17676, April 10, 1998), and by adding a new airworthiness directive (AD), Amendment 39–14510, to read as follows:

2006–06–02 Eurocopter France: Amendment 39–14510. Docket No. FAA–2005–23159; Directorate Identifier 2005–SW–10–AD. Supersedes AD 98–08–14, Amendment 39–10463, Docket No. 97–SW–21–AD.

Applicability: Model SA–365N, SA365N1, AS–365N2, and SA–366G1 helicopters with a main gearbox (MGB) suspension diagonal cross-member (diagonal cross-member), part number (P/N) 365A38–3023–20, –21, –22, –23, or –24, installed, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the diagonal cross-member, pivoting of the MGB, severe vibrations, and subsequent forced landing, do the following:

(a) For Model SA–365N and SA–365N1 helicopters, before accumulating 15,000 operating cycles; and for Model AS–365N2 and SA–366G1 helicopters, before accumulating 11,000 operating cycles:

(1) Inspect the diagonal cross-member for a crack in the area of the center borehole. Use a borescope with a 90-degree drive, a video assembly with optical fiber illumination, or any other appropriate device that allows you to visually inspect the center area of the part.

(2) Repeat the inspection required by paragraph (a)(1) of this AD at intervals not to exceed 250 operating cycles or 50 hours time-in-service, whichever occurs first.

Note 1: ''Operating cycles'' are defined in the Airworthiness Limitations Section of the Master Servicing Recommendations.

(b) If a crack is found as a result of the inspections required by this AD, before further flight, replace the diagonal cross-member with an airworthy diagonal cross-member.

(c) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Rotorcraft Directorate, FAA, ATTN: Gary Roach, Aviation Safety Engineer, Regulations and Guidance Group, Fort Worth, Texas 76193–0111, telephone (817) 222–5130, fax (817) 222–5961, for information about previously approved alternative methods of compliance.

(d) This amendment becomes effective on April 17, 2006.

Note 2: The subject of this AD is addressed in Direction Generale De L-Aviation Civile (France) AD 1997–093–041(A) R2, dated June 25, 2003, and 2003–241(A), dated June 25, 2003.

Issued in Fort Worth, Texas, on March 1, 2006.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 06–2358 Filed 3–10–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 1991F–0457] (formerly Docket No. 91F–0457)

Food Additives Permitted For Direct Addition to Food for Human Consumption; Glycerides and Polyglycides

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a mixture of glycerides and polyethylene glycol mono- and di-esters of fatty acids of hydrogenated vegetable oils as an excipient in dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure. This action is in response to a petition filed by Gattefosse Corp.

DATES: This rule is effective March 13, 2006. Submit written or electronic objections and requests for a hearing by April 12, 2006. See section VII of this document for information on the filing of objections. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 as of March 13, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 1991F–0457, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Raphael A. Davy, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1272.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of December 19, 1991 (56 FR 65907), FDA announced that a food additive petition (FAP 9A4155) had been filed by Parexel International Corp., One Alewife Place, Cambridge, MA 02140 on behalf of Gattefosse S.A., Saint-Priest, France. The petition proposed to amend the food additive regulations to provide for the safe use of a mixture of glycerides and polyethylene glycol esters of fatty acids of vegetable origin as an excipient in vitamin tablets and liquid formulations. Subsequently, in a letter dated January 7, 1998, the petitioner informed the agency that the petition was being amended by narrowing the polyethylene glycol esters (commonly known as polyglycides) to one class of compounds, namely, the polyethylene glycol esters of fatty acids from hydrogenated vegetable oils. Further, under an e-mail dated October 5, 2005, the petitioner later clarified that the additive was intended for use as an excipient in all dietary supplement tablets, capsules, and liquid formulations that are intended for

ingestion in daily quantities measured in drops or similar small units of measure.

In evaluating the safety of the petitioned substance, FDA has reviewed the safety of the additive (glycerides and polyglycides mixture) and the chemical impurities that may be present in the additive as a result of the manufacturing process. The mono-, di-, and triglycerides component of the additive are commonly found in food. In addition, mono-, and di-glycerides are affirmed as generally recognized as safe (GRAS) for use in food (§ 184.1505 (21 CFR 184.1505)). The ''polyglycides,'' consist of mono- and di-esters of polyethylene glycol, made using fatty acids derived from hydrogenated oils of vegetable origin. Although the additive itself (glycerides and polyglycides mixture) has not been shown to cause cancer, it may contain minute amounts of carcinogenic residues resulting from the manufacture of the polyethylene glycol. In particular, the additive may contain traces of 1,4-dioxane and ethylene oxide, which have been shown to cause cancer in test animals.

II. Determination of Safety

Under the general safety standard in section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additives anticancer, or Delaney, clause of the act (section 409(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is evaluated properly under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

III. Safety of the Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive as an excipient in dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure will result in an estimated average daily intake of no more than 720 milligrams per person per day (mg/p/d) of polyglycides, based on the consumption of 2 dietary supplement doses per day and assuming that the polyglycide portion comprises 75 percent of the total excipient in the dose (Ref. 1). Although the filing notice specifically referenced vitamin tablets and liquid formulations only, this estimate considered use of the additive in all dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure, due to the petitioner's clarification of the additive's intended use. The estimate is conservative as it assumes that all dietary supplements would be formulated with the additive. This estimate does not include the daily intake of the glycerides because glycerides are GRAS for use with no limit other than current good manufacturing practice (§ 184.1505).

Based on the available toxicological data on this new food additive mixture, and considering the cumulative exposure of the components of the mixture from the use of other ingredients, the agency concludes that the estimated dietary exposure to polyglycides resulting from the petitioned use of this additive is well within an acceptable margin of safety.

FDA has evaluated the safety of this additive under the general safety standard, considering all available toxicological data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by 1,4-dioxane and ethylene oxide, the carcinogenic chemicals that may be present as impurities in the additive. The risk evaluation of 1,4-dioxane and ethylene oxide has two aspects: (1) Assessment of exposure to the impurities from the petitioned use of the additive and (2) extrapolation of the risk observed in the animal bioassays to the conditions of exposure to humans.

A. 1,4-Dioxane

FDA has estimated the exposure to 1,4-dioxane from the petitioned use of the additive as an excipient in dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure to be 800 nanograms per person per day (ng/p/d) (Ref. 1). This estimate is conservative as it was based on the assumptions that the additive (glycerides and polyglycides mixture) would be the sole excipient in all dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure, and that the additive would be used in all dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure at a maximum practical 80 percent use level.

The agency used data from a carcinogenesis bioassay on 1,4-dioxane, conducted by the National Cancer Institute, to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The results of the bioassay on 1,4-dioxane demonstrated that the material was carcinogenic for female rats under the conditions of the study. The authors reported that the test material caused significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

Based on the agency's estimate that exposure to 1,4-dioxane will not exceed 800 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from exposure to 1,4-dioxane resulting from the petitioned use of the subject additive is 2.8×10^{-8} or 28 in 1 billion. Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to 1,4-dioxane is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk is also likely to be substantially less than the estimated upper-bound limit of lifetime human risk. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to 1,4-dioxane would result from the petitioned use of the additive.

B. Ethylene Oxide

FDA has estimated the exposure to ethylene oxide from the petitioned use of the additive as an excipient in dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure to be 80 ng/p/d, using the same

additive exposure assumptions described above for 1,4-dioxane (Ref. 1).

The agency used data from a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, Germany, to estimate the upper-bound limit of lifetime human risk from exposure to ethylene oxide resulting from the petitioned use of the additive. The authors reported that the test material caused significantly increased incidence of squamous cell carcinomas of the forestomach and carcinomas in situ of the glandular stomach in female rats.

Based on the agency's estimate that exposure to ethylene oxide will not exceed 80 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from exposure to ethylene oxide resulting from the petitioned use of the subject additive is 15×10^{-8} or 150 in 1 billion. Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to ethylene oxide is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk is also likely to be substantially less than the estimated upper-bound limit of lifetime human risk. Therefore, FDA concludes that there is reasonable certainty that no harm from exposure to ethylene oxide would result from the petitioned use of the additive.

C. Need for Specifications

Because 1,4-dioxane and ethylene oxide are animal carcinogens and because the additive is intended to be ingested in its entirety, the agency has concluded that specifications are necessary to ensure that safe levels of 1,4-dioxane and ethylene oxide impurities in the petitioned food additive are maintained in future batches. Thus, the agency is including in this regulation a specification limit of not greater than 10 parts per million (ppm) for 1,4-dioxane and not greater than 1 ppm for ethylene oxide. We are also including in this regulation specifications for total ester content, acid value, hydroxyl value, and lead in order to ensure that the product in the marketplace reflects the identity and purity of the material evaluated (Ref. 2).

IV. Conclusion

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the food additive as an excipient in dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure is safe. Therefore, the regulations in 21 CFR part 172 should be amended as set forth in this document.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Environmental Impact

The agency has carefully considered the potential environmental effects of this final rule. 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 Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Division of Dockets Management and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated January 22, 2004, from the Division of Biotech and GRAS Notice Review to Division of Petition Review, ''FAP 9A4155: Gattefosse Corp. Polyglycides From Hydrogenated Vegetable Oils. Revised Estimate of Exposure for 1,4-Dioxane and Ethylene Oxide.''

2. Memorandum dated October 30, 1998, from Chemistry Review Branch to the Division of Product Policy, ''FAP 9A4155: (MATS Milestone 2.3) American Clinical Research Consultants, Inc., on behalf of Gattefosse S.A. Polyglycides for use as Tablet Excipients. Submission of 1–7–98.''

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Section 172.736 is added to subpart H to read as follows:

§ 172.736 Glycerides and polyglycides of hydrogenated vegetable oils.

The food additive glycerides and polyglycides of hydrogenated vegetable oils may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is manufactured by heating a mixture of hydrogenated oils of vegetable origin and polyethylene glycol in the presence of an alkaline catalyst followed by neutralization with any acid that is approved or is generally recognized as safe for this use to yield the finished product.

(b) The additive consists of a mixture of mono-, di- and tri-glycerides and polyethylene glycol mono- and di-esters of fatty acids (polyglycides) of hydrogenated vegetable oils and meets the following specifications:

(1) Total ester content, greater than 90 percent as determined by a method entitled ''Determination of Esterified Glycerides and Polyoxyethylene Glycols,'' approved November 16, 2001, printed by Gattefosse S.A.S., and incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Office of Food Additive Safety, 5100 Paint Branch Pkwy., College Park, MD 20740 or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(2) Acid value, not greater than 2, and hydroxyl value, not greater than 56 as determined by the methods entitled ''Acid Value,'' p. 934 and ''Hydroxyl Value,'' p. 936, respectively, in the Food Chemicals Codex, 5th ed., effective January 1, 2004, and incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academies Press, 500 Fifth St. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(3) Lead, not greater than 0.1 mg/kg as determined by the American Oil Chemists' Society (A.O.C.S.) method Ca 18c–91, ''Determination of Lead by Direct Graphite Furnace Atomic Absorption Spectrophotometry,'' updated 1995, and incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from American Oil Chemists' Society, P. O. Box 3489, Champaign, IL 61826–3489, or may be examined in the library at the Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(4) 1,4-Dioxane, not greater than 10 milligrams per kilogram (mg/kg), and ethylene oxide, not greater than 1 mg/kg, as determined by a gas chromatographic method entitled ''Determination of Ethylene Oxide and 1,4-Dioxane by Headspace Gas Chromatography,'' approved November 5, 1998, printed by Gattefosse S.A.S., and incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51; see paragraph (b)(1) of this section for availability of the incorporation by reference.

(c) The additive is used or intended for use as an excipient in dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure.

Dated: March 2, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–2354 Filed 3–10–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–06–006]

RIN 1625–AA09

Drawbridge Operation Regulations; Jamaica Bay and Connecting Waterways, New York City, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard has temporarily changed the regulation governing the operation of the New York City Highway Bridge (Belt Parkway), at mile 0.8, across Mill Basin, at New York City, New York. This temporary final rule allows the bridge owner to open only one of the two moveable spans for the passage of vessel traffic from March 8, 2006 through September 7, 2006. This rule is necessary to facilitate bridge deck replacement.

DATES: This temporary rule is effective from March 8, 2006 through September 7, 2006.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD01–06–006] and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Leung-Yee, Project Officer, First Coast Guard District, (212) 668–7195.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On January 30, 2006, we published a notice of proposed rulemaking (NPRM) entitled ''Drawbridge Operation Regulations''; Jamaica Bay and Connecting Waterways, New York, in the **Federal Register** (71 FR 4852). We received no comments in response to the notice of proposed rulemaking. No public hearing was requested and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Making this rule effective in less than 30 days after publication in the **Federal Register** will allow this rule to become effective in time for the March 8, 2006, deck replacement construction start date.

The deck replacement for the New York City Highway Bridge is vital necessary work that must be performed without delay as a result of deterioration of the existing bridge deck which could fail if not replaced with all due speed. In order to assure the continued safe and reliable operation of the bridge, construction work should begin on schedule on March 8, 2006.

Background and Purpose

The New York City Highway Bridge (Belt Parkway), has a vertical clearance of 34 feet at mean high water and 39 feet at mean low water in the closed position. The existing regulations are listed at 33 CFR 117.795(b).

The owner of the bridge, New York City Department of Transportation (NYCDOT), requested a temporary change to the drawbridge operation regulations to facilitate the replacement of the bridge roadway deck.