ed., 2d Supp., 1986. Second, the petitioner does not provide a basis for concluding that higher limits for arsenic and lead are necessary.

III. Hydrogenated Menhaden Oil

As stated above, one comment suggested that fully hydrogenated menhaden oil should be affirmed as GRAS. When hydrogenation of menhaden oil is allowed to go to completion, fully hydrogenated menhaden oil (or hydrogenated menhaden oil) is obtained. As stated above, fully hydrogenated menhaden oil is a component of the hardened menhaden oil that has a history of safe use in margarine and shortening in Europe since before 1958 (Refs. 1 and 2).

Hydrogenated menhaden oil is chemically very closely related to partially hydrogenated menhaden oil. Hydrogenated menhaden oil has the same kind of fatty acids as those in partially hydrogenated menhaden oil, except that hydrogenated menhaden oil has a smaller amount of double bonds. The iodine value for hydrogenated menhaden oil is therefore below 10. Hydrogenated menhaden oil is similar to saturated fatty acids from beef tallow or coconut oil, except that it contains some longer chain fatty acids (C_{20} and C_{22}) that are of no significance with regard to human metabolism.

IV. Conclusions

Having evaluated the information in the petition along with other available information, the agency concludes that the use of partially hydrogenated menhaden oil as an edible fat or oil can be affirmed as GRAS. The agency is basing this conclusion on the chemical similarity between partially hydrogenated menhaden oil and partially hydrogenated common edible vegetable oils such as partially hydrogenated soybean and corn oil, which have a long history of broad, safe food use in this country and on the established history of use in Europe of partially hydrogenated menhaden oil in margarine and shortening, foods which have a broad pattern of use in the human diet, as well as on the published articles and other data on the use of partially hydrogenated menhaden oil as an edible fat or oil. Taken together, this widely available information provides the basis for a consensus among qualified experts that, based on its history of safe use in food, this ingredient is safe for use as an edible fat or oil.

The agency is also affirming that the use of hydrogenated menhaden oil is GRAS. This oil is chemically similar to partially hydrogenated menhaden oil. In addition, it has always been present in hardened mehaden oils that have a history of safe use in food (Refs. 1 and 2). The published and unpublished animal studies also support its safety. These factors lead FDA to conclude that GRAS affirmation for the use of this substance as an edible fat oil is justified.

The agency further concludes that although hydrogenated menhaden oil is very closely related to partially hydrogenated menhaden oil, it should be identified separately in the regulations set forth below. If the oil is completely hydrogenated, the label of a product that contains the oil shall use the term "hydrogenated" rather than "partially hydrogenated" (21 CFR 101.4(b)(14)).

Therefore, the agency is affirming that the use of partially hydrogenated and hydrogenated menhaden oils as food oils is GRAS under conditions of current good manufacturing practice (21 CFR 184.1(b)(1)).

V. Environmental Effects

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action 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 (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VI. Economic Effects

FDA, in accordance with the Regulatory Flexibility Act, has considered the effects that this regulation would have on small entities, including small businesses, and has determined that the effect of this regulation is to provide for the use of partially hydrogenated menhaden oil for both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, the agency has analyzed the economic effects of this final rule and has determined that this rule will not be a major rule as defined by that Order.

The agency's finding of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

VII. References

The following references have been placed on display in 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. Crump, G. B., "The Technology of Margarine Manufacture," R. T. Holman, W. O. Lundberg, and T. Malkin (eds), *Progress in the Chemistry of Fats and Other Lipids*, Pergamon Press, New York, NY, pp. 285–321 (1958).
2. Waterman, H. I., *The Hydrogenation of Fatty Oils*, Elsevier Publishing Co., New York, NY, pp. 25–27 (1951).
3. Memorandum dated June 6, 1988, from Michael A. Adams, FDA, to L. Lin, FDA, Re: Chemistry Review of the Petition.
4. Memorandum dated September 6, 1988, from Stuart L. Graham, FDA, to Lawrence Lin, FDA, Re: Toxicological Review of the Petition.
5. Klasing, S. A., and S. M. Pilch, "Review of Epidemiological and Clinical Evidence on the Role of *omega*-3 Fatty Acids in Health and Disease," in Quick Response Report No. 3, Federation of American Societies for Experimental Biology, Bethesda, MD, June 1986.
6. Committee on Diet, Nutrition, and Cancer, "Diet, Nutrition, and Cancer," National Academy Press, Washington, DC, 1982.
7. Senti, F. R., "Health Aspects of Dietary *Trans* Fatty Acids," Federation of American Societies for Experimental Biology, Bethesda, MD, August 1985.

8a. Sebedio, J. L., and R. G. Ackman, "Hydrogenation of Menhaden Oil: 1. Fatty Acid and C_{20} Monoethylenic Isomer Compositions as a Function of the Degree of Hydrogenation," *Journal of American Oil Chemists Society*, 60: 1986–1991, 1983.

8b. Sebedio, J. L., and R. G. Ackman, "Hydrogenation of Menhaden Oil: 2. Formation and Evaluation of Dienoic and Trienoic Fatty Acids as a Function of the Degree of Hydrogenation," *Journal of American Oil Chemists Society*, 60: 1992–1996, 1983.

9a. Barlow, S. M., and I. F. Duthie, "A Brief Evaluation of the Safety of Partially Hydrogenated Marine Oils in the Human Diet. 1. Cardiac Lipidosis Phenomenon in Experimental Animals," *Nutrition Abstracts and Review in Clincial Nutrition*, 54: 17–30, 1984.

9b. Duthie, I. F., and S. M. Barlow, "An Evaluation of the Safety of Partially Hydrogenated Marine Oils in the Human Diet. 2. Longer Term Cardiac Lesion Phenomenon in Experimental Animals," *Nutrition Abstracts and Review in Clinical Nutrition*, 54: 89–97, 1984.

9c. Duthie, I. F., S. M. Barlow, R. Ashby, J. M. Tesh, J. C. Whitney, A. Saunders, E. Chapman, K. R. Norum, H. Svaar, and J. Opstvedt, "Feeding of Partially Hydrogenated Fish Oils to Rats in Comparison with Partially Hydrogenated Soybean Oil and Refined Rapeseed Oil," *Acta Medica Scandinavica*, Supplementum 726: 1–89, 1988.

List of Subjects in 21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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: Sections 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

2. New § 184.1472 is added to subpart B to read as follows:

§ 184.1472 Hydrogenated and partially hydrogenated menhaden oils.

(a) 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.

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

(1) *Color.* Opaque white solid.

(2) *Odor.* Odorless.

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

(4) *Iodine number.* Not more than 85 for partially hydrogenated menhaden oil and not more than 10 for fully hydrogenated menhaden oil.

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

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

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

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

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

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

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

(c) 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.

(d) 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: August 18, 1989.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–21783 Filed 9–14–89; 8:45 am]

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21 CFR Parts 430 and 453

[Docket No. 89N–0202]

Antibiotic Drugs; Clindamycin Phosphate Gel

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new dosage form of clindamycin phosphate, clindamycin phosphate gel. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective October 16, 1989; comments, notice of participation, and request for hearing by October 16, 1989; data, information, and analyses to justify a hearing by November 14, 1989.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4290.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) as amended, with respect to a request for approval of a new dosage form of clindamycin phosphate, clindamycin phosphate gel. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended by adding new paragraphs (a)(95) and (b)(97) to 21 CFR 430.5, by adding new paragraph (b)(97) to 21 CFR 430.6, by redesignating 21 CFR 453.522 as 21 CFR 453.522a, and by adding new 21 CFR 453.522 and 453.522b