poultry, fat at 0.08 ppm; poultry, liver at 0.03 ppm; poultry, muscle at 0.01 ppm; sheep, liver at 0.60 ppm; sheep, kidney at 0.60 ppm; sheep, muscle at 0.10 ppm; sheep, fat at 0.80 ppm. Independently validated analytical methods for plants, plant products, and animal matrices suitable for enforcement purposes have been submitted for measuring NNI-0001. Typically, plant matrices samples are extracted, concentrated, and quantified by liquid chromatography/tandem mass spectrometry (LC/MS/MS) using deuterated internal standards. Contact: Carmen Rodia, (703) 306-0327, e-mail address: *rodia.carmen@epa.gov*.

2. *PP 6F7161*. (Docket ID number EPA–HQ–OPP–2007–0029). Bayer CropScience LLC, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709, proposes to establish a tolerance for residues of the herbicide glufosinate-ammonium and its metabolites expressed as butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid (expressed as glufosinate free acid equivalents) in or on food commodities aspirated grain fractions at 25.0 parts per million (ppm); non-transgenic canola, meal at 1.1 ppm; non-transgenic canola, seed at 0.4 ppm; non-transgenic field corn, forage at 4.0 ppm; non-transgenic field corn, grain at 0.2 ppm; non-transgenic field corn, stover at 6.0 ppm; non-transgenic soybean at 2.0 ppm; and non-transgenic soybean, hulls at 5.0 ppm. The enforcement analytical method utilizes gas chromatography for detecting and measuring levels of glufosinate-ammonium and its metabolites with a general limit of quantitation (LOQ) of 0.05 ppm. This method allows detection of residues at or above the proposed tolerances. Contact: James Stone, telephone number: (703) 305-7391, e-mail address: *stone.james@epa.gov*.

3. *PP 6F7162*. (Docket ID number EPA–HQ–OPP–2007–0030). Syngenta Crop Protection, Inc., P. O. Box 18300, Greensboro, NC 72409, proposes to establish tolerances for residues of the herbicide mesotrione in or on food commodities asparagus at 0.01 ppm; grass, forage at 0.01 ppm; grass, hay at 0.01 ppm; grass, seed screenings at 0.01 ppm; grass, straw at 0.10 ppm; oats, forage at 0.01 ppm; oats, grain at 0.01 ppm; oats, hay, at 0.01 ppm; oats, straw at 0.01 ppm; okra at 0.01 ppm; rhubarb at 0.01 ppm; sorghum, forage at 0.01 ppm; sorghum, grain at 0.01 ppm; sorghum, stover at 0.01 ppm; sorghum, sweet at 0.01 ppm; and sugarcane at 0.01 ppm. Practical and specific analytical method RAM 366/01 is available for detecting and measuring the level of mesotrione in or on various crop commodities. Contact: James Stone, telephone number: (703) 305-7391, e-mail address: *stone.james@epa.gov*.

Amendment to Existing Tolerance

PP 6H7114. (Docket ID number EPA–HQ–OPP–2007–0096). Pytech Chemicals GmbH, 9330 Zionsville Road, IN 46268, proposes to amend the tolerance in 40 CFR 180.438, section (3) by adding gamma-cyhalothrin to lambda-cyhalothrin. The residue definition under section (3) should read as follows: (3) A food additive tolerance of 0.01 parts per million is established for residues of the insecticide lambda-cyhalothrin (*S*)-alpha-cyano-3-phenoxybenzyl-(Z)-(1*R*,3*R*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,1-dimethylcyclopropanecarboxylate) and (*R*)-alpha-cyano-3-phenoxybenzyl-(Z)-(1*S*,3*S*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, or the isolated active isomer gamma-cyhalothrin (*S*)-alpha-cyano-3-phenoxybenzy-(Z)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate. An adequate analytical method is available for enforcement purposes. Contact: Bewanda Alexander, (703) 305-7460, e-mail address: *alexander.bewanda@epa.gov*.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 13, 2007.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. E7–3117 Filed 2–27–07; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's Office of Agreements (202–523–5793 or *tradeanalysis@fmc.gov*).

Agreement No.: 011733–020.

Title: Common Ocean Carrier Platform Agreement.

Parties: A.P. Moller-Maersk A/S; CMA CGM; Hamburg-Süd; Hapag-Lloyd AG; Mediterranean Shipping Company S.A.; and United Arab Shipping Company (S.A.G.) as shareholder parties, and Alianca Navegacao e Logistica Ltda.; Kawasaki Kisen Kaisha Ltd.; MISC Berhad; Mitsui O.S.K. lines Ltd.; Nippon Yusen Kaisha; Safmarine Container Lines N.V.; Senator Lines GmbH; Compania Sud Americana de Vapores, S.A.; Companhia Libra Navegacao; Norasia Container Lines Limited; Tasman Orient Line C.V.; and Emirates Shipping Lines as non-shareholder parties.

Filing Party: Mark J. Fink, Esq.; Sher & Blackwell LLP; 1850 M Street, NW., Suite 900; Washington, DC 20036.

Synopsis: The amendment adds Emirates Shipping Lines as a non-shareholder party to the agreement.

Agreement No.: 011988.

Title: EUKOR/WWL Mexico Space Charter Agreement.

Parties: EUKOR Car Carriers, Inc. (''EUKOR'') and Wallenius Wilhelmsen Logistics AS (''WWL'').

Filing Party: Wayne R. Rohde, Esq.; Sher & Blackwell LLP; 1850 M Street, NW., Suite 900; Washington, DC 20036.

Synopsis: The agreement authorizes EUKOR to charter space to WWL for the carriage of ro-ro and other non-containerized cargo in the trade from Mexico to the United States.

Dated: February 23, 2007.

By Order of the Federal Maritime Commission.

Bryant L. VanBrakle,

Secretary.

[FR Doc. E7–3506 Filed 2–27–07; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (''OMB'') for review, as required by the Paperwork Reduction Act (''PRA''). The Federal Trade Commission (''FTC'' or ''Commission'') is seeking public comments on its proposal to extend through July 31,

2010 the current OMB clearance for information collection requirements contained in its proposed Affiliate Marketing Rule (or ''proposed Rule''). That clearance expires on July 31, 2007.

DATES: Comments must be filed by April 30, 2007.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''Affiliate Marketing Rule: FTC File No. R411006'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope and should be mailed or delivered, with two complete copies, to the following address: Federal Trade Commission, Room H–135 (Annex J), 600 Pennsylvania Ave., NW., Washington, DC 20580. Because paper mail in the Washington area and at the Commission is subject to delay, please consider submitting your comments in electronic form, as prescribed below. However, if the comment contains any material for which confidential treatment is requested, it must be filed in paper form, and the first page of the document must be clearly labeled ''Confidential.'' [1]

Comments filed in electronic form should be submitted by following the instructions on the Web-based form at *https://secure.commentworks.com/AffiliateMarketingRule*. To ensure that the Commission considers an electronic comment, you must file it on the Web-based form at the *https://secure.commentworks.com/AffiliateMarketingRule* weblink. If this notice appears at *www.regulations.gov*, you may also file an electronic comment through that Web site. The Commission will consider all comments that regulations.gov forwards to it.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments will be considered by the Commission and will be available to the public on the FTC Web site, to the extent practicable, at *www.ftc.gov.* As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at *http://www.ftc.gov/ftc/privacy.htm*.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Anthony Rodriguez or Loretta Garrison, Attorneys, Division of Privacy and Identity Protection, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–2252.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act (''PRA''), 44 U.S.C. 3501–3520, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the existing paperwork clearance for the regulations noted herein.

The FTC invites comments on: (1) Whether the required collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (2) the accuracy of the agency's estimate of the burden of the required collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before April 30, 2007.

The Affiliate Marketing Rule, 16 CFR part 680, was proposed by the FTC under section 214 of the Fair and Accurate Credit Transactions Act (''FACT Act''), Pub. L. No. 108–159 (December 6, 2003). The FACT Act amended the Fair Credit Reporting Act, 15 U.S.C. 1681 *et seq.*, which was enacted to enable consumers to protect the privacy of their consumer credit information. As mandated by the FACT Act, the proposed Rule specifies disclosure requirements for certain affiliate companies subject to the Commission's jurisdiction. Except as discussed below, these requirements constitute ''collections of information'' for purposes of the PRA. Specifically, the FACT Act and the proposed Rule require covered entities to provide consumers with notice and an opportunity to opt out of the use of certain information before sending marketing solicitations. The proposed Rule generally provides that, if a company communicates certain information about a consumer (''eligibility information'') to an affiliate, the affiliate may not use that information to make or send solicitations to the consumer unless the consumer is given notice and a reasonable opportunity to opt out of such use of the information and the consumer does not opt out.

To minimize compliance costs and burdens for entities, particularly any small businesses that may be affected, the proposed Rule contains model disclosures and opt-out notices that may be used to satisfy the statutory requirements. The proposed Rule also gives covered entities flexibility to satisfy the notice and opt-out requirement by sending the consumer a free-standing opt-out notice or by adding the opt-out notice to the privacy notices already provided to consumers, such as those provided in accordance with the provisions of Title V, subtitle A of the GLBA. For covered entities that choose to prepare a free-standing opt-out notice, the time necessary to prepare it would be minimal because those entities could simply use the model disclosure. For covered entities that choose to incorporate the model opt-out notice into their GLBA privacy notices the time necessary to do so also would be minimal. Arguably, verbatim adoption of the model notice would not even be a PRA ''collection of information.'' [2]

Burden Statement

Except where otherwise specifically noted, staff's estimates of burden are based on its knowledge of the consumer credit industries and knowledge of the entities over which the Commission has jurisdiction. This said, estimating PRA burden of the proposed Rule's disclosure requirements is difficult given the highly diverse group of affected entities that includes affiliated companies which may use certain eligibility information shared by their

[1] Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

[2] ''The public disclosure of information originally supplied by the Federal government to the recipient for purpose of disclosure to the public is not included within [the definition of collection of information].'' 5 CFR 1320.3(c)(2).

affiliates to send marketing notices to consumers who are not regulated by a federal financial regulatory agency.

The estimates provided in this burden statement may well overstate actual burden. First, an uncertain but possibly significant number of entities subject to the FTC's jurisdiction do not have affiliates and would thus not be covered by section 214 of the FACT Act or the proposed Rule. Second, the Commission's staff does not know how many companies subject to the FTC's jurisdiction under the proposed rule actually share eligibility information among affiliates and, of those, how many affiliates use such information to make marketing solicitations to consumers. The staff considered the wide variations in covered entities and the fact that, in some instances, covered entities may make the required disclosures in the ordinary course of business, apart from the FACT Act Rule, voluntarily as a service to their customers, while still other entities may choose to rely on the exceptions to the proposed Rule's notice and opt-out requirements.[3]

Staff's estimates assume a higher burden will be incurred during the first year of the OMB clearance period with a lesser burden for each of the subsequent two years, since the opt-out notice to consumers is required to be given only once. Institutions may provide for an indefinite period for the opt-out or they may time limit it, but for no less than five years. Given this minimum time period, Commission staff did not estimate burden for preparing and distributing extension notices by entities that limit the duration of the opt-out time period. The relevant PRA time frame for burden calculation is three years from renewed OMB clearance, and the five-year notice period will not begin until this proposed Rule becomes final.

Staff's labor cost estimates take into account: Managerial and professional time for reviewing internal policies and determining compliance obligations; technical time for creating the notice and opt-out, in either paper or electronic form; and clerical time for disseminating the notice and opt-out.[4] In addition, staff's cost estimates presume that the availability of model disclosures and opt-out notices will simplify the compliance review and implementation processes, thereby significantly reducing the cost of compliance. Moreover, the proposed Rule gives entities considerable flexibility to determine the scope and duration of the opt-out. Indeed, this flexibility permits entities to send a single joint notice on behalf of all of its affiliates.

Estimated total annual hours burden: 2,662,000 hours, rounded.

Staff estimates that approximately 1.17 million (rounded) non-GLBA entities under the jurisdiction of the FTC have affiliates and would be affected by the proposed Rule.[5] Staff further estimates that there are an average of 5 businesses per family or affiliated relationship, and that the affiliated entities will choose to send a joint notice, as permitted by the proposed Rule. Thus an estimated 233,400 (rounded) non-GLBA entities may send the new affiliate marketing notice. Staff also estimates that non-GLBA entities under the jurisdiction of the FTC would each incur 14 hours of burden during the first year of the clearance period, comprised of a projected 7 hours of managerial time, 2 hours of technical time, and 5 hours of clerical assistance.

Based on the above, total annual burden for non-GLBA entities during the first year of the clearance period would be approximately 2,646,000 hours and the total annual labor cost would be approximately $86,676,000, rounded.[6] These estimates include the start-up burden and attendant costs, such as determining compliance obligations. Paperwork burden in later years would be significantly lower, with non-GLBA entities each incurring 10 hours of annual burden during the remaining two years of the clearance.[7] Thus, the estimated annual burden for non-GLBA entities, averaged over the three-year clearance period, would be 2,646,000 hours and $66,065,000 in labor costs.

Entities that are subject to the Commission's GLBA privacy notice regulation already provide privacy notices to their customers. Because the FACT Act and the proposed Rule contemplate that the new affiliate marketing notice can be included in the GLBA notices, the burden on GLBA regulated entities would be greatly reduced. Accordingly, the GLBA entities would incur 6 hours of burden during the first year of the clearance period, comprised of a projected 5 hours of managerial time and 1 hour of technical time to execute the notice, given that the proposed Rule provides a model.[8] Staff also estimates that 3,350 GLBA entities under the FTC's jurisdiction would be affected, so that the total annual burden for GLBA entities during the first year of the clearance period would approximate 20,000 hours and total annual labor cost would approximate $673,000.[9] The paperwork burden in subsequent years would be significantly lower, with GLBA entities each incurring 4 hours of annual burden (3 hours of managerial time and 1 hour of technical time) during the remaining two years of the clearance, which amounts to 13,400 hours and $443,540 in labor costs in each of the ensuing two years. Thus, averaged over the three-year clearance period, the estimated annual burden for GLBA entities is 15,600 hours and $520,000 in labor costs.

Cumulatively for both GLBA and non-GLBA entities, the average annual burden over the prospective three-year clearance period, rounded, is approximately 2,662,000 burden hours and $87,349,000 in labor costs. GLB entities are already providing notices to their customers so there are no new capital or non-labor costs, as this notice may be consolidated into their current notices. For non-GLB entities, the rule provides for simple and concise model forms that institutions may use to comply. Thus, any capital or non-labor

[3] Exceptions include, for example, having a preexisting business relationship with a consumer, using information in response to a communication initiated by the consumer or to solicitations authorized or requested by the consumer.

[4] No clerical time was included in staff's burden analysis for GLBA entities as the notice would likely be combined with existing GLBA notices.

[5] This estimate is derived from an analysis of a database of U.S. businesses based on SIC codes for businesses that market goods or services to consumers, which included the following industries: transportation services; communication; electric, gas, and sanitary services; retail trade; finance, insurance, and real estate; and services (excluding business services and engineering, management services). This estimate excludes businesses not subject to the FTC's jurisdiction as well as businesses that do not use data or information subject to the rule.

[6] The figure is derived from the estimated 7 hours of managerial labor at $34.21 per hour; 2 hours of technical labor at $29.80 per hour; and 5 hours of clerical labor at $14.44 per hour (a combined $371.27) for the estimated 233,400+ non-GLBA business families subject to the proposed Rule. The hourly rates are based on average annual Bureau of Labor Statistics National Compensation Survey data, June 2005 (with 2005 as the most recent whole year information available at the BLS Web site). *http://www.bls.gov/ncs/ocs/sp/ncbl0832.pdf* (Table 1.1).

[7] This estimate assumes that in subsequent years, non-GLBA entities would spend 4 hours of managerial time, 1 hour of technical time, and 5 hours of clerical time each year. Thus, the resulting estimated burden for each of the remaining two years of the clearance period would be 2,334,590 hours and approximately $55,759,000 in labor costs.

[8] As stated above, no clerical time is included in the estimate because the notice likely would be combined with existing GLBA notices.

[9] 3,350 GLBA entities × [($34.20 × 5 hours) + ($29.80 × 1 hour)].

costs associated with compliance for these entities are negligible.

William Blumenthal,

General Counsel.

[FR Doc. E7–3397 Filed 2–27–07; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Scientific, Technical and Operational Services for Epidemiology, Surveillance and Laboratory Program, Contract Solicitation Number (CSN) 2006–N–08556

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting of the aforementioned Special Emphasis Panel.

Time And Date: 12 p.m.–3 p.m., March 21, 2007 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of the scientific merit of research applications in response to CSN 2006–N–08556, ''Scientific, Technical and Operational Services for Epidemiology, Surveillance and Laboratory Program.''

Contact Person For More Information: Christine Morrison, PhD., Designated Federal Officer, 1600 Clifton Road, Mailstop D72, Atlanta, GA 30333, telephone (404) 639–3098.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–3470 Filed 2–27–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0425]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 30, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Premarket Notification—21 CFR Part 807; Subpart E—(OMB Control Number 0910–0120)—Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) require a person who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), Product Development Protocol or be reclassified into Class I or Class II before being marketed. The FDA makes the final decision of whether a device is equivalent or not equivalent.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) added section 510(o) to the act to establish new regulatory requirements for reprocessed single-use devices (SUDs). MDUFMA was signed into law on October 26, 2002.

Section 510(o) of the act requires that FDA review the types of reprocessed SUDs subject to premarket notification requirements and identify which of these devices require the submission of validation data to ensure their substantial equivalence to predicate devices. Section 510(o) also requires that FDA review critical and semi-critical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require the submission of premarket notifications to ensure their substantial equivalence to predicate devices.

FDA has identified the reprocessed SUDs that require the submission of validation data to date. The requirement to submit validation data for certain reprocessed single-use devices has been incorporated into the premarket notification program. As with all other devices, new premarket notifications for reprocessed SUDs will be required as new manufacturers enter the market or manufacturers with cleared premarket notifications make significant changes to their device. The burden estimates in this document include the burden for submitting premarket notifications for reprocessed SUDs with the burden for all other devices. FDA may amend the lists of reprocessed SUDs that require the submission of premarket notifications with validation data as necessary.

Section 807.81 states when a premarket notification is required. A premarket notification is required to be submitted by a person who is:

- Introducing a device to the market for the first time;
- Introducing or reintroducing a device which is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device.

Section 807.87 specifies information required in a premarket notification submission.

Section 204 of the Food and Drug Administration Modernization Act