

Mariana Islands, dated February 5, 1990, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of February 5, 1990:

The Islands of Agrihan and Anatahan for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.518, Disaster Assistance)

Grant C. Peterson,

Associate Director, State and Local Programs and Support, Federal Emergency Management Agency.

[FR Doc. 90-4545 Filed 2-27-90; 8:45 am]

BILLING CODE 6718-21-M

[FEMA-853-DR]

Oregon; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Oregon (FEMA-853-DR), dated January 24, 1990, and related determinations.

DATES: February 15, 1990.

FOR FURTHER INFORMATION CONTACT:

Neva K. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472 (202) 646-3614.

NOTICE: The notice of a major disaster for the State of Oregon, dated January 24, 1990, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of January 24, 1990:

Clatsop County for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.518, Disaster Assistance)

Grant C. Peterson,

Associate Director, State and Local Programs and Support, Federal Emergency Management Agency.

[FR Doc. 90-4546 Filed 2-27-90; 8:45 am]

BILLING CODE 6718-21-M

FEDERAL MARITIME COMMISSION

[Docket No. 90-08]

Military Sealift Command v. Sea-Land Service, Inc., et al.; Filing of Complaint and Assignment

Notice is given that a complaint filed by Military Sealift Command ("Complainant") against Sea-Land Service, Inc., P&O Containers (TFL)

Limited, Nedlloyd Lijnen, B.V., and Compania Transatlantica Espanola, S.A. (hereinafter collectively referred to as "Respondents") was served February 22, 1990. Complainant alleges that Respondents have violated sections 10(b)(12), 10(c)(1) and 10(c)(6) of the Shipping Act of 1984 ("Act"), 46 U.S.C. app. 1709(b)(12), (c)(1) and (c)(6), by reason of Article 5(i) of Agreement No. 203-011171 and Article 5.4(a) of Agreement No. 232-011217, by subjecting Complainant to an unreasonable refusal to deal and by allocating Complainant to a specific carrier. Complainant further alleges that certain of Respondents' tariffs fail to contain contracts of affreightment in violation of section 8(a)(1)(e) of the Act, 46 U.S.C. app. 1707.

This proceeding has been assigned to Administrative Law Judge Joseph N. Ingolia ("Presiding Officer"). Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the Presiding Officer in this proceeding shall be issued by February 22, 1991, and the final decision of the Commission shall be issued by June 24, 1991.

Joseph C. Polking,

Secretary.

[FR Doc. 90-4464 Filed 2-27-90; 8:45 am]

BILLING CODE 6730-01-M

Ocean Freight Forwarder License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR Part 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarder and Passenger Vessel Operations, Federal Maritime Commission, Washington, DC 20573.

James L. Butler III, dba J. L. Butler Forwarding, 62 S. Front Street, Memphis,

TN 38103. Officer: James L. Butler, Sole Proprietor

General Air Freight Consolidators, Inc. dba General Ocean Freight Container Line, 9000 Bellanca Avenue, Suite 14 & 16, Los Angeles, CA 90045. Officer: Simon T. Wu, President

Miguel D. Marave dba Marave & Associates, 8915 S. LA Cienega Blvd. Unit A, Inglewood, CA 90301. Officer: Miguel D. Marave, Sole Proprietor

Argents Air Express Ltd. dba Argents International, 123 South Main Street, Royal Oak, Michigan 48067. Officers: William J. Chiappetta, President/Director, Joseph A. Chiappetta, Assistant Secretary, Cynthia L. Chiappetta, Vice President/Secretary/Director, Gary L. Clements, Vice President Int'l Sales

Alliance Brokers International, Inc., 1240 E. Northwest Hwy, Ste 109, Grapevine, TX 76051. Officers: Robert Carlson, Vice President/Export, Jeff Bell, Vice President, James R. Mason, Treasurer/Stockholder, Roger Littleton, President

Dated: February 22, 1990.

Joseph C. Polking,

Secretary.

[FR Doc. 90-4465 Filed 2-27-90; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

The Long-Term Credit Bank of Japan, Ltd., Tokyo, Japan; Proposal to Underwrite and Deal in Certain Securities to a Limited Extent, Purchase and Sell Precious Metals and Derivative Products, Act as a Futures Commission Merchant, and Purchase and Sell Notional Principal Contracts

The Long-Term Credit Bank of Japan, Limited, Tokyo, Japan ("Applicant"), has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) (the "BHC Act"), and § 225.23(a)(3) of the Board's Regulation Y (12 CFR 225.23(a)(3)), for prior approval to engage through Greenwich Capital Markets, Inc., Greenwich, Connecticut ("Company"), in the following activities:

(1) Underwriting and dealing, to a limited extent, in commercial paper (which will be of prime quality, short-term, sold in minimum denominations of \$100,000, and exempt from the registration requirements of the Securities Act of 1933), municipal revenue bonds (including industrial developments bonds that are limited to "public ownership" industrial development bonds, where the issuer or the governmental unit on behalf of which the bonds are issued is the sole owner of the financed facility), 1-4 family mortgage-related securities, and

consumer receivable-related securities ("ineligible securities");

(2) purchasing and selling, for the account of Company, precious metals, and forward, options and futures contracts, and options on futures contracts for such precious metals;

(3) acting as a futures commission merchant by providing execution, clearance, and advisory services with respect to futures and options on futures on broad-based bond and stock indices; and

(4) purchasing and selling for the account of Company, notional principal contracts based on securities that state member banks are permitted to underwrite and deal in under section 16 of the Banking Act of 1933 (12 U.S.C. 24 (Seventh) & 335) ("eligible securities"), sovereign debt obligations, currencies, loans, commodities, and interest-rate indices such as the London Interbank Offered Rate; and providing brokerage services and investment advice with respect to such transactions and contracts to institutional customers.

Section 4(c)(8) of the BHC Act provides that a bank holding company may, with prior Board approval, engage directly or indirectly in any activities "which the Board after due notice and opportunity for hearing has determined (by order or regulation) to be so closely related to banking or managing or controlling banks as to be a proper incident thereto."

A particular activity may be found to meet the "closely related to banking" test if it is demonstrated that banks have generally provided the proposed activity; that banks generally provide services that are operationally or functionally so similar to the proposed activity so as to equip them particularly well to provide the proposed activity; or that banks generally provide services that are so integrally related to the proposed activity as to require their provision in a specialized form. *National Courier Ass'n v. Board of Governors*, 516 F.2d 1229, 1337 (DC Cir. 1975). In addition, the Board may consider any other basis that may demonstrate that the activity has a reasonable or close relationship to banking or managing or controlling banks. Board Statement Regarding Regulation Y, 49 FR 806 (1984).

In determining whether an activity meets the second, or proper incident to banking, test of section 4(c)(8), the Board must consider whether the performance of the activity by an affiliate of a holding company "can reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency that outweigh

possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.

Applicant has applied to underwrite and deal in ineligible securities as set forth in the Board's Orders approving those activities for a number of bank holding companies, with certain exceptions. See, e.g., Citicorp, J.P. Morgan & Co. Incorporated and Bankers Trust New York Corporation, 73 Federal Reserve Bulletin 473 (1987); and Chemical New York Corporation, The Chase Manhattan Corporation, Bankers Trust New York Corporation, Citicorp, Manufacturers Hanover Corporation, and Security Pacific Corporation, 73 Federal Reserve Bulletin 731 (1987), as modified by Order Approving Modifications to Section 20 Orders (Order dated September 21, 1989). In particular, Applicant has proposed that certain limitations placed on the underwriting and dealing activities in the above Orders be limited to Applicant's bank affiliates.

Applicant also proposes to purchase and sell, for the account of Company, (i) precious metals, including gold and silver bullion, bars, rounds, and coins; and (ii) forward, options and futures contracts, and options on futures contracts for precious metals ("precious metal contracts"). Applicant states that the purchase and sale of precious metal contracts will be an incident to Company's activities of dealing in precious metals and eligible and ineligible securities, and for the purpose of hedging cash positions in precious metals and hedging Company's portfolio of eligible and ineligible securities. Applicant maintains that purchasing and selling precious metals contracts is an effective method of reducing risk associated with holding eligible and ineligible securities. In conducting its activities, Applicant has committed to abide by the policies and limitations found in the Board's Statement concerning the use of these types of contracts. Statement of policy concerning bank holding companies engaging in futures, forward and options contracts on U.S. Government and agency securities and money market instruments, 12 CFR 225.142.

Applicant also has applied to act as a futures commission merchant ("FCM") in the provision of execution, clearance and advisory services with respect to (a) the Standard & Poor's Over-the-Counter 250 Stock Index futures contract, (b) the Major Market Index Maxi Stock Index futures contract, (c) the Major Market Index Mini Stock Index futures contract, (d) the New York Stock Exchange Index Composite futures contract, (e) options

on New York Stock Exchange Composite Index futures contracts, (f) the Value Line Average Stock Index futures contract, (g) the Value Line Futures (Maxi) Index futures contract, (h) the Value Line Futures (Mini) Index futures contract, (i) the Financial Times Stock Index futures contract, (j) the Nikkei Stock Average futures contract, (k) the GNMA Cash Settled futures contract, (l) the National Over-the-Counter Index futures contract, and (m) the NASD Financial futures contract. Applicant maintains that the Board has previously approved the execution and clearance of the listed futures contracts. Applicant contends that providing investment advice with respect to these futures contracts is closely related to banking and a proper incident thereto since the Board has previously approved investment advice with respect to broad-based bond and stock indices. Northern Trust Company, 74 Federal Reserve Bulletin 502 (1988). Company would conduct its FCM activities in accordance with the limitations of 12 CFR 225.25(b)(18) and (b)(19).

Applicant has proposed to purchase and sell notional principal contracts based upon all eligible securities, loans, currencies, foreign debt sovereign obligations, commodities, and interest-rate indices such as the London Interbank Offered Rate, and act as broker or agent, and advisor regarding financial strategies to institutional customers with respect to the foregoing transactions and instruments. Applicant contends that these activities are permissible under the Board's prior decisions permitting bank holding companies to broker and originate interest rate swaps. The Sumitomo Bank, Limited, 75 Federal Reserve Bulletin 582 (1989) ("Sumitomo"). Applicant has applied to conduct these activities subject to the structure and guidelines established by the Board in Sumitomo.

Applicant contends that approval of the application would not be barred by section 20 of the Glass-Steagall Act (12 U.S.C. 377). Section 20 of the Glass-Steagall Act prohibits the affiliation of a member bank with a firm that is "engaged principally" in the "underwriting, public sale or distribution" of securities. With regard to the proposed ineligible securities underwriting and dealing activities, Applicant states that, consistent with section 20, it would not be "engaged principally" in such activities on the basis of the restriction on the amount of the proposed activity relative to the total business conducted by the underwriting subsidiary previously

approved by the Board. See Board's Order dated September 21, 1989.

In publishing the proposal for comment, the Board does not take any position on issues raised by the proposal under the BHC Act. Notice of the proposal is published solely in order to seek the views of interested persons on the issues presented by the application and does not represent a determination by the Board that the proposal meets or is likely to meet the standards of the BHC Act.

Any views or requests for a hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, DC 20551, not later than March 14, 1990. Any request for a hearing must, as required by § 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)), be accompanied by a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented in a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

This application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of New York.

Board of Governors of the Federal Reserve System, February 22, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90-4494 Filed 2-27-90; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

Particulate Sampler Performance Testing; Meeting

Name: Particulate Sampler Performance Testing.

Time and date: 1 p.m.-4 p.m., March 22, 1990.

Place: Alice Hamilton Laboratory, NIOSH, CDC, Conference Room C, 5555 Ridge Avenue, Cincinnati, Ohio 45213.

Status: Open to the public, limited only by the space available.

Purpose: To conduct an open meeting for the review of a project entitled, "Particulate Sampler Performance Testing." This project will update respirable dust sampler performance testing developed within NIOSH. Use of modern instrumentation for the testing will result in a combination of tighter performance criteria and a larger set of acceptable samplers.

Contact person for additional information: David L. Bartley, Ph.D., NIOSH, CDC, 4576 Columbia Parkway, Cincinnati, Ohio 45226, Telephone: Commercial (513) 841-4277, FTS: 684-4277.

Dated: February 22, 1990.

Elvin Hilyer,

Associate Director for Policy Coordination Centers for Disease Control.

[FR Doc. 90-4508 Filed 2-27-90; 8:45 am]

BILLING CODE 4160-19-M

Evaluation of Toxic Gas Monitors for Indoor and Workplace Air; Meeting

Name: Evaluation of Toxic Gas Monitors for Indoor and Workplace Air.

Time and Date: 10 a.m.-12 noon, March 15, 1990.

Place: Alice Hamilton Laboratory, NIOSH, CDC, Conference Room B, 5555 Ridge Avenue, Cincinnati, Ohio 45213.

Status: Open to the public, limited only by the space available.

Purpose: To conduct an open meeting for the review of a project titled "Evaluation of Toxic Gas Monitors for Indoor and Workplace Air." This project is based on a laboratory evaluation of instruments chosen for their ability to monitor indoor air contaminants such as carbon dioxide, formaldehyde, total organic vapors, carbon monoxide, chlorine, hydrogen sulfide, ammonia, and sulfur dioxide. The results of this project will assist the potential user of gas monitoring instrumentation in the choice of an instrument for a given application. Commercial availability of monitors for commonly monitored gases/vapors (as those mentioned above) will be assessed.

Contact Person for Additional Information: Jerome P. Smith, Ph.D., NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone: Commercial (513) 841-4293, FTS: 684-4293.

Dated: February 22, 1990.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 90-4507 Filed 2-27-90; 8:45 am]

BILLING CODE 4160-19-M

Food and Drug Administration

[Docket No. 90F-0036]

Nippon Synthetic Chemical Industry Co., Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Nippon Synthetic Chemical Industry Co., Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of boric acid as a stabilizer in ethylene-vinyl acetate-vinyl alcohol copolymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 0B4188) has been filed by Nippon Synthetic Chemical Industry Co., Ltd., 9-6, Nozaki-cho, Kita-ku, Osaka, Japan, proposing that § 178.2010 Antioxidants and/or stabilizers (21 CFR 178.2010) be amended to provide for the safe use of boric acid as a stabilizer in ethylene-vinyl acetate-vinyl alcohol copolymers intended for use in contact with food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: February 20, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90-4512 Filed 2-27-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90M-0054]

Alcon Laboratories, Inc.; Premarket Approval of Models MT3-MT7 Non-Ultraviolet-Absorbing and MT3U-MT7U Ultraviolet-Absorbing Anterior Chamber Intraocular Lenses

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Alcon Laboratories, Inc., Fort Worth, TX, for premarket approval under the Medical Device Amendments of 1976 (the amendments) of the Models MT3-MT7 Non-Ultraviolet-absorbing and MT3U/MT7U Ultraviolet-absorbing Anterior

Chamber Intraocular Lenses. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of January 31, 1990, of the approval of the application.

DATES: Petitions for administrative review by March 30, 1990.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy C. Brogdon, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1212.

SUPPLEMENTARY INFORMATION: On January 25, 1989, Alcon Laboratories, Inc., Forth Worth, TX 76134-2099, submitted to CDRH an application for premarket approval of the Models MT3-MT7 Non-Ultraviolet-Absorbing and Models MT3U-MT7U Ultraviolet-Absorbing Anterior Chamber Intraocular Lenses. The Models MT3-MT7 and MT3U-MT7U are designed for use in the anterior chamber for the visual correction of aphakia in patients 60 years of age or older who are undergoing: (1) A primary intracapsular cataract extraction (ICCE) or (2) a primary extracapsular cataract extraction (ECCE) provided that this be performed after the physician has compared the published results or his/her own results from the anterior chamber lenses with posterior chamber lenses or (3) a primary ECCE where there is a structural reason why the Model MT3-MT7 or MT3U-MT7U is preferred (secondary intent) or (4) a secondary procedure in an aphakic patient. The device is available in a range of powers from 4 diopters (D) through 32 D in 0.5-D increments.

On January 25, 1990, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On January 31, 1990, CDRH approved the application by a letter to the applicant from the director of the Office of Device Evaluation, CDRH.

Under the amendments, intraocular lenses are regulated as class III devices (premarket approval). A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the

name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact Nancy C. Brogdon (HFZ-460), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before March 30, 1990, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: February 21, 1990.

Walter E. Gundaker,

Acting Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 90-4510 Filed 2-27-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90M-0053]

IntraOptics, Inc.; Premarket Approval of Models SK15 and SK16 Posterior Chamber Intraocular Lenses

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by IntraOptics, Inc., Huntington, WV, for premarket approval under the Medical Device Amendments of 1976 (the amendments) of the Models SK15 and SK16 Posterior Chamber Intraocular Lenses. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of January 24, 1990, of the approval of the application.

DATES: Petitions for administrative review by February 28, 1990.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy C. Brogdon, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 1390 Piccard Drive, Rockville, MD 20850, (301) 427-1212.

SUPPLEMENTARY INFORMATION: On November 17, 1987, IntraOptics, Inc., Huntington, WV 25708, submitted to CDRH an application for premarket approval of the Models SK15 and SK16 Posterior Chamber Intraocular Lenses. The devices are indicated for use in the visual correction of aphakia in primary implantations in patients 60 years of age or older where a cataractous lens has been removed by extracapsular cataract extraction methods. The lenses are intended for replacement in either the ciliary sulcus or capsular bag following extracapsular cataract extraction. The devices are available in a range of powers from 10 diopters (D) through 30 D in 0.5-D increments.

On April 21, 1988, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On January 24, 1990, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

Under the amendments, intraocular lenses are regulated as class III devices (premarket approval). A summary of the