in § 510.23(c) more than once on the same shipment.

(g) *Licensed non-vessel-operating common carriers; compensation.*

(1) A non-vessel-operating common carrier or person related thereto licensed under this part may collect compensation when, and only when, the following certification is made together with the certification required under paragraph (c) of this section:

The undersigned certifies that neither it nor any related person has issued a bill of lading or otherwise undertaken common carrier responsibility as a non-vessel-operating common carrier for the ocean transportation of the shipment covered by this bill of lading.

(2) Whenever a person acts in the capacity of a non-vessel-operating common carrier as to any shipment, such person shall not collect compensation, nor shall any underlying ocean common carrier pay compensation to such person for such shipment.

(h) A freight forwarder may not receive compensation from a common carrier with respect to any shipment in which the forwarder has a beneficial interest or with respect to any shipment in which any holding company, subsidiary, affiliate, officer, director, agent, or executive of such forwarder has a beneficial interest.

§ 510.24 Records required to be kept.

Each licensee shall maintain in an orderly and systematic manner, and keep current and correct, all records and books of account in connection with its business of forwarding. These records must be kept in the United States in such manner as to enable authorized Commission personnel to readily determine the licensee's cash position, accounts receivable and accounts payable. The licensee must maintain the following records for a period of five years:

(a) *General financial data.* A current running account of all receipts and disbursements, accounts receivable and payable, and daily cash balances, supported by appropriate books of account, bank deposit slips, cancelled checks, and monthly reconciliation of bank statements.

(b) *Types of services by shipment.* A separate file shall be maintained for each shipment. Each file shall include a copy of each document prepared, processed, or obtained by the licensee, including each invoice for any service arranged by the licensee and performed by others, with respect to such shipment.

(c) *Receipts and disbursements by shipment.* A record of all sums received and/or disbursed by the licensee for services rendered and out-of-pocket expenses advanced in connection with each shipment, including specific dates and amounts.

(d) *Special contracts.* A true copy, or if oral, a true and complete memorandum, of every special arrangement or contract with a principal, or modification or cancellation thereof, to which it may be a party. Authorized Commission personnel and *bona fide* shippers shall have access to such records upon reasonable request.

§ 510.25 Anti-rebate certifications.

By March 1st of each year, the Chief Executive Officer of every licensee shall certify that it has a policy against rebates, that it has promulgated such policy to all appropriate individuals in the firm, that it has taken steps to prevent such illegal practices which measures must be fully described in detail, and, that it will cooperate with the Commission in any investigation of suspected rebates. This certification shall be in accordance with the following format:

(Name of Filing Firm)

Certification of Policies and Efforts to Combat Rebating in the Foreign Commerce of the United States

Pursuant to the provisions of section 15(b) of the Shipping Act of 1984, and Federal Maritime Commission regulations promulgated pursuant thereto, 46 CFR Parts 510 and 582,

I, ————, Chief Executive Officer of (name of firm), holder of valid ocean freight forwarder license #———, state under oath that:

1. It is the policy of (name of firm) to prohibit the participation of said freight forwarder in the payment, solicitation, or receipt of any rebate, directly or indirectly, to or by any carrier or shipper, which is unlawful under the provisions of the Shipping Act of 1984.

2. Each owner, officer, employee and agent of (name and firm) was notified or reminded of this policy on or before ———— of the present year.

3. (Set forth the details of measures instituted within the filing firm or otherwise to prohibit participation in the payment of illegal rebates in the foreign commerce of the United States.)

4. (Name of firm) affirms that it will fully cooperate with the Commission in its investigation of suspected rebating in United States foreign trades.

———————

Signature

Subscribed to and sworn before me this — day of ————, 19—.

———————

Notary Public

§ 510.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

This section displays the control numbers assigned to information collection requirements of the Commission in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511. The Commission intends that this part comply with the requirements of section 3507(f) of the Paperwork Reduction Act, which requires that agencies display a current control number assigned by the Director of the Office of Management and Budget (OMB) for each agency information collection requirement:

Section	Current OMB control No.
510.12 (Form FMC–18)	3072–0018
510.14	3072–0018
510.15	3072–0018
510.19 (Form FMC–18)	3072–0018
510.21 through 510.25	3072–0018

By the Commission.

Francis C. Hurney,

Secretary.

[FR Doc. 84–24312 Filed 9–13–84; 8:45 am]

BILLING CODE 6730–01–M

46 CFR Parts 515, 520, 525, 530, and 540

[Docket No. 84–18]

The Shipping Act of 1984; Final Rules for Marine Terminal Operations and Passenger Vessels

AGENCY: Federal Maritime Commission.

ACTION: Final rules.

SUMMARY: On March 20, 1984, the President signed the Shipping Act of 1984, which became effective on June 18, 1984. The Commission hereby issues final rules to supersede previously issued interim rules to implement the Shipping Act of 1984. In addition, minor style and technical changes have been made. The parts which are included in this rulemaking are: Part 515 [filing of tariffs by marine terminal operators—old part 533]; Part 520 [filing of tariffs by terminal barge operators in Pacific Slope States—old part 550]; Part 525 [free time and demurrage—old part 526]; Part 530 [truck detention at New York—old part 551]; and Part 540 [security for the protection of the public on passenger vessels]. Along with the final rule on Part 510 (Ocean Freight Forwarders), published separately, all of Subchapter B is now final.

EFFECTIVE DATE: October 15, 1984.

FOR FURTHER INFORMATION CONTACT: Robert G. Drew, Director, Bureau of Tariffs, Federal Maritime Commission, 1100 L Street, NW., Washington, D.C., (202) 523–5796.

SUPPLEMENTARY INFORMATION: These final rules, together with the simultaneous but separately published final rule on Part 510 (Ocean Freight Forwarders) finalize Subchapter B of Chapter IV, Title 46 of the Code of Federal Regulations. The new Title for Subchapter B is: "Regulations Affecting Ocean Freight Forwarders, Marine Terminal Operations and Passenger Vessels".

This proceeding was instituted by a Notice entitled "Interim Rules to Implement the Shipping Act of 1984", published in the **Federal Register** on May 3, 1984 (49 FR 18846), which cited the Federal Maritime Commission's interim rulemaking authority under section 17(b) of the Shipping Act of 1984 (46 U.S.C. app. 1716(b)) and the necessity, under that statute, for publishing superseding, final rules by December 15, 1984. These rules are being published as such final, superseding rules, without prejudice, however, to the promulgation of any further rules that may be desirable, from time to time, before or after December 15, 1984.

The Interim Rules, finalized herein, restructure the Commission's Code of Federal Regulations' Part numbers for logic and convenience. The "new" numbers are effective as of June 18, 1984, while the "old" numbers appeared in the October 1, 1983, Title 46 (Shipping), Part 400 to End, edition of the CFR.

The major changes made by the Interim Rules to the old rules involved the Authority Citations, penalty provisions, and the exclusion of forest products, bulk cargo and recyclable metal scrap, waste paper and paper waste from the tariff-filing requirements—all to implement the Shipping Act of 1984. See 49 FR 18846.

The Supplementary Information to the interim rules also mentioned Docket No. 83–38, *Notice of Inquiry and Intent to Review Regulations of Ports and Marine Terminal Operators*, presided over by Commissioner Robert Setrakian. The issues in that proceeding may affect marine terminal operations and suggest further amendments to the rules in the parts published here. Such further rulemaking, if necessary, may be outside the scope of the Interim Rules and, therefore, require a separate rulemaking. Accordingly, at this time, the Commission will not defer finalization of these marine-terminal-related rules.

The Interim Rules published on May 3, 1984, generated only two comments: one from the Maryland Port Administration which endorsed the language modifications to Part 515, "Filing of Tariffs by Terminal Operators"; and the other from the National Maritime Council which had no further comment other than recognizing that the Interim Rules were required for technical compliance with the 1984 Act. The Commission, therefore, sees no need to make any substantive changes in any of the Interim Rules, and is publishing them as final, superseding rules in this proceeding in their entirety.

In preparing the various parts for publication, certain other non-substantive changes suggested themselves. Most of such minor changes made here involve style (e.g., for OMB Control Numbers or exemptions under the Paperwork Reduction Act; changing "provided, however" to "except"; elimination of gender specific references, etc.), grammar, syntax, numbering, punctuation, correction of typographical errors, and removal of superfluous verbiage—all without affecting substance.

In addition, we are restoring to the "Authority Citation" in old Part 550 (new Part 520), reference to Sec. 3 of the Shipping Act, 1916 (46 U.S.C. app. 804); we are deleting obsolete, effective-date provisions appearing in (old) §§ 553.4 and 540.4(b); a new map of the New York Port District is being provided for (new) Part 530; and we think a more descriptive nomenclature is "Marine Terminal Operators" instead of merely "Terminal Operators."

The Federal Maritime Commission has determined that this rule is not a "major rule" as defined in Executive Order 12291 dated February 17, 1981, because it will not result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovations, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Chairman of the Federal Maritime Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities, including small businesses, small organizational units and small governmental jurisdictions.

List of Subjects

46 CFR Parts 515, 520, 525, and 530

Barges, Cargo, Cargo vessels, Harbors, Imports, Maritime carriers, Motor carriers, Ports, Rates and fares, Reporting and recordkeeping requirements, Trucks, Water carriers, Waterfront facilities, Water transportation.

46 CFR Part 540

Rates and fares, Passenger vessels, Reporting and recordkeeping requirements, Surety bonds.

Corrections

These final rules are subject to review and editing of form before publication in the Code of Federal Regulations. Users are requested to notify the Commission of any omissions and typographical-type errors in order that corrections can be made before the Commission's CFR book goes to press in January, 1985.

Therefore, pursuant to 5 U.S.C. 552, 553; secs. 3, 17, 18(a), 21, and 43 of the Shipping Act, 1916 (46 U.S.C. app. 804, 816, 817(a), 820, and 841a); sec. 2 of the Intercoastal Shipping Act, 1933 (46 U.S.C. app. 844); secs. 8, 10, 15 and 17 of the Shipping Act of 1984 (46 U.S.C. app. 1707, 1709, 1714 and 1716), and secs. 2 and 3, Pub. L. 89–777, 80 Stat. 1356–1358 (46 U.S.C. app. 817d and 817e):

1. The Title to Subchapter B is revised to read as follows:

SUBCHAPTER B—REGULATIONS AFFECTING OCEAN FREIGHT FORWARDERS, MARINE TERMINAL OPERATIONS AND PASSENGER VESSELS

2. Title 46 Code of Federal Regulations, Parts 515, 520, 525, 530, and 540 are revised to read as follows:

PART 515—FILING OF TARIFFS BY MARINE TERMINAL OPERATORS

Sec.

515.1 Scope.
515.2 Purpose.
515.3 Persons who must file.
515.4 Filing of tariffs and tariff changes.
515.5 Compliance with this part and other terminal tariff filing requirements.
515.6 Definitions.
515.91 OMB Control numbers assigned pursuant to the Paperwork Reduction Act

Authority: 5 U.S.C. 553; secs. 17, 21, 43 of the Shipping Act, 1916 (46 U.S.C. app. 816, 820, 841a); secs. 10, 15, 17 of the Shipping Act of 1984 (46 U.S.C. app. 1709, 1714, 1716).

§ 515.1 Scope.

This part sets forth rules and regulations for the filing of terminal tariffs by persons engaged in carrying on the business of furnishing wharfage, dock, warehouse or other terminal facilities within the United States or a

commonwealth, territory, or possession thereof, in connection with a common carrier by water in the foreign or domestic offshore commerce of the United States.

§ 515.2 Purpose.

The purpose of this part is to enable the Commission to discharge its responsibilities under section 17 of the Shipping Act, 1916 and section 10 of the Shipping Act of 1984, by keeping informed of practices, rates and charges related thereto, instituted and to be instituted by marine terminals, and by keeping the public informed of such practices. Compliance is mandatory and failure to file the required tariffs may result in a penalty of not more than $5,000 for each day such violation continues. Additionally, if willful and knowing, the Shipping Act of 1984 provides a civil penalty of not more than $25,000 for each day a violation continues.

§ 515.3 Persons who must file.

Except with regard to bulk cargo, forest products, recycled metal scrap, waste paper, and paper waste, every person other than the Department of Defense (including the military department and all agencies of the Department of Defense), carrying on the business of furnishing wharfage, dock, warehouse, or other terminal facilities as described in § 515.1, including, but not limited to terminals owned or operated by States and their political subdivisions; railroads who perform port terminal sevices not covered by their line haul rates; common carriers who perform port terminal services; and warehousemen who operate port terminal facilities, shall file in duplicate with the Bureau of Tariffs, Federal Maritime Commission, and shall keep open for inspection at all its places of business, a schedule or tariff showing all its rates, charges, rules, and regulations relating to or connected with the receiving, handling, storing, and/or delivering of property at its terminal facilities, except that rates and charges for terminal services performed for water carriers pursuant to negotiated contracts, and for storage of cargo and services incidental thereto by public warehousemen pursuant to storage agreements covered by issued warehouse receipts need not be filed for purposes of this part.

§ 515.4 Filing of tariffs and tariff changes.

Every tariff or tariff change shall be filed on or before its effective date, except as required by Commission Order or by agreements approved pursuant to section 15 of the Shipping Act, 1916 and/or effective under section 6 of the Shipping Act of 1984, and be kept open for public inspection as provided in § 515.3.

§ 515.5 Compliance with this part and other terminal tariff filing requirements.

Persons who file tariffs pursuant to requirements of Commission Orders or agreements, approved under section 15 of the Shipping Act, 1916 and/or effective under section 6 of the Shipping Act of 1984, shall not be relieved of such requirements by this part. Marine Terminal Operators who file tariffs with the Interstate Commerce Commission pursuant to statute or rule of that Commission may satisfy the requirements of this part of filing with the Federal Maritime Commission a copy of any such tariff filed with the Interstate Commerce Commission.

§ 515.6 Definitions.

(a) The definitions of terminal services set forth in paragraph (d) of this section shall be set forth in tariffs filed pursuant to this part except that other definitions of terminal services may be used if they are correlated by footnote or other appropriate method to the definitions set forth herein. Any additional services which are offered shall be listed and charges therefor shall be shown in terminal tariffs.

(b) These definitions shall apply to "port terminal facilities" which are defined as one or more structures comprising a terminal unit, and include, but are not limited to wharves, warehouses, covered and/or open storage spaces, cold storage plants, grain elevators and/or bulk cargo loading and/or unloading structures, landings, and receiving stations, used for the transmission, care and convenience of cargo and/or passengers in the interchange of same between land and water carriers or between two water carriers.

(c) For the purpose of this section, "point of rest" means that area on the terminal facility which is assigned for the receipt of inbound cargo from the ship and from which inbound cargo may be delivered to the consignee, and that area which is assigned for the receipt of outbound cargo from shippers for vessel loading.

(d) *Definitions of terminal services*—

(1) *Dockage* means the charge assessed against a vessel for berthing at a wharf, pier, bulkhead structure, or bank or for mooring to a vessel so berthed.

(2) *Wharfage* mans a charge assessed against the cargo or vessel on all cargo passing or conveyed over, onto, or under wharves or between vessels (to or from barge, lighter, or water), when berthed at wharf or when moored in slip adjacent to wharf. Wharfage is solely the charge for use of wharf and does not include charges for any other service.

(3) *Free time* means the specified period during which cargo may occupy space assigned to it on terminal property free of wharf demurrage or terminal storage changes immediately prior to the unloading or subsequent to the discharge of such cargo on or off the vessel.

(4) *Wharf demurrage* means a charge assessed against cargo remaining in or on terminal facilities after the expiration of free time unless arrangements have been made for storage.

(5) *Terminal storage* means the service of providing warehouse or other terminal facilities for the storage of inbound or outbound cargo after the expiration of free time, including wharf storage, shipside storage, closed or covered storage, open or ground storage, bonded storage and refrigerated storage, after storage arrangements have been made.

(6) *Handling* means the service of physically moving cargo between point of rest and any place on the terminal facility, other than the end of ship's tackle.

(7) *Loading and unloading* means the service of loading or unloading cargo between any place on the terminal and railroad cars, trucks, lighters or barges or any other means of conveyance to or from the terminal facility.

(8) *Usage* means the use of terminal facility by any rail carrier, lighter operator, trucker, shipper or consignee, its agents, servants, and/or employees, when it performs its own car, lighter or truck loading or unloading, or the use of said facilities for any other gainful purpose for which a charge is not otherwise specified.

(9) *Checking* means the service of counting and checking cargo against appropriate documents for the account of the cargo or the vessel, or other person requesting same.

(10) *Heavy lift* means the service of providing heavy lift cranes and equipment for lifting cargo.

§ 515.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

This section displays the control numbers assigned to information collection requirements of the Commission in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511. The Commission intends that this section comply with the requirements of section 3507(f) of the Paperwork Reduction Act, which

requires that agencies display a current control number assigned by the Director of the Office of Management and Budget (OMB) for each agency information collection requirement:

Section	Current OMB control No.
515.3 through 515.5	3072-0002

PART 520—FILING OF TARIFFS BY TERMINAL BARGE OPERATORS IN PACIFIC SLOPE STATES

§ 520.1 Scope.

(a) The rules and regulations set forth in this part cover the filing of tariffs by terminal barge operators in Pacific Slope States in the foreign and domestic commerce of the United States.

(b) Terminal barge operators moving containers or containerized cargo by barge between points in the Continental United States shall file a schedule of their rates, charges and services solely with the Federal Maritime Commission where:

(1) The cargo is moving between a point in a foreign country or a noncontiguous State, territory, or possession and a point in the United States.

(2) The transportation by barge between points in the United States is furnished by a terminal operator as a service substitute in lieu of a direct vessel call by the common carrier by water transporting the containers or containerized cargo under a through bill of lading.

(3) Such terminal operator is a Pacific Slope State municipality, or other public body or agency subject to the jurisdiction of the Federal Maritime Commission, and the only one furnishing the particular circumscribed barge service on January 2, 1975.

(4) Such terminal operator is in compliance with the rules and regulations of the Federal Maritime Commission for the operation of such barge service.

(c) The terminal operator providing such service shall be subject to the provisions of the Shipping Act, 1916 and/or the Shipping Act of 1984.

(5 U.S.C. 553; secs. 3, 18(a) and 43 of the Shipping Act, 1916 (46 U.S.C. app. 804, 817(a) and 841(a)); sec. 2 of the Intercoastal Shipping Act, 1933 (46 U.S.C. app. 844); and secs. 8 and 17 of the Shipping Act of 1984 (46 U.S.C. app. 1707 and 1716))

§ 520.2 Tariff filing requirements.

(a) Terminal barge operators subject to this part shall comply with the tariff filing requirements of Part 580 of this Chapter with respect to the publication of rates, charges and services for cargo moving in the foreign and/or domestic offshore commerce of the United States.

(b) Terminal barge operators, while exempt from the tariff filing form requirements of Part 550 of this Chapter with respect to their operations as water carriers carrying cargo in the domestic offshore trades, shall comply with all other required regulations, where applicable.

(c) Tariff(s) filed pursuant to § 520.2(a) shall specifically provide that the rates charged are based upon factors normally considered by a regular commercial operator in the same service.

Note.—In accordance with 44 U.S.C. 3506(c)(5), any information request or requirement in this part is not subject to the requirements of section 3507(f) of the Paperwork Reduction Act, because there are nine or fewer respondents.

(5 U.S.C. 553; secs. 3, 18(a) and 43 of the Shipping Act, 1916 (46 U.S.C. app. 804, 817(a) and 841(a)); sec. 2 of the Intercoastal Shipping Act, 1933 (46 U.S.C. app. 844); and secs. 8 and 17 of the Shipping Act of 1984 (46 U.S.C. app. 1707 and 1716))

PART 525—FREE TIME AND DEMURRAGE CHARGES ON IMPORT PROPERTY APPLICABLE TO ALL COMMON CARRIERS BY WATER

§ 525.1 Free time and demurrage charges at the Port of New York.

(a) Free time of five days (exclusive of Saturdays, Sundays, and legal holidays), computed from the start of business on the first day after complete discharge of the vessel, is adequate free time on import property at New York under present conditions.

(b) Free time on import property at New York shall not be less than five days, except on property of such a special nature as to require earlier removal because of local ordinances or other governmental regulations, or because piers are not equipped to care for such property for such period, or except as the Commission may hereafter direct.

(c) Except as provided in §§ 530.3(e)(2), 530.4(e) and 530.4(g) of this Chapter, where a carrier is for any reason, unable, or refuses, to tender cargo for delivery during free time, free time must be extended for a period equal to the duration of the carrier's disability or refusal. If such condition arises after the expiration of free time, either no demurrage or first period demurrage, whichever is specified in the appropriate tariff, will be charged for a period equal to the duration of the carrier's inability or refusal.

(d) Where a consignee is prevented from removing its cargo by factors beyond its control (such as, but not limited to, longshoremen's strikes, trucking strikes or weather conditions) which affect an entire port area or a substantial portion thereof, and when a consignee is prevented from removing its cargo by a longshoremen's strike which affects only one pier or less than a substantial portion of the port area, carriers shall (after expiration of free time) assess demurrage against imports at the rate applicable to the first demurrage period, for such time as the inability to remove the cargo may continue. Every departure from the regular demurrage charges shall be reported to the Commission.

(e) The Commission makes no finding approving or disapproving demurrage rates presently effective as to import property at the port of New York.

(f) Following a longshoremen's strike of five (5) days or more:

(1) Free time shall be extended for a period not less than five (5) days (exclusive of Saturdays, Sundays, and legal holidays) beyond the time at which it would normally terminate, for cargo which was in a free time period at the commencement of the longshoremen's strike.

(2) First period demurrage shall be extended for a period not less than five (5) calendar days beyond the time at which it would normally terminate, for cargo which was subject to first period demurrage at the commencement of the longshoremen's strike.

(g) The extensions set forth in paragraphs (f)(1) and (f)(2) of this section, shall apply only: (1) If the cargo is actually picked up within such extended time or (2) if, pursuant to an appointment system adopted by both carriers and consignees, cargo is picked up within twenty-four (24) hours of advance notification that cargo is available for pickup and readily accessible, in which latter event, time shall not be extended more than twenty-four (24) hours beyond the additional free time or demurrage period.

Note.—In accordance with 44 U.S.C. 3506(c)(5), any information request or requirement in this part is not subject to the requirements of section 3507(f) of the Paperwork Reduction Act, because ;there are nine or fewer respondents.

(5 U.S.C. 553; secs. 17 and 43 of the Shipping Act, 1916 (46 U.S.C. app. 816, 841a); secs. 10 and 17 of the Shipping Act of 1984 (46 U.S.C. app. 1709 and 1716))

PART 530—TRUCK DETENTION AT THE PORT OF NEW YORK

Sec.

530.1 General provisions.
530.2 Documentation.
530.3 Terminals operating on appointment system.
530.4 Terminals operating a non-appointment system.
530.5 Combination non-appointment/appointment system.
530.6 Computation of time.
530.7 Penalties.
530.8 Submission of claims for penalties.
530.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.
Appendix A—New York/New Jersey Port District
Appendix B—Motor carrier Preference Slip

Authority: 5 U.S.C. 553; secs. 17 and 43 of the Shipping Act, 1916 (46 U.S.C. app. 816 and 841a); secs. 10 and 17 of the Shipping Act of 1984 (46 U.S.C. app. 1709 and 1716).

§ 530.1 General provisions.

(a) *The Port of New York* is that area designated as "The Port District" on the map (Appendix A).

(b) For purposes of this part, a terminal operator is any person who receives cargo from motor carriers and/or delivers cargo to motor carriers in connection with transportation by common carrier by water, excluding persons who operate marine terminal facilities controlled by the Department of Defense including the military department and all agencies of the Department of Defense.

(c) Motor carriers (common, contract, or private), terminal operators, including steamship companies acting as terminal operators, and steamship companies whose action or inaction otherwise impedes expeditious pickup and delivery of cargo by motor carriers at marine terminal facilities within the Port of New York, shall be subject to the provisions established by terminal operators in accordance with this part, which provisions shall be reflected in the tariff of each such terminal operator.

(d) Importers and exporters, or motor carriers or other agents of importers or exporters, and terminal operators at marine terminal facilities in the Port of New York, shall be entitled to receive remuneration in accordance with the provisions of this part.

(e) The person responsible for operating each marine terminal facility within the Port of New York shall identify itself to the Federal Maritime Commission not more than 10 days after the effective date of this part and shall thereafter promptly notify the Commission of any change in responsibility. Based thereon, the Federal Maritime Commission (Commission) will publish and maintain a current list identifying, as to each such marine terminal facility, the party responsible for receipt and settlement of claims arising under this part.

(f) All communications to the Federal Maritime Commission required by this part shall be directed to the Federal Maritime Commission, Office of the Secretary, 1100 L Street NW., Washington, D.C. 20573.

(g)(1) Except as provided in paragraph (g)(2) of this section, no penalty shall be imposed upon a terminal operator under this part if receipt or delivery of cargo at a marine terminal facility is prevented or delayed by strike or work stoppage, act of God, fire, serious accident, or severe or unusual weather condition. The Commission shall be notified in writing by the party claiming the existence of the condition who shall specify the date and time of commencement and termination of any such strike, work stoppage, or severe or unusual weather or other condition.

(2) No terminal operator shall be absolved from liability under this part for delays resulting from inadequate or insufficient labor, and/or equipment, other than reasonable delays necessary to obtain special equipment required for handling unusual cargo on a non-appointment basis

(h) Terminal operators shall not be liable for delays due to United States Government regulations; nor shall terminal operators be liable for time consumed by receipt or delivery of cargo by marks other than by bill of lading, provided at the request of the shipper, consignee or motor carrier.

(i) Steamship companies responsibile for house-to-house movement of containers, i.e., containers moving as a unit from origin to destination, are responsible under this part for delay occasioned by lack of sufficient chassis, or unavailability, action or inaction of their container inspection personnel. For purposes of this part, "containers" shall include empty as well as stuffed containers.

(j) Disputes concerning liability under any provisions of this part shall be settled by an impartial Adjudicator selected by the Commission.

(k) Terminal operators are not required to deliver cargo to motor carriers prior to the time that the ocean vessel which transported said cargo is fully discharged. If a terminal operator exercises the option of delivering cargo to motor carriers prior to the time that the ocean carrier which transported said cargo is fully discharged, the terminal operator shall notify the consignee or its designated agent that the cargo is on the pier, at its place of rest, and segregated by bill of lading, and shall identify the terminal operator employee giving such notification.

(l) Marine terminal facilities in the Port of New York shall be operated in accordance with the appointment, non-appointment, or combination appointment/non-appointment procedures established by the terminal operator in accordance with this part. Each terminal operator shall identify in its respective tariff whether its marine terminal facility will be operated on an appointment, non-appointment, or combination appointment/non-appointment basis. Said tariff shall incorporate the specific procedures applicable at each such marine terminal facility, which procedures shall comply with the provisions of this part, be prominently displayed at the marine facility, and shall be modified on not less than 30 days' notice.

(m) Compliance is mandatory and failure of terminal operators or motor carriers to follow the provisions of this part may result in the assessment of penalties as specified in § 530.7.

§ 530.2 Documentation.

(a)(1) Delivery orders shall not be mailed or delivered to terminal operators, nor mailed or delivered to steamship companies for receipt on behalf of terminal operators, prior to arrival of motor carrier vehicles at marine terminal facilities. Dock receipts may be lodged with terminal operators or steamship companies for receipt on behalf of terminal operators prior to arrival of motor carrier vehicles at marine terminal facilities. Upon arrival at marine terminal facilities, motor carrier vehicle operators shall have physical possession of delivery orders required by this part, and shall either have physical possession of dock receipts required by this part or shall have had said dock receipts lodged with the terminal operator or steamship company in accordance with the above-described procedure. Motor carrier vehicles having physical possession of delivery orders or dock receipts immediately shall be issued a sequentially numbered and time-stamped gate pass by order of arrival. When dock receipts are lodged with the terminal operator or steamship company, the sequentially numbered and time-stamped gate pass immediately shall be issued upon tender of the dock receipt to the gateman by the motor carrier vehicle driver. The sequential number and all time stamps and notations recorded on the gate pass and any other arrival document shall be recorded on the copy of the delivery

order or dock receipt retained by the motor carrier. Motor carrier vehicles not complying with the requirements of this paragraph shall be denied entry to the marine terminal facility.

(2) Motor carriers shall be permitted to receive cargo on Open Delivery Orders, i.e., single delivery orders covering multiple truckloads or shipments, and deliver cargo on Open Dock Receipts, i.e., single dock receipts covering multiple truckloads or shipments, upon presenting to the terminal operator, subsequent to receipt or delivery of the initial load, satisfactory evidence of authorization to effect receipt or delivery of the remaining truckloads or shipments, as established by the terminal operator and published in its tariff.

(b) Dock receipts required as full and complete documentation for receipt of export cargo shall include the following information:

(1) Name of the motor carrier.

(2) Name of forwarding agent. (If none, insert "none".)

(3) Shipper.

(4) Name of vessel.

(5) Pier, berth, or area designated for receipt of cargo.

(6) Port of discharge.

(7) Container identification and seal number. (On full container loads.)

(8) Booking number.

(9) Cargo to be held on dock should be so indicated in space provided for vessel name.

(10) Marks, number of packages, commodity, cube and weight.

(11) An original and three copies of the dock receipt authorized by the steamship line that is to receive the cargo must be tendered to the terminal operator, one copy of which shall be returned to and retained by the motor carrier in accordance with § 530.2(a)(1).

(c) Delivery order required as full and complete documentation for the delivery of import cargo shall provide the following information:

(1) Name and address of party issuing delivery order.

(2) Address of terminal.

(3) Name and address of motor carrier making pickup.

(4) Vessel name.

(5) Voyage number or estimated date of arrival.

(6) Bill of Lading number.

(7) Port of Lading.

(8) City of destination. (On full container loads.)

(9) Container identification number. (On full container loads.)

(10) Booking number. (On receipt of empty containers.)

(11) Marks, number of packages, commodity, cube and weight. When partial lots are to be delivered, they should be identified by marks.

(12) Date free time expires.

(13) Date through which demurrage is paid/guaranteed after free time has expired.

(14) An original and two copies of the delivery order, the original legibly signed in ink, with the name of the signer typed below the signature, shall be tendered to the terminal operator, one copy of which shall be returned to and retained by the motor carrier in accordance with § 530.2(a)(1).

(d)(1) Terminal operators shall not honor delivery orders with strikeouts or other changes to the original.

(2) If a motor carrier named in an original delivery order substitutes another motor carrier in its place, the motor carrier named in the original delivery order shall provide a turnover order to the second carrier containing all information required by the original delivery order. Both the original delivery order and the turnover order must be presented to the terminal operator by the motor carrier requesting delivery of cargo. Upon written request, in accordance with procedures established by the terminal operator and published in its tariff, special arrangements may be made to accommodate general agency situations.

(e) If a motor carrier presents documents to the terminal operator which do not contain all information required by this part, or which are complete but contain inaccurate information, said motor carrier shall be required to surrender its gate pass and shall be denied service; or, at the request of said motor carrier, the terminal operator may correct or complete the deficient document and service said motor carrier in accordance with this part.

(f) If documents are rejected by the terminal operator, or service is refused for any other reason, the terminal operator shall provide the motor carrier written explanation, time-stamped, of the deficiencies in documentation or other reason(s) for refusal of service, and shall attach thereto a copy of the deficient document, if any.

(g) Section 530.2(e) shall not be applicable if documents are incorrect because of substitution of one vessel for another, redocking of a vessel from a scheduled pier to another, or change in consignment of an export shipment from a scheduled vessel to another due to an early closeout of the scheduled vessel or other such rescheduling for the convenience of the steamship company or terminal operator. Delay occasioned in such circumstances shall be included in the computation of time for purposes of this rule and chargeable to the party responsible for such change.

§ 530.3 Terminals operating on appointment system.

Subject to the following provisions of this section, terminal operators shall establish the basis upon which appointments will be available and shall publish in their tariffs reasonable methods and procedures for booking appointments.

(a)(1) Except for good cause, all requests for appointments shall be granted. If a request for an appointment is not granted, the terminal operator shall record the request and reason for refusal.

(2) Appointments, when granted, shall be identified by sequentially assigned numbers. The terminal operator shall record the date and time of requests for appointments, the name of the person making the requests; the date, time and identification number of scheduled appointments; and shall identify the terminal operator employee granting the appointment.

(b) Appointments to receive delivery of cargo shall not be granted by terminal operators unless and until a freight release covering subject cargo has been provided by the steamship company. Appointments shall be granted only if the terminal operator is advised of the nature, type and quantity of cargo to be delivered or received. If, because of the size, weight or shape of the cargo, special equipment is required, the terminal operator shall so advise the motor carrier at the time the appointment is granted, and the motor carrier shall advise the terminal operator of the type of "rolling stock" which it will employ to effectuate the interchange of cargo.

(c)(1) Gate passes shall be issued to motor carriers by order of arrival at the marine terminal facility. Motor carriers arriving after the time of a scheduled appointment shall be deemed to have missed the appointment and may be denied service.

(2) Except where a terminal operator has arranged for delivery of cargo on the last day of free time, or on the first or second day of demurrage, in accordance with paragraph (e)(2) of this section, motor carriers may cancel appointments (without penalty), provided the terminal operator is given three (3) working hours' notice of said cancellation.

(d)(1) Upon receipt of a gate pass issued pursuant to paragraph (c)(1) of this section, motor carrier personnel holding dock receipts or other satisfactory evidence of authorization to effect delivery or cargo shall proceed

immediately to the receiving clerk of the terminal operator who shall immediately time-stamp the gate pass upon presentation of documents. After said documents are determined to be in proper order, the motor carrier shall be routed for unloading.

(2) Upon receipt of a gate pass issued pursuant to paragraph (c)(1) of this section, motor carrier personnel holding delivery orders or other satisfactory evidence of authorization to receive delivery of cargo shall proceed to the Bureau of Customs for completion of required procedures, and thereafter, shall immediately proceed to the delivery clerk of the terminal operator who shall immediately time-stamp the gate pass upon presentation of documents. After said documents are determined to be in proper order, the motor carrier shall be routed for loading.

(e)(1) See § 525.1(c) of this chapter for provisions regarding extension of free time.

(2) At full-appointed terminals, if an appointment is not available as requested, an appointment shall be granted within 72 hours (three business days) of said request, except as provided by paragraphs (e)(2)(i) and (e)(2)(ii) of this section.

(i) *Cargo permitted 5 days' free time–Extension of free time.* (A) If an appointment is requested at least 48 hours prior to the expiration of free time, the terminal operator shall arrange to deliver cargo prior to expiration of free time, or extend free time until an appointment is granted.

(B) If an appointment is requested less than 48 hours—but more than 24 hours—prior to expiration of free time, the terminal operator shall arrange for delivery of cargo prior to the close of business on the first working day of demurrage for which first demurrage day the cargo shall be liable, or, after said first demurrage day, cargo shall assume non-demurrage status until an appointment is granted.

(C) If an appointment is requested less than 24 hours prior to expiration of free time, the terminal operator shall arrange for delivery of cargo prior to the close of business on the second working day of demurrage for which two (2) demurrage days the cargo shall be liable, or, after said two (2) demurrage days, cargo shall assume non-demurrage status until an appointment is granted.

(ii) *Cargo permitted 2 or 3 days' free time—Extension of free time.* (A) If an appointment is requested at least 24 hours prior to expiration of free time, the terminal operator shall arrange to deliver cargo prior to expiration of free time or extend free time until an appointment is granted.

(B) If an appointment is requested less than 24 hours prior to expiration of time, the terminal operator shall arrange for delivery of cargo prior to the close of business on the first working day of demurrage for which first demurrage day the cargo shall be liable, or, after said first demurrage day, cargo shall assume non-demurrage status until an appointment is granted.

§ 530.4 Terminals operating a non-appointment system.

(a) Each business day shall be divided into a number of "service periods" (for example, periods commencing at 8 a.m., 10 a.m., 1 p.m., 3 p.m.) as scheduled by the terminal operator according to the nature and capabilities of the particular facility.

(b) Motor carriers arriving at marine terminal facilities shall be issued sequentially numbered time-stamped gate passes by order of arrival, valid for entry to the terminal facility at the time of commencement of the service period indicated thereon.

(c) Upon receipt of a gate pass issued pursuant to paragraph (b) of this section, motor carrier personnel holding dock receipts or other satisfactory evidence of authorization to effect delivery of cargo shall proceed immediately to the receiving clerk of the terminal operator who shall immediately time-stamp the gate pass upon presentation of documents. After said documents are determined to be in proper order, the motor carrier shall be routed for unloading.

(d) Upon receipt of a gate pass issued pursuant to paragraph (b) of this section, motor carrier personnel holding delivery orders or other satisfactory evidence of authorization to receive delivery of cargo shall proceed to the Bureau of Customs for completion of required procedures and thereafter immediately proceed to the delivery clerk of the terminal operator, who shall immediately time-stamp the gate pass upon presentation of documents. After said documents are determined to be in proper order, the motor carrier shall be routed for loading.

(e) A motor carrier entitled to a gate pass scheduling service for a later service period, but unwilling to wait for that service, may elect, not more than 30 minutes after issuance of said gate pass, to receive a preference slip (Appendix B), entitling said motor carrier to service on the next business day as specified thereon. However, free time will not be extended if cargo is on the last day of free time, nor will collection of demurrage charges be suspended.

(f) Motor carriers arriving at a marine terminal facility after the capacity of said facility has been reached may be turned away, but shall be given preference for service on the next business day according to the order in which they arrived and were turned away. Motor carriers turned away under these circumstances shall be issued a preference slip (Appendix B), sequentially numbered, which shall assure preference for service on the next business day and, where cargo is on the last day of free time, create a one-day extension of free time, or suspend collection of demurrage charges for one day as to cargo already on demurrage. The preference slip shall be attached to the gate pass when said gate pass is issued and all notations recorded on the preference slip shall be duplicated in the motor carrier's copy of the delivery order or dock receipt.

(g) If, at the commencement of its scheduled service period, a motor carrier is not available to receive cargo which is on the last day of free time, and because of the unavailability of said motor carrier, the terminal operator is unable to provide service on that day, there shall be no extension of free time.

(h) If all vehicles scheduled for a service period are discharged prior to the end of that period, the motor carrier available and holding the next sequenced gate pass shall be served.

(i) It shall be the responsibility of the motor carrier to determine from the terminal operator whether cargo to be delivered to said motor carrier is on the pier, at its place of rest, and segregated by bill of lading.

§ 530.5 Combination non-appointment/appointment system.

(a) An express line or non-appointment line may be established in conjunction with an appointment system in such a manner as the terminal operator determines best suits the needs of the particular facility.

(b) All rules applicable to non-appointment facilities (§ 530.4) shall be applicable to the non-appointment portion of a combination non-appointment/appointment terminal operation.

(c) If a motor carrier attempts to make an appointment at a facility operating a combination system, and no appointment is available, and then said motor carrier seeks service as a non-appointment vehicle, said motor carrier shall be treated as a non-appointment vehicle for purposes of extension of free time.

§ 530.6 Computation of time.

(a) Validation time is: (1) Time of issuance of a gate pass upon a motor

carrier's arrival at a marine terminal facility or (2) if, upon arrival, a motor carrier is scheduled for a later service period, the time of commencement of that scheduled service period, or (3) if a motor carrier is issued a preference slip pursuant to § 530.4(e) or § 530.4(f), the time scheduled thereon.

(b) Time for purposes of this part shall accrue from validation or appointment time. Delay demonstrated by the terminal operator to be due to United States Government regulations, action or inaction of motor carrier personnel, or other such cause, shall be excluded from computation of time. Time elapsed, if any, between appointment or validation time and presentation of documents to the delivery or receiving clerk shall be presumed to be due to such cause.

§ 530.7 Penalties.

(a) A terminal operator who refuses to serve a motor carrier after rejecting, for lack of full and complete documentation, a delivery order or dock receipt which does contain the information required by this part, shall be subject to a penalty of $30.

(b) If a motor carrier fails to meet a scheduled appointment at a marine terminal facility, said motor carrier shall be subject to a charge of $15. If, pursuant to § 530.3(b) a motor carrier is advised that special equipment will be required and the motor carrier fails to meet said appointment, the motor carrier shall be subject to a charge of $30.

(c) If, pursuant to § 530.2(e), a terminal operator completes or corrects deficient documents presented by a motor carrier, a charge of $15 shall be assessed against said motor carrier.

(d) If, contrary to § 530.3(b) a freight release covering subject cargo has not been authorized prior to a scheduled appointment, the terminal operator that granted said appointment shall be assessed a penalty of $30.

(e) If, pursuant to § 530.1(k) or a request under § 530.4(i) a terminal operator notifies a motor carrier that cargo is on the pier, at its place of rest, and segregated by bill of lading, and cargo is not on the pier, at its place of rest, and segregated by bill of lading, when the motor carrier attempts to obtain said cargo, the terminal operator shall be subject to a penalty of $30.

(f) *Time allowances*—(1) *Containers handled as a single unit.* If service is not completed within the following times, penalty charges will accrue against the terminal operator at a rate or $4 per 15 minutes, or any fraction thereof, in excess of these times.

Appointment	75 minutes.
Non-appointment	120 minutes.

(2) *Non-containerized cargo.* When vehicles are loaded by the terminal operator, or unloaded by the terminal operator at the request of the motor carrier, within the time periods set forth below, there will be no penalty. If a vehicle is not loaded or unloaded within the following time periods, penalty charges will accrue against the terminal operator at a rate of $4.00 per 15 minutes, or any fraction thereof, in excess of these times.

(i) *Non-Appointment Vehicles:*

0 to 5,000 pounds	210 minutes.
5,001 to 10,000 pounds	240 minutes.
10,001 to 15,000 pounds	270 minutes.
15,001 to 30,000 pounds	285 minutes.
Over 30,000 pounds	300 minutes.

(ii) *Appointment Vehicles:*

2,000 pounds or less	90 minutes.
2,001 to 5,000 pounds	120 minutes.
5,001 to 10,000 pounds	150 minutes.
10,001 to 15,000 pounds	180 minutes.
15,001 to 20,000 pounds	210 minutes.
20,001 to 25,000 pounds	240 minutes.
Over 25,000 pounds	270 minutes.

(g) When freight is unloaded by the driver or other personnel of the motor carrier and unloading is not completed within the times prescribed by paragraph (f) of this section, as computed from the time that the vehicle is spotted at a place convenient for unloading, the terminal operator shall be entitled to a penalty payment of $4 for each 15 minute period or any fraction thereof in excess of the specified time, unless the delay is demonstrated by the motor carrier to have been occasioned by the action or inaction of the terminal operator.

(h) A motor carrier admitted to a marine terminal facility for loading or unloading—or holding an appointment for loading or unloading—shall be completely loaded or unloaded prior to the close of that business day. If the motor carrier is not completely loaded or unloaded when the terminal closes on that business day, time for purposes of this part shall accrue only while the terminal is conducting operations. In addition:

(1) Motor carriers holding appointments shall be entitled to a penalty payment of $30 from the terminal operator whether the shutout of the vehicle was due to refusal of management to authorize overtime, or labor's refusal to work overtime.

(2) Non-appointment vehicles shall be entitled to a penalty payment of $30 from the terminal operator if the shutout of the vehicle was due to refusal of management to authorize overtime. If the shutout results from labor's refusal to work overtime, the terminal operator shall not be subject to a penalty.

(3) Management shall be presumed to have refused to authorize overtime, unless the terminal operator establishes otherwise.

§ 530.8 Submission of claims for penalties.

(a) All communication required by this section shall be via certified mail; return receipt requested.

(b) Any person claiming payments under this section shall file a written claim with the terminal operator or motor carrier against whom said claim is made.

(c)(1) Claims shall be filed within forty-five (45) calendar days from the date on which the claim arose or said claim shall be barred. The party against whom claim is made shall within twenty (20) calendar days from receipt of said claim make payment thereon or reject. In rejecting a claim, the terminal operator or motor carrier shall set forth the reason or reasons for said rejection and shall provide available documentation substantiating said rejection. Claims rejected because they do not contain sufficient information may be resubmitted no later than twenty (20) days from receipt of rejection.

(2) Rejected claims may be submitted for review within twenty (20) days of receipt of rejection to the Adjudicator who will affirm or reverse the rejection of claims within 30 days of receipt of the request for review. All decisions of Adjudicator shall be final and binding.

(d)(1) Claims submitted by motor carriers, or importers or exporters on whose behalf motor carriers act, shall include the motor carrier's copy of the applicable delivery order or dock receipt, any other relevant document, a brief, but complete description of the facts giving rise to the claim, and a statement of the amount claimed.

(2) Claims filed by terminal operators shall include the terminal operator's copy of the applicable delivery order or dock receipt, a copy of the gate pass and any other arrival documents issued, copies of all other relevant documents, a brief explanation of the facts giving rise to the claim, and a statement of the amount claimed.

(e)(1) If the party identified as the terminal operator at a marine terminal facility under § 530.1(e) rejects a claim pursuant to § 530.1(1) or § 530.2(g), or otherwise denies a claim on the ground that the delay was caused by the steamship company, the original claim and a statement of the reasons for rejection shall be forwarded within seven days to the steamship company alleged by the terminal operator to be liable for the claim, copy to the claimant.

(2) The steamship company shall pay or reject the claim within twenty (20) calendar days from receipt thereof.

(3) If the claim is rejected by the steamship company, the claimant may submit both rejections to the Adjudicator who shall review the rejection of the claim by both parties and determine liability as between the two.

§ 530.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

This section displays the control numbers assigned to information collection requirements of the Commission in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511. The Commission intends that this section comply with the requirements of section 3507(f) of the Paperwork Reduction Act, which requires that agencies display a current control number assigned by the Director of the Office of Management and Budget (OMB) for each agency information collection requirement:

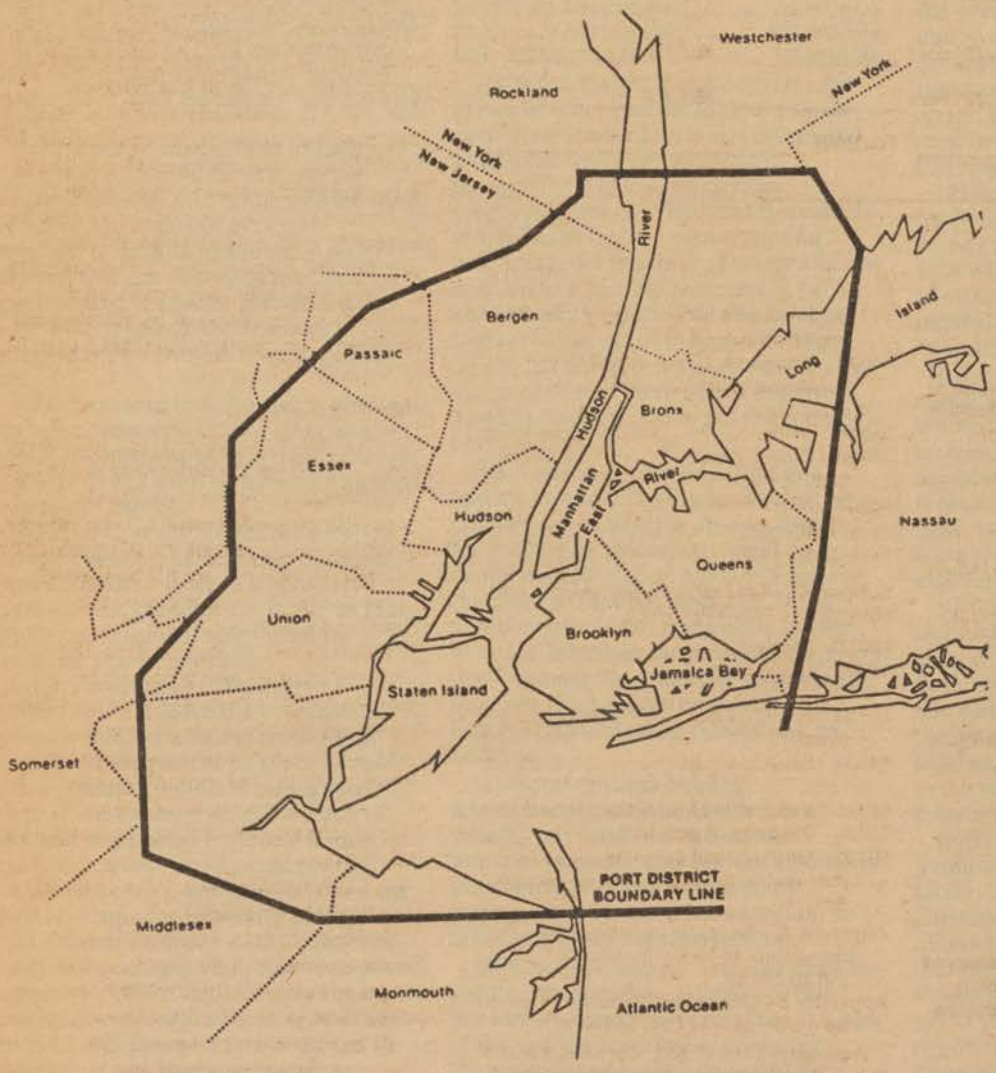
Section	Current OMB control No.
530.1 through 530.3	3072-0010
530.8	3072-0010

BILLING CODE 6730-01-M

Appendix A to 46 CFR Part 530

(From 1981 "New York Port Handbook")

New York/New Jersey Port District



BILLING CODE 6730-01-C

Appendix B to 46 CFR Part 530

Motor Carrier Preference Slip
(See § 530.4)

No. _____ TIME STAMP

STEVEDORING CO. INC.

LOCATION (Pier/Berth/Shed) _____

MOTOR CARRIER _____

The above indicated vehicle could not be serviced today. Preference for service will be given the next business day at _____ a.m./p.m.

D/R's _____ Pkgs./Pieces _____ WEIGHT _____

D/O's _____ Pkgs./Pieces _____ WEIGHT _____

CONTAINER # _____ GATEMAN _____

PART 540—SECURITY FOR THE PROTECTION OF THE PUBLIC

Subpart A—Proof of Financial Responsibility, Bonding and Certification of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation

Sec.

540.1 Scope.
540.2 Definitions.
540.3 Proof of financial responsibility, when required.
540.4 Procedure for establishing financial responsibility.
540.5 Insurance, guaranties, escrow accounts, and self-insurance.
540.6 Surety bonds.
540.7 Evidence of financial responsibility.
540.8 Denial, revocation, suspension, or modification.
540.9 Miscellaneous.
Form FMC–131
Form 132A
Form 133A

Subpart B—Proof of Financial Responsibility, Bonding and Certification of Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages

540.20 Scope.
540.21 Definitions.
540.22 Proof of financial responsibility, when required.
540.23 Procedure for establishing financial responsibility.
540.24 Insurance, surety bonds, self-insurance, guaranties, and escrow accounts.
540.25 Evidence of financial responsibility.
540.26 Denial, revocation, suspension, or modification.
540.27 Miscellaneous.
Form FMC–132B
Form FMC–133B

Subpart C—Assessment, Remission, and Mitigation of Civil Penalties

540.30 Scope.
540.31 Definitions.
540.32 Procedure.
540.33 Petition for remission or mitigation of penalty.
540.34 Settlement; execution of agreement form.
540.35 Referral to Department of Justice.
540.36 Payment of penalties.
590.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.
Appendix A—Example of Settlement Agreement to be used under 46 CFR 540.30–540.36
Appendix B—Example of promissory not to be used under 46 CFR 540.36

Authority: 5 U.S.C. 552, 553; secs. 2 and 3, Pub. L. 89–777, 80 Stat. 1356–1358 (46 U.S.C. app. 817e, 817d); Sec. 43 of the Shipping Act, 1916 (46 U.S.C. app. 841a); Sec. 17 of the Shipping Act of 1984 (46 U.S.C. app. 1716).

Subpart A—Proof of Financial Responsibility, Bonding and Certification of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation

§ 540.1 Scope.

(a) The regulations contained in this subpart set forth the procedures whereby persons in the United States who arrange, offer, advertise or provide passage on a vessel having berth or stateroom accommodations for 50 or more passengers and embarking passengers at U.S. ports shall establish their financial responsibility or, in lieu thereof, file a bond or other security for obligations under the terms of ticket contracts to indemnify passengers for nonperformance of transportation to which they would be entitled. Included also are the qualifications required by the Commission for issuance of a Certificate (Performance) and the basis for the denial, revocation, modification, or suspension of such Certificates.

(b) Failure to comply with this part may result in denial of an application for a certificate. Vessels operating without the proper certificate may be denied clearance and their owners may also be subject to a civil penalty of not more than $5,000 in addition to a civil penalty of $200 for each passage sold, such penalties to be assessed by the Federal Maritime Commission (46 U.S.C. app. 91, 817d and 817e).

§ 540.2 Definitions.

As used in this subpart, the following terms shall have the following meanings:

(a) *Person* includes individuals, corporations, partnerships, associations, and other legal entities existing under or authorized by the laws of the United States or any State thereof or the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands or any territory or possession of the United States, or the laws of any foreign country.

(b) *Vessel* means any commercial vessel having berth or stateroom accommodations for 50 or more passengers and embarking passengers at U.S. ports.

(c) *Commission* means the Federal Maritime Commission.

(d) *United States* includes the Commonwealth of Puerto Rico, the Virgin Islands or any territory or possession of the United States.

(d) *Berth or stateroom accommodation* or *passenger accommodations* includes all temporary and all permanent passenger sleeping facilities.

(f) *Certificate (Performance)* means a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation issued pursuant to this subpart.

(g) *Passenger* means any person who is to embark on a vessel at any U.S. port and who has paid any amount for a ticket contract entitling him to water transportation.

(h) *Passenger revenue* means those monies wherever paid by passengers who are to embark at any U.S. port for water transportation and all other accommodations, services and facilities relating thereto.

(i) *Unearned passenger revenue* means that passenger revenue received for water transportation and all other accommodations, services, and facilities relating thereto not yet performed.

(j) *Insurer* means any insurance company, underwriter, corporation, or association or underwriters, ship owners' protection and indemnity association, or other insurer acceptable to the Commission.

(k) *Evidence of insurance* means a policy, certificate of insurance, cover note, or other evidence of coverage acceptable to the Commission.

§ 540.3 Proof of financial responsibility, when required.

No person in the United States may arrange, offer, advertise or provide passage on a vessel unless a Certificate (Performance) has been issued to or covers such person.

§ 540.4 Procedure for establishing financial responsibility.

(a) In order to comply with section 3 of Pub. L. 89–777 (80 Stat. 1357, 1358) enacted November 6, 1966, there must be filed an application on Form FMC–131 for a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation. Copies of Form FMC–131 may be obtained from the Secretary, Federal Maritime Commission, Washington, D.C. 20573, or at the Commission's offices at New York, NY; New Orleans, LA; San Francisco, CA; Miami, FL; Los Angeles, CA; Hato Rey, PR; and Chicago, IL.

(b) An application for a Certificate (Performance) shall be filed in duplicate with the Secretary, Federal Maritime Commission, by the vessel owner or charterer at least 60 days in advance of the arranging, offering, advertising, or providing of any water transportation or tickets in connection therewith except that any person other than the owner or charterer who arranges, offers, advertises, or provides passage on a vessel may apply for a Certificate (Performance). Late filing of the application will be permitted only for good cause shown. All applications and evidence required to be filed with the Commission shall be in English, and any monetary terms shall be expressed in terms of U.S. currency. The Commission shall have the privilege of verifying any statements made or any evidence submitted under the rules of this subpart. An application for a Certificate (Performance) shall be accompanied by a filing fee remittance of $1,600.

(c) The application shall be signed by a duly authorized officer or representative of the applicant with a copy of evidence of his or her authority. In the event of any material change in the facts as reflected in the application, an amendment to the application shall be filed no later than five (5) days following such change. For the purpose of this subpart, a material change shall be one which: (1) Results in a decrease in the amount submitted to establish financial responsibility to a level below that required to be maintained under the rules of this subpart, or (2) requires that the amount to be maintained be increased above the amount submitted to establish financial responsibility. Notice of the application for, issuance, denial, revocation, suspension, or modification of any such Certificate shall be published in the **Federal Register.**

§ 540.5 Insurance, guaranties, escrow accounts, and self-insurance.

Except as provided in § 540.9(j), the amount of coverage required under this section and § 540.6(b) shall be in an amount determined by the Commission to be no less than 110 percent of the unearned passenger revenue of the applicant on the date within the 2 fiscal years immediately prior to the filing of the application which reflects the greatest amount of unearned passenger revenue, except that the Commission, for good cause shown, may consider a time period other than the previous 2-fiscal-year requirement in this section or other methods acceptable to the Commission to determine the amount of coverage required. Evidence of adequate financial responsibility for the purposes of this subpart may be established by one or a combination (including § 540.6 *Surety Bonds*) of the following methods:

(a) Filing with the Commission evidence of insurance, issued by an insurer, providing coverage for indemnification of passengers in the event of the nonperformance of water transportation.

(1) Termination or cancellation of the evidence of insurance, whether by the assured or by the insurer, and whether for nonpayment of premiums, calls or assessments or for other cause, shall not be effected: (i) Until notice in writing has been given to the assured or to the insurer and to the Secretary of the Commission at its office, in Washington, D.C. 20573, by certified mail, and (ii) until after 30 days expire from the date notice is actually received by the Commission, or until after the Commission revokes the Certificate (Performance), whichever occurs first. Notice of termination or cancellation to the assured or insurer shall be simultaneous to such notice given to the Commission. The insurer shall remain liable for claims covered by said evidence of insurance arising by virtue of an event which had occurred prior to the effective date of said termination or cancellation. No such termination or cancellation shall become effective while a voyage is in progress.

(2) The insolvency or bankruptcy of the assured shall not constitute a defense to the insurer as to claims included in said evidence of insurance and in the event of said insolvency or bankruptcy, the insurer agrees to pay any unsatisfied final judgments obtained on such claims.

(3) No insurance shall be acceptable under these rules which restricts the liability of the insurer where privity of the owner or charterer has been shown to exist.

(4) Paragraphs (a)(1) through (a)(3) of this section shall apply to the guaranty as specified in paragraph (c) of this section.

(b) Filing with the Commission evidence of an escrow account, acceptable to the Commission, for indemnification of passengers in the event of nonperformance of water transportation.

(c) Filing with the Commission a guaranty on Form FMC–133A, by a guarantor acceptable to the Commission, for indemnification of passengers in the event of nonperformance of water transportation.

(d) Filing with the Commission for qualification as a self-insurer such evidence acceptable to the Commission as will demonstrate continued and stable passenger operations over an extended period of time in the foreign or domestic trade of the United States. In addition, applicant must demonstrate financial responsibility by maintenance of working capital and net worth, each in an amount calculated as in the introductory text of this section, except that the Commission, for good cause shown, may waive the requirement as to the amount of working capital. The Commission will take into consideration

all current contractual requirements with respect to the maintenance of such working capital and/or net worth to which the applicant is bound. Evidence must be submitted that the working capital and net worth required above are physically located in the United States. This evidence of financial responsibility shall be supported by and subject to the following which are to be submitted on a continuing basis for each year or portion thereof while the Certificate (Performance) is in effect:

(1) A current quarterly balance sheet, except that the Commission, for good cause shown, may require only an annual balance sheet;

(2) A current quarterly statement of income and surplus, except that the Commission, for good cause shown, may require only an annual statement of income and surplus;

(3) An annual current balance sheet and an annual current statement of income and surplus to be certified by appropriate certified public accountants;

(4) An annual current statement of the book value or current market value of any assets physically located within the United States together with a certification as to the existence and amount of any encumbrances thereon;

(5) An annual current credit rating report by Dun and Bradstreet or any similar concern found acceptable to the Commission;

(6) A list of all contractual requirements or other encumbrances (and to whom the applicant is bound in this regard) relating to the maintenance of working capital and net worth;

(7) All financial statements required to be submitted under this section shall be due within a reasonable time after the close of each pertinent accounting period;

(8) Such additional evidence of financial responsibility as the Commission may deem necessary in appropriate cases.

§ 540.6 Surety bonds.

(a) Where financial responsibility is not established under § 540.5, a surety bond shall be filed on Form FMC–132A. Such surety bond shall be issued by a bonding company authorized to do business in the United States and acceptable to the Commission for indemnification of passengers in the event of nonperformance of water transportation.

(b) In the case of a surety bond which is to cover all passenger operations of the applicant subject to these rules, such bond shall be in an amount calculated as in the introductory text of § 540.5.

(c) In the case of a surety bond which is to cover an individual voyage, such bond shall be in an amount determined by the Commission to equal the gross passenger revenue for that voyage.

(d) The liability of the surety under the rules of this subpart to any passenger shall not exceed the amount paid by any such passenger, except that, no such bond shall be terminated while a voyage is in progress.

§ 540.7 Evidence of financial responsibility.

Where satisfactory proof of financial responsibility has been given or a satisfactory bond has been provided, a Certificate (Performance) covering specified vessels shall be issued evidencing the Commission's finding of adequate financial responsibility to indemnify passengers for nonperformance of water transportation. The period covered by the Certificate (Performance) shall be indeterminate, unless a termination date has been specified thereon.

§ 540.8 Denial, revocation, suspension, or modification.

(a) Prior to the denial, revocation, suspension, or modification of a Certificate (Performance), the Commission shall advise the applicant of its intention to deny, revoke, suspend, or modify and shall state the reasons therefor. If the applicant, within 20 days after the receipt of such advice, requests a hearing to show that the evidence of financial responsibility filed with the Commission does meet the rules of this subpart, such hearing shall be granted by the Commission, except that a Certificate (Performance) shall become null and void upon cancellation or termination of the surety bond, evidence of insurance, guaranty, or escrow account.

(b) A Certificate (Performance) may be denied, revoked, suspended, or modified for any of the following reasons:

(1) Making any willfully false statement to the Commission in connection with an application for a Certificate (Performance);

(2) Circumstances whereby the party does not qualify as financially responsible in accordance with the requirements of the Commission;

(3) Failure to comply with or respond to lawful inquiries, rules, regulations or orders of the Commission pursuant to the rules of this subpart.

(c) If the applicant, within 20 days after notice of the proposed denial, revocation, suspension, or modification under paragraph (b) of this section, requests a hearing to show that such denial, revocation, suspension, or modification should not take place, such hearing shall be granted by the Commission.

§ 540.9 Miscellaneous.

(a) If any evidence filed with the application does not comply with the requirements of this subpart, or for any reason fails to provide adequate or satisfactory protection to the public, the Commission will notify the applicant stating the deficiencies thereof.

(b) Any financial evidence submitted to the Commission under the rules of this subpart shall be written in the full and correct name of the person to whom the Certificate (Performance) is to be issued, and in case of a partnership, all partners shall be named.

(c) The Commission's bond (Form FMC–132A), guaranty (Form FMC–133A), and application (Form FMC–131) forms are hereby incorporated as a part of the rules of this subpart. Any such forms filed with the Commission under this subpart must be in duplicate.

(d) Any securities or assets accepted by the Commission (from applicants, insurers, guarantors, escrow agents, or others) under the rules of this subpart must be physically located in the United States.

(e) Each applicant, insurer, escrow agent and guarantor shall furnish a written designation of a person in the United States as legal agent for service of process for the purposes of the rules of this Subpart. Such designation must be acknowledged, in writing, by the designee. In any instance in which the designated agent cannot be served because of its death, disability, or unavailability, the Secretary, Federal Maritime Commission, will be deemed to be the agent for service of process. A party serving the Secretary in accordance with the above provision must also serve the Certificant, insurer, escrow agent, or guarantor, as the case may be, by registered mail at its last known address on file with the Commission.

(f) [Reserved]

(g) Financial data filed in connection with the rules of this subpart shall be confidential except in instances where information becomes relevant in connection with hearings which may be requested by applicant pursuant to § 540.8 (a) or (b).

(h) Every person who has been issued a Certificate (Performance) must submit to the Commission a semiannual statement of any changes that have taken place with respect to the information contained in the application or documents submitted in support thereof. Negative statements are required to indicate no change. Such

statements must cover every 6-month period of the fiscal year immediately subsequent to the date of the issuance of the Certificate (Performance). In addition, the statements will be due within 30 days after the close of every such 6-month period.

(i) [Reserved]

(j) The amount of: (1) Insurance as specified in § 540.5(a), (2) the escrow account as specified in § 540.5(b), (3) the guaranty as specified in § 540.5(c), or (4) the surety bond as specified in § 540.6, shall not be required to exceed 10 million dollars (U.S.).

(k) Every person in whose name a Certificate (Performance) has been issued shall be deemed to be responsible for any unearned passage money or deposits in the hands of its agents or of any other person or organization authorized by the certificant to sell the certificant's tickets. Certificants shall promptly notify the Commission of any arrangements, including charters and subcharters, made by it or its agent with any person pursuant to which the certificant does not assume responsibility for all passenger fares and deposits collected by such person or organization and held by such person or organization as deposits or payment for services to be performed by the certificant. If responsibility is not assumed by the certificant, the certificant also must inform such person or organization of the certification requirements of Pub. L. 89–777 and not permit use of its name or tickets in any manner unless and until such person or organization has obtained the requisite Certificate (Performance) from the Commission.

Form FMC–131

FEDERAL MARITIME COMMISSION

Washington, D.C. 20573

Application for Certificate of Financial Responsibility

In compliance with the provisions of Pub. L. 89–777 and 46 CFR Part 540, application is hereby made for a Certificate of Financial Responsibility (check one or both as applicable):

[ ] for indemnification of passengers for nonperformance. [ ] Initial application [ ] Certificate has previously been applied for (if so, give date of application and action taken thereon).

[ ] to meet liability incurred for death or injury to passengers or other persons. [ ] Initial application [ ] Certificate has previously been applied for (if so, give date of application and action taken thereon).

Instructions

Submit two (2) typed copies of the application to the Secretary, Federal Maritime Commission, Washington, D.C. 20573. The application is in four parts: Part I—General; Part II—Performance; Part III—Casualty and Part IV—Declaration. Applicants must answer all questions in Part I and Part IV, then Parts II and/or Part III as appropriate. Instructions relating to Part II and Part III are contained at the beginning of the respective part. If the information required to be submitted under 46 CFR Part 540 has been previously submitted under other rules and regulations of the Commission, state when and for what reason such information was submitted. If previously submitted, it is not necessary to resubmit. If additional space is required, supplementary sheets may be attached.

Part I—General

Answer All Questions

1(a) Legal business name:

(b) English equivalent of legal name if customarily written in language other than English:

(c) Trade name or names used:

2(a) State applicant's legal form of organization, i.e., whether operating as an individual, corporation, partnership, association, joint stock company, business trust, or other organized group of persons (whether incorporated or not), or as a receiver, trustee, or other liquidating agent, and describe current business activities and length of time engaged therein.

(b) If a corporation, association, joint stock company, business trust, or other organization, give:

Name of State or country in which incorporated or organized.

Date of the incorporation or organization.

(c) If a partnership, give name and address of each partner:

3. Give following information regarding any person or company controlling, controlled by, or under common control with you (answer only if applying as a self-insurer under Part II or Part III).

Name	Address	Business and relationship to you

4. In relation to the passenger transportation engaged in by you to or from U.S. ports:

Do you own all the vessels? [ ] Yes [ ] No (If "No" indicate the nature of the arrangements under which those not owned by you are available to you (e.g., bareboat, time, voyage, or other charter, or arrangement).)

5. Name of each passenger vessel having accommodations for 50 or more passengers and embarking passengers at U.S. ports:

Name	Country of registry	Registration No.	Maximum number of berth or stateroom accommodations

6. Submit a copy of passenger ticket or other contract evidencing the sale of passenger transportation.

7. Name and address of applicant's U.S. agent or other person authorized to accept legal service in the United States.

Part II—Performance

Answer items 8–15 if applying for Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance. If you are filing evidence of insurance, escrow account, guaranty or surety bond under Subpart A of 46 CFR Part 540 and providing at least ten (10) million dollars (U.S.) of coverage, you need not answer questions 10–15.

8. If you are providing at least ten (10) million dollars (U.S.) of coverage, state type of evidence and name and address of applicant's insurer, escrow agent, guarantor or surety (as appropriate).

9.* A Certificate (Performance) is desired for the following proposed passenger voyage or voyages: (Give itinerary and indicate whether the Certificate is for a single voyage, multiple voyages or all voyages scheduled annually.)

Vessel	Voyage date	Voyage itinerary

10. Items 11–15 are optional methods; answer only the one item which is applicable to this application. Check the appropriate box below:

[ ] Insurance (item 11).
[ ] Escrow (item 12).
[ ] Surety bond (item 13).
[ ] Guaranty (item 14).
[ ] Self-insurer (item 15).

11(a) Total amount of performance insurance which is to be computed in accordance with § 540.5 of 46 CFR Part 540. (Evidence of insurance must be filed with the Federal Maritime Commission before a Certificate (Performance) may be issued.)

(b) Method by which insurance amount is determined (attach data substantiating that amount is not less than that prescribed in § 540.5 of 46 CFR Part 540.)

(c) Name and address of applicant's insurer for performance policy.

12(a) Name and address of applicant's escrow agent. (Applicant may pledge cash or U.S. Government securities, in lieu of a surety bond, to fulfill the indemnification provisions of Pub. L. 89–777.)

(b) Total escrow deposit which is to be computed in accordance with § 540.5 of 46 CFR Part 540. (Escrow agreement must be filed with the Federal Maritime Commission before a Certificate (Performance) will be issued.) Cash $———. U.S. Government Securities $———.

(c) Method by which escrow amount is determined (attach data substantiating that amount is not less than that prescribed by § 540.5 of 46 CFR Part 540).

* The filing of sailing schedules will be acceptable in answers to this question.

13(a) Total amount of surety bond in accordance with § 540.6 of 46 CFR Part 540. (The bond must be filed with the Federal Maritime Commission before a Certificate (Performance) may be issued.)

(b) Method by which bond amount is determined (attach data substantiating that amount is not less than that prescribed in § 540.6 of 46 CFR Part 540).

(c) Name and address of applicant's surety on performance bond.

14(a) Total amount of guaranty which is to be computed in accordance with § 540.5 of 46 CFR Part 540. (Guaranty must be filed with the Federal Maritime Commission before a Certificate (Performance) may be issued.)

(b) Method by which guaranty amount is determined (attach data substantiating that amount is not less than that prescribed in § 540.5 46 CFR Part 540).

(c) Name and address of applicant's guarantor.

15. If applicant intends to qualify as a self-insurer for a Certificate (Performance) under § 540.5 of 46 CFR Part 540, attach all data, statements, and documentation required therein.

Part III—Casualty

Answer Items 16–22 if Applying for Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons

16. Name of passenger vessel subject to section 2 of Pub. L. 89–777 operated by you to or from U.S. ports which has largest number of berth or stateroom accommodations. State the maximum number of berth or stateroom accommodations.

17. Amount of death or injury liability coverage based on number of accommodations aboard vessel named in item 16 above, calculated in accordance with § 540.24 of 46 CFR Part 540.

Items 18–22 Are Optional Methods: Answer Only the One Item Which is Applicable to This Application

18(a) Total amount of applicant's insurance. (Evidence of the insurance must be filed with the Federal Maritime Commission before a Certificate (Casualty) will be issued.)

(b) Name and address of applicant's insurer.

19(a) Total amount of surety bond. (Bond must be filed with the Federal Maritime Commission before a Certificate (Casualty) will be issued.)

(b) Name and address of applicant's surety for death or injury bond.

20(a) Total amount of escrow deposit. (Escrow agreement must be filed with the Federal Maritime Commission before a Certificate (Casualty) will be issued.)

(d) Name and address of applicant's escrow agent.

21(a) Total amount of guaranty. (Guaranty must be filed with the Federal Maritime Commission before a Certificate (Casualty) will be issued.)

(b) Name and address of applicant's guarantor.

22. If applicant intends to qualify as a self-insurer for a Certificate (Casualty) under § 540.24(c) of 46 CFR Part 540, attach all data, statements and documentation required therein.

Part IV—Declaration

This application is submitted by or on behalf of

(a) Name.
(b) Name and title of official.
(c) Home office— Street and number.
(d) City.
(e) State or country.
(f) ZIP Code.
(g) Principal office in the United States— Street and number.
(h) City.
(i) State.

I Declare that I have examined this application, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct and complete.

By _____
(Signature of official)

_____
(Date)

Comments:

From FMC–132A

Passenger Vessel Surety Bond (46 CFR Part 540)

Know all men by these presents, that we _____ (Name of applicant), of _____ (City), _____ (State and country), as Principal (hereinafter called Principal), and _____ (Name of surety), a company created and existing under the laws of _____ (State and country) and authorized to do business in the United States as Surety (hereinafter called Surety) are held and firmly bound unto the United States of America in the penal sum of _____, for which payment, well and truly to be made, we bind ourselves and our heirs, executors, administrators, successors, and assigns, jointly and severally, firmly by these presents.

Whereas the Principal intends to become a holder of a Certificate (Performance) pursuant to the provisions of Subpart A of Part 540 of Title 46, Code of Federal Regulations and has elected to file with the Federal Maritime Commission such a bond to insure financial responsibility and the supplying transportation and other services subject to Subpart A of Part 540 of Title 46, Code of Federal Regulations, in accordance with the ticket contract between the Principal and the passenger, and

Whereas this bond is written to assure compliance by the Principal as an authorized holder of a Certificate (Performance) pursuant to Subpart A of Part 540 of Title 46, Code of Federal Regulations, and shall inure to the benefit of any and all passengers to whom the Principal may be held legally liable for any of the damages herein described.

Now, therefore, the condition of this obligation is such that if the Principal shall pay or cause to be paid to passengers any sum or sums for which the Principal may be held legally liable by reason of the Principal's failure faithfully to provide such transportation and other accommodations and services in accordance with the ticket contract made by the Principal and the passenger while this bond is in effect for the supplying of transportation and other services pursuant to and in accordance with the provisions of Subpart A of Part 540 of Title 46, Code of Federal Regulations, then this obligation shall be void, otherwise, to remain in full force and effect.

The liability of the Surety with respect to any passenger shall not exceed the passage price paid by or on behalf of such passenger.

The liability of the Surety shall not be discharged by any payment or succession of payments hereunder, unless and until such payment or payments shall amount in the aggregate to the penalty of the bond, but in no event shall the Surety's obligation hereunder exceed the amount of said penalty. The Surety agrees to furnish written notice to the Federal Maritime Commission forthwith of all suits filed, judgments rendered, and payments made by said Surety under this bond.

This bond is effective the —— day of ———, 19—, 12:01 a.m., standard time at the address of the Principal as stated herein and shall continue in force until terminated as hereinafter provided. The Principal or the Surety may at any time terminate this bond by written notice sent by certified mail to the other and to the Federal Maritime Commission at its office in Washington, D.C., such termination to become effective thirty (30) days after actual receipt of said notice by the Commission, except that no such termination shall become effective while a voyage is in progress. The Surety shall not be liable hereunder for any refunds due under ticket contracts made by the Principal for the supplying of transportation and other services after the termination of this bond as herein provided, but such termination shall not affect the liability of the Surety hereunder for refunds arising from ticket contracts made by the Principal for the supplying of transportation and other services prior to the date such termination becomes effective.

In witness whereof, the said Principal and Surety have executed this instrument on —— day of ———, 19—.

PRINCIPAL

Name _____
By _____
(Signature and title)
Witness _____

SURETY

[SEAL] Name _____
By _____
(Signature and title)
Witness _____

Only corporations or associations of individual insurers may qualify to act as surety, and they must establish to the satisfaction of the Federal Maritime Commission legal authority to assume the obligations of surety and financial ability to discharge them.

Form FMC–133A

Guaranty in Respect of Liability for Nonperformance, Section 3 of the Act

1. Whereas _____ (Name of applicant) (Hereinafter referred to as the "Applicant") is the Owner or Charterer of the passenger Vessel(s) specified in the annexed

Schedule ("the Vessels"), which are or may become engaged in voyages to or from United States ports, and the Applicant desires to establish its financial responsibility in accordance with Section 3 of Pub. L. 89–777, 89th Congress, approved November 6, 1966 ("the Act") then, provided that the Federal Maritime Commission ("FMC") shall have accepted, as sufficient for that purpose, the Applicant's application, supported by this Guaranty, and provided that FMC shall issue to the Applicant a Certificate (Performance) ("Certificate"), the undersigned Guarantor hereby guarantees to discharge the Applicant's legal liability to indemnify the passengers of the Vessels for nonperformance of transportation within the meaning of Section 3 of the Act, in the event that such legal liability has not been discharged by the Applicant within 21 days after any such passenger has obtained a final judgment (after appeal, if any) against the Applicant from a United States Federal or State Court of competent jurisdiction, or has become entitled to payment of a specified sum by virtue of a compromise settlement agreement made with the Applicant, with the approval of the Guarantor, whereby, upon payment of the agreed sum, the Applicant is to be fully, irrevocably and unconditionally discharged from all further liability to such passenger for such nonperformance.

2. The Guarantor's liability under this Guaranty in respect to any passenger shall not exceed the amount paid by such passenger; and the aggregate amount of the Guarantor's liability under this Guaranty shall not exceed $———.

3. The Guarantor's liability under this Guaranty shall attach only in respect of events giving rise to a cause of action against the Applicant, in respect of any of the Vessels, for nonperformance of transportation within the meaning of Section 3 of the Act, occurring after the Certificate has been granted to the Applicant, and before the expiration date of this Guaranty, which shall be the earlier of the following dates:

(a) The date whereon the Certificate is withdrawn, or for any reason becomes invalid or ineffective; or

(b) The date 30 days after the date of receipt by FMC of notice in writing (including telex or cable) that the Guarantor has elected to terminate this Guaranty except that:

(i) If, on the date which would otherwise have been the expiration date under the foregoing provisions (a) or (b) of this Clause 3, any of the Vessels is on a voyage whereon passengers have been embarked at a United States port, then the expiration date of this Guaranty shall, in respect of such Vessel, be postponed to the date on which the last passenger on such voyage shall have finally disembarked; and,

(ii) Such termination shall not affect the liability of the Guarantor for refunds arising from ticket contracts made by the Applicant for the supplying of transportation and other services prior to the date such termination becomes effective.

4. If, during the currency of this Guaranty, the Applicant requests that a vessel owned or operated by the Applicant, and not specified in the annexed Schedule, should become subject to this Guaranty, and if the Guarantor accedes to such request and so notifies FMC in writing (including telex or cable), then, provided that within 30 days of receipt of such notice, FMC shall have granted a Certificate, such Vessel shall thereupon be deemed to be one of the Vessels included in the said Schedule and subject to this Guaranty.

5. The Guarantor hereby designates ————, with offices at ————, as the Guarantor's legal agent for service of process for the purposes of the Rules of the Federal Maritime Commission, Subpart A of Part 540 of Title 46, Code of Federal Regulations, issued under Section 3 of Pub. L. 89–777 (80 Stat. 1357, 1358), entitled "Security for the Protection of the Public."

———
(Place and Date of Execution)

———
(Type Name of Guarantor)

———
(Type Address of Guarantor)

By ———
(Signature and Title)

Schedule of Vessels Referred to in Clause 1

Vessels Added to This Schedule in Accordance With Clause 4

Subpart B—Proof of Financial Responsibility, Bonding and Certification of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages

§ 540.20 Scope.

The regulations contained in this subpart set forth the procedures whereby owners or charterers of vessels having berth or stateroom accommodations for 50 or more passengers and embarking passengers at U.S. ports shall establish their financial responsibility to meet any liability which may be incurred for death or injury to passengers or other persons on voyages to or from U.S. ports. Included also are the qualifications required by the Commission for issuance of a Certificate (Casualty) and the basis for the denial, revocation, suspension, or modification of such Certificates.

§ 540.21 Definitions.

As used in this subpart, the following terms shall have the following meanings:

(a) *Person* includes individuals, corporations, partnerships, associations, and other legal entities existing under or authorized by the laws of the United States or any state thereof or the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands or any territory or possession of the United States, or the laws of any foreign country.

(b) *Vessel* means any commercial vessel having berth or stateroom accommodations for 50 or more passengers and embarking passengers at U.S. ports.

(c) *Commission* means the Federal Maritime Commission.

(d) *United States* includes the Commonwealth of Puerto Rico, the Virgin Islands or any territory or possession of the United States.

(e) *Berth or stateroom accommodations* or *passenger accommodations* includes all temporary and all permanent passenger sleeping facilities.

(f) *Certificate (Casualty)* means a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages issued pursuant to this subpart.

(g) *Voyage* means voyage of a vessel to or from U.S. ports.

(h) *Insurer* means any insurance company, underwriter, corporation or association of underwriters, ship owners' protection and indemnity association, or other insurer acceptable to the Commission.

(i) *Evidence of insurance* means a policy, certificate of insurance, cover note, or other evidence of coverage acceptable to the Commission.

(j) For the purpose of determining compliance with § 540.22, "passengers embarking at United States ports" means any persons, not necessary to the business, operation, or navigation of a vessel, whether holding a ticket or not, who board a vessel at a port or place in the United States and are carried by the vessel on a voyage from that port or place.

§ 540.22 Proof of financial responsibility, when required.

No vessel shall embark passengers at U.S. ports unless a Certificate (Casualty) has been issued to or covers the owner or charterer of such vessel.

§ 540.23 Procedure for establishing financial responsibility.

(a) In order to comply with section 2 of Pub. L. 89–777 (80 Stat. 1357, 1358) enacted November 6, 1966, there must be filed an Application on Form FMC–131 for a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages. Copies of Form FMC–131 may be obtained from the Secretary, Federal Maritime Commission, Washington, DC 20573, or at the Commission's offices at New York, NY; New Orleans, LA; San Francisco, CA; Miami, FL; Los Angeles, CA; Hato Rey, PR; and Chicago, IL.

(b) An application for a Certificate (Casualty) shall be filed in duplicate

with the Secretary, Federal Maritime Commission, by the vessel owner or charterer at least 60 days in advance of the sailing. Late filing of the application will be permitted only for good cause shown. All applications and evidence required to be filed with the Commission shall be in English, and any monetary terms shall be expressed in terms of U.S. currency. The Commission shall have the privilege of verifying any statements made or any evidence submitted under the rules of this subpart. An application for a Certificate (Casualty) shall be accompanied by a filing fee remittance of $800.

(c) The application shall be signed by a duly authorized officer or represenative of the applicant with a copy of evidence of his authority. In the event of any material change in the facts as reflected in the application, an amendment to the application shall be filed no later than five (5) days following such change. For the purpose of this subpart, a material change shall be one which: (1) Results in a decrease in the amount submitted to establish financial responsibility to a level below that required to be maintained under the rules of this subpart, or (2) requires that the amount to be maintained be increased above the amount submitted to establish financial responsibility. Notice of the application for, issuance, denial, revocation, suspension, or modification of any such Certificate shall be published in the **Federal Register.**

§ 540.24 Insurance, surety bonds, self-insurance, guaranties, and escrow accounts.

Evidence of adequate financial responsibility for the purposes of this subpart may be established by one of the following methods:

(a) Filing with the Commission evidence of insurance issued by an insurer providing coverage for liability which may be incurred for death or injury to passengers or other persons on voyages in an amount based upon the number of passenger accommodations aboard the vessel, calculated as follows:

Twenty thousand dollars for each passenger accommodation up to and including 500; plus

Fifteen thousand dollars for each additional passenger accommodation between 501 and 1,000; plus

Ten thousand dollars for each additional passenger accommodation between 1,001 and 1,500; plus

Five thousand dollars for each passenger accommodation in excess of 1,500;

except that, if the applicant is operating more than one vessel subject to this subpart, the amount prescribed by this paragraph shall be based upon the number of passenger accommodations on the vessel being so operated which has the largest number of passenger accommodations.

(1) Termination or cancellation of the evidence of insurance, whether by the assured or by the insurer, and whether for nonpayment of premiums, calls or assessments, or for other cause, shall not be effected: (i) Until notice in writing has been given to the assured or to the insurer and to the Secretary of the Commission at its office in Washington, D.C. 20573, by certified mail, and (ii) until after 30 days expire from the date notice is actually received by the Commissioner, or until after the Commission revokes the Certificate (Casualty), whichever occurs first. Notice of termination or cancellation to the assured or insurer shall be simultaneous to such notice given to the Commission. The insurer shall remain liable for claims covered by said evidence of insurance arising by virtue of an event which had occurred prior to the effective date of said termination or cancellation. No such termination or cancellation shall become effective while a voyage is in progress.

(2) The insolvency or bankruptcy of the assured shall not constitute a defense to the insurer as to claims included in said evidence of insurance and in the event of said insolvency or bankruptcy, the insurer agrees to pay any unsatisfied final judgments obtained on such claims.

(3) No insurance shall be acceptable under these rules which restricts the liability of the insurer where privity of the owner or charterer has been shown to exist.

(4) Paragraphs (a)(1) through (a)(3) of this section shall apply to the guaranty as specified in paragraph (d) of this section.

(b) Filing with the Commission a surety bond on Form FMC–132B issued by a bonding company authorized to do business in the United States and acceptable to the Commission. Such surety bond shall evidence coverage for liability which may be incurred for death or injury to passengers or other persons on voyages in an amount calculated as in paragraph (a) of this section, and shall not be terminated while a voyage is in progress.

(c) Filing with the Commission for qualification as a self-insurer such evidence acceptable to the Commission as will demonstrate continued and stable passenger operations over an extended period of time in the foreign or domestic trade of the United States. In addition, applicant must demonstrate financial responsibility by maintenance of working capital and net worth, each in an amount calculated as in paragraph (a) of this section. The Commission will take into consideration all current contractual requirements with respect to the maintenance of working capital and/or net worth to which the applicant is bound. Evidence must be submitted that the working capital and net worth required above are physically located in the United States. This evidence of financial responsibility shall be supported by and subject to the following which are to be submitted on a continuing basis for each year or portion thereof while the Certificate (Casualty) is in effect:

(1) A current quarterly balance sheet, except that the Commission, for good cause shown, may require only an annual balance sheet;

(2) A current quarterly statement of income and surplus except that the Commission, for good cause shown, may require only an annual statement of income and surplus;

(3) An annual current balance sheet and an annual current statement of income and surplus to be certified by appropriate certified public accountants;

(4) An annual current statement of the book value or current market value of any assets physically located within the United States together with a certification as to the existence and amount of any encumbrances thereon;

(5) An annual current credit rating report by Dun and Bradstreet or any similar concern found acceptable to the Commission;

(6) A list of all contractual requirements or other encumbrances (and to whom the applicant is bound in this regard) relating to the maintenance of working capital and net worth;

(7) All financial statements required to be submitted under this section shall be due within a reasonable time after the close of each pertinent accounting period;

(8) Such additional evidence of financial responsibility as the Commission may deem necessary in appropriate cases.

(d) Filing with the Commission a guaranty on Form FMC–133B by a guarantor acceptable to the Commission. Any such guaranty shall be in an amount calculated as in paragraph (a) of this section.

(e) Filing with the Commission evidence of an escrow account, acceptable to the Commission, the amount of such account to be calculated as in paragraph (a) of this section.

(f) The Commission will, for good cause shown, consider any combination of the alternatives described in

paragraphs (a) through (e) of this section for the purpose of establishing financial responsibility.

§ 540.25 Evidence of financial responsibility.

Where satisfactory proof of financial responsibility has been established, a Certificate (Casualty) covering specified vessels shall be issued evidencing the Commission's finding of adequate financial responsibility to meet any liability which may be incurred for death or injury to passengers or other persons on voyages. The period covered by the certificate shall be indeterminate unless a termination date has been specified therein.

§ 540.26 Denial, revocation, suspension, or modification.

(a) Prior to the denial, revocation, suspension, or modification of a Certificate (Casualty), the Commission shall advise the applicant of its intention to deny, revoke, suspend, or modify, and shall state the reasons therefor. If the applicant, within 20 days after the receipt of such advice, requests a hearing to show that the evidence of financial responsibility filed with the Commission does meet the rules of this subpart, such hearing shall be granted by the Commission, except that a Certificate (Casualty) shall become null and void upon cancellation or termination of evidence of insurance, surety bond, guaranty, or escrow account.

(b) A Certificate (Casualty) may be denied, revoked, suspended, or modified for any of the following reasons:

(1) Making any willfully false statement to the Commission in connection with an application for a Certificate (Casualty);

(2) Circumstances whereby the party does not qualify as financially responsible in accordance with the requirements of the Commission;

(3) Failure to comply with or respond to lawful inquiries, rules, regulations, or orders of the Commission pursuant to the rules of this subpart.

(c) If the applicant, within 20 days after notice of the proposed denial, revocation, suspension, or modification under paragraph (b) of this section, requests a hearing to show that such denial, revocation, suspension, or modification should not take place, such hearing shall be granted by the Commission.

§ 540.27 Miscellaneous.

(a) If any evidence filed with the application does not comply with the requirements of this subpart, or for any reason, fails to provide adequate or satisfactory protection to the public, the Commission will notify the applicant stating the deficiencies thereof.

(b) Any financial evidence submitted to the Commission under the rules of this subpart shall be written in the full and correct name of the person to whom the Certificate (Casualty) is to be issued, and in case of a partnership, all partners shall be named.

(c) The Commission's bond (Form FMC–132B), guaranty (Form FMC–133B), and application (Form FMC–131 as set forth in Subpart A of this part) forms are hereby incorporated as a part of the rules of this subpart. Any such forms filed with the Commission under this subpart must be in duplicate.

(d) Any securities or assets accepted by the Commission (from applicants, insurers, guarantors, escrow agents, or others) under the rules of this subpart must be physically located in the United States.

(e) Each applicant, insurer, escrow agent, and guarantor shall furnish a written designation of a person in the United States as legal agent for service of process for the purposes of the rules of this subpart. Such designation must be acknowledged, in writing, by the designee. In any instance in which the designated agent cannot be served because of death, disability, or unavailability, the Secretary, Federal Maritime Commission, will be deemed to be the agent for service of process. A party serving the Secretary in accordance with the above provision must also serve the certificant, insurer, escrow agent, or guarantor, as the case may be, by registered mail, at its last known address on file with the Commission.

(f) In the case of any charter arrangements involving a vessel subject to the regulations of this subpart, the vessel owner (in the event of a subcharter, the charterer shall file) must within 10 days file with the Secretary of the Commission evidence of any such arrangement.

(g) Financial data filed in connection with the rules of this subpart shall be confidential except in instances where information becomes relevant in connection with hearings which may be requested by applicant pursuant to § 540.26(a) or § 540.26(b).

(h) Every person who has been issued a Certificate (Casualty) must submit to the Commission a semiannual statement of any changes that have taken place with respect to the information contained in the application or documents submitted in support thereof. Negative statements are required to indicate no change. Such statements must cover every such 6-month period commencing with the first 6-month period of the fiscal year immediately subsequent to the date of the issuance of the Certificate (Casualty). In addition, the statements will be due within 30 days after the close of every 6-month period.

Form FMC–132B

(5–67)

FEDERAL MARITIME COMMISSION

Surety Co. Bond No. ————
FMC Certificate No. ————

Passenger Vessel Surety Bond (46 CFR Part 540)

Know all men by these presents, that We ———— (Name of applicant), of ———— (City), ———— (State and country), as Principal (hereinafter called Principal), and ———— (Name of surety), a company created and existing under the laws of ———— (State and country) and authorized to do business in the United States, as Surety (hereinafter called Surety) are held and firmly bound unto the United States of America in the penal sum of ————, for which payment, well and truly to be made, we bind ourselves and our heirs, executors, administrators, successors, and assigns, jointly and severally, firmly by these presents.

Whereas, the Principal intends to become a holder of a Certificate (Casualty) pursuant to the provisions of Subpart B of Part 540 of Title 46, Code of Federal Regulations, and has elected to file with the Federal Maritime Commission such a bond to insure financial responsibility to meet any liability it may incur for death or injury to passengers or other persons on voyages to or from U.S. ports, and

Whereas, this bond is written to assure compliance by the Principal as an authorized holder of a Certificate (Casualty) pursuant to Subpart B of Part 540 of Title 46, Code of Federal Regulations, and shall inure to the benefit of any and all passengers or other persons to whom the Principal may be held legally liable for any of the damages herein described.

Now, therefore, the condition of this obligation is such that if the Principal shall pay or cause to be paid to passengers or other persons any sum or sums for which the Principal may be held legally liable by reason of the Principal's failure faithfully to meet any liability the Principal may incur for death or injury to passengers or other persons on voyages to or from U.S. ports, while this bond is in effect pursuant to and in accordance with the provisions of Subpart B of Part 540 of Title 46, Code of Federal Regulations, then this obligation shall be void, otherwise, to remain in full force and effect.

The liability of the Surety with respect to any passenger or other persons shall in no event exceed the amount of the Principal's legal liability under any final judgment or settlement agreement, except that, if the aggregate amount of such judgments and settlements exceeds an amount computed in accordance with the formula contained in section 2(a) of Pub. L. 89–777, then the

Surety's total liability under this surety bond shall be limited to an amount computed in accordance with such formula.

The Surety agrees to furnish written notice to the Federal Maritime Commission forthwith of all suits filed, judgments rendered, and payments made by said Surety under this bond.

This bond is effective the —— day of ———, 19—, 12:01 a.m., standard time, at the address of the Principal as stated herein and shall continue in force until terminated as hereinafter provided. The Principal or the Surety may at any time terminate this bond by written notice sent by certified mail to the other and to the Federal Maritime Commission at its Office in Washington, D.C., such termination to become effective thirty (30) days after actual receipt of said notice by the Commission, except that no such termination shall become effective while a voyage is in progress. The Surety shall not be liable hereunder for any liability incurred for death or injury to passengers or other persons on voyages to or from U.S. ports after the termination of this bond as herein provided, but such termination shall not affect the liability of the Surety hereunder for such liability incurred for death or injury to passengers or other persons on voyages to or from U.S. ports prior to the date such termination becomes effective.

In witness whereof, the said Principal and Surety have executed this instrument on the —— day of ———, 19—.

PRINCIPAL

Name ———

By ———

(Signature and title)

Witness ———

SURETY

Name ———

By [SEAL] ———

(Signature and title)

Witness ———

Only corporations or associations of individual insurers may qualify to act as Surety, and they must establish to the satisfaction of the Federal Maritime Commission legal authority to assume the obligations of surety and financial ability to discharge them.

Form FMC–133B

(5–67)

FEDERAL MARITIME COMMISSION

Guaranty No. ———

FMC Certificate No. ———

Guaranty in Respect of Liability for Death or Injury, Section 2 of the Act

1. Whereas ——— (Name of Applicant) (Hereinafter referred to as the "Applicant") is the Owner or Charterer of the passenger Vessel(s) specified in the annexed Schedule ("the Vessels"), which are or may become engaged in voyages to or from U.S. ports, and the Applicant desires to establish its financial responsibility in accordance with section 2 of Pub. L. 89–777, 89th Congress, approved November 6, 1966 ("the Act") then, provided that the Federal Maritime Commission ("FMC") shall have accepted, as sufficient for that purpose, the Applicant's application, supported by this Guaranty, and provided that FMC shall issue to the Applicant a Certificate (Casualty) ("Certificate"), the undersigned Guarantor hereby guarantees to discharge the applicant's legal liability in respect of claims for damages for death or injury to passengers or other persons on voyages of the Vessels to or from U.S. ports, in the event that such legal liability has not been discharged by the Applicant within 21 days after any such passenger or other person, or, in the event of death, his or her personal representative, has obtained a final judgment (after appeal, if any) against the Applicant from a U.S. Federal or State Court of competent jurisdiction, or has become entitled to payment of a specified sum by virtue of a compromise settlement agreement made with the Applicant, with the approval of the Guarantor, whereby, upon payment of the agreed sum, the Applicant is to be fully, irrevocably and unconditionally discharged from all further liability to such passenger or other person, or to such personal representative, with respect to such claim.

2. The Guarantor's liability under this Guaranty shall in no event exceed the amount of the Applicant's legal liability under any such judgment or settlement agreement, except that, if the aggregate amount of such judgments and settlements exceeds an amount computed in accordance with the formula contained in section 2(a) of the Act, then the Guarantor's total liability under this Guaranty shall be limited to an amount computed in accordance with such formula.

3. The Guarantor's liability under this Guaranty shall attach only in respect of events giving rise to causes of action against the Applicant in respect of any of the Vessels for damages for death or injury within the meaning of section 2 of the Act, occurring after the Certificate has been granted to the Applicant and before the expiration date of this Guaranty, which shall be the earlier of the following dates:

(a) The date whereon the Certificate is withdrawn, or for any reason becomes invalid or ineffective; or

(b) The date 30 days after the date of receipt by FMC of notice in writing (including telex or cable) that the Guarantor has elected to terminate this Guaranty, except that if, on the date which would otherwise have been the expiration date of this Guaranty under the foregoing provisions of this Clause 3, any of the Vessels is on a voyage in respect of which such Vessel would not have received clearance in accordance with section 2(e) of the Act without the Certificate, then the expiration date of this Guaranty shall, in respect of such Vessel, be postponed to the date on which the last passenger on such voyage shall have fully disembarked.

4. If, during the currency of this Guaranty, the Applicant requests that a vessel owned or operated by the Applicant, and not specified in the annexed Schedule, should become subject to this Guaranty, and if the Guarantor accedes to such request and so notifies FMC in writing (including telex or cable), then provided that, within 30 days of receipt of such notice FMC shall have granted a Certificate, such vessel shall thereupon be deemed to be one of the Vessels included in the said Schedule and subject to this Guaranty.

5. The Guarantor hereby designates ———, with offices at ———, as the Guarantor's legal agent for Service of process for the purposes of the Rules of the Federal Maritime Commission, Subpart B of Part 540 of Title 46, Code of Federal Regulations, issued under section 2 of the Pub. L 89–777 (80 Stat. 1357, 1358), entitled "Security for the Protection of the Public."

———

(Place and Date of Execution)

———

(Name and Guarantor)

———

(Address of Guarantor)

By ———

(Name and Title)

Schedule of Vessels Referred to in Clause 1

Vessels Added to This Schedule in Accordance With Clause 4

Subpart C—Assessment, Remission, and Mitigation of Civil Penalties

§ 540.30 Scope.

Sections 2 and 3 of Pub. L. 89–777 subject any person who violates the provisions of those sections to a civil penalty of not more than $5,000 in addition to a civil penalty of $200 for each passage sold, such penalties to be assessed by the Federal Maritime Commission. These sections further provide that such penalties may be "remitted or mitigated" by the Commission "upon such terms as they in their discretion shall deem proper." This subpart sets forth regulations prescribing standards and procedures for the collection, mitigation, and remission of civil penalties incurred under sections 2 and 3 of Pub. L. 89–777, and the rules and regulations promulgated pursuant thereto.[1]

§ 540.31 Definitions.

As used in this subpart, the following terms shall have the following meanings:

(a) *Person* includes individuals, corporations, partnerships, associations, and other legal entities existing under or authorized by the laws of the United States or any State thereof or the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, or any territory or possession of the United States, or the laws of any foreign country.

(b) *Commission* means the Federal Maritime Commission.

[1] Sections 2(d) and 3(d) of Pub. L. 89–777 authorize the Federal Maritime Commission to prescribe such regulations as may be necessary to carry out the provisions of secs. 2 and 3.

(c) *The Act* means Pub. L. 89–777 (80 Stat. 1356, 1357, 1358)).

(d) *Offender* means any person charged with a violation.

§ 540.32 Procedure.

(a) If it is adjudged or otherwise determined that a violation has occurred and it is decided to invoke a statutory penalty, a registered letter will be sent to the offender informing him of the nature of the violation, the statutory and factual basis of the penalty, and the amount of the penalty. This notification shall further advise the offender that, within 20 days, or such longer period as the Commission in its discretion may allow, he or she may either pay the penalty demanded or petition for the remission or mitigation of such penalty.

(b) All correspondence, petitions, forms, or other instruments regarding the collection, remission or mitigation of any penalty under this subpart should be addressed to the Bureau of Hearing Counsel, Federal Maritime Commission, Washington, D.C. 20573.

§ 540.33 Petition for remission of mitigation of penalty.

(a) An offender may submit any oral or written material or information in answer to the notification letter explaining, mitigating, showing extenuating circumstances, or, where there has been no formal proceeding on the merits, denying the violation. Material or information so presented will be considered in making the final determination as to whether to mitigate the penalty and the amount for which it will be mitigated, or whether to remit it in full.

(b) When no penalty is invoked or the penalty is remitted, no further action by the offender will be necessary. When the penalty is mitigated, such mitigation will be made conditional upon the full payment within 15 days or such longer period as the Commission in its discretion may allow unless the offender within that time executes a promissory note as provided by § 540.36.

§ 540.34 Settlement; execution of agreement form.

When a statutory penalty is mitigated and the offender agrees to settle for that amount, he or she shall be provided with a Settlement Agreement Form (Appendix A), to be signed, in duplicate, and returned. This form, after reciting the nature of the violation, will contain a statement evidencing the offender's agreement to settlement of the Commission's penalty claim for the amount set forth in the agreement and shall also embody an "approval and acceptance" provision. Upon settlement of the penalty in the agreed amount, one copy of the Settlement Agreement shall be returned to the debtor with the "Approval and Acceptance" thereon signed by the Director, Bureau of Hearing Counsel.

§ 540.35 Referral to Department of Justice.

(a) The Commission will refer violations to the Department of Justice with the recommendation that action be taken to collect the full statutory penalty when:

(1) The offender, within the prescribed time, does not explain the violation, petition for mitigation or remission, or otherwise respond to letters or inquiries.

(2) The offender, having responded to such letters or inquiries, fails or refuses to pay the statutory or mitigated penalty, as determined by the Commission, within the prescribed time.

(b) No action looking to the remission or mitigation of a penalty shall be taken on any petition, irrespective of the amount involved, if the case has been referred to the Department of Justice for collection.

§ 540.36 Payment of penalties.

Payment of penalties by the offender shall be made by:

(a) A bank cashier's check or other instrument acceptable to the Commission.

(b) Regular installments by check after the execution of a promissory note containing a confess-judgment agreement (Appendix B).

(c) A combination of the alternatives described in paragraphs (a) and (b) of this section. All checks or other instruments submitted in payment of claims shall be made payable to "Federal Maritime Commission."

§ 540.91 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

This section displays the control numbers assigned to information collection requirements of the Commission in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511. The Commission intends that this section comply with the requirements of section 3507(f) of the Paperwork Reduction Act, which requires that agencies display a current control number assigned by the Director of the Office of Management and Budget (OMB) for each agency information collection requirement:

Section	Current OMB control No.
540.4 (Form FMC–131)	3072–0012
540.5	3072–0011
540.6	3072–0011
540.8	3072–0011
540.9	3072–0011
540.23 (Form FMC–131)	3072–0012
540.24	3072–0011
540.26	3072–0011
540.27	3072–0011

Appendix A—Example of Settlement Agreement To Be Used Under 46 CFR 540.30–540.36

Settlement Agreement FMC File No. ———

This Agreement is entered into between:

(1) the Federal Maritime Commission and,

(2) ——— hereinafter referred to as Respondent.

WHEREAS, the Commission is considering the institution of an assessment proceeding against Respondent for the recovery of civil penalties provided under the ——— Act ———, for ——— alleged violation(s) of Section(s) ———.

WHEREAS, this course of action is the result of practices believed by the Commission to have been engaged in by Respondent to wit;

———

———

WHEREAS, the parties are desirous of expeditiously settling the matter according to the conditions and terms of this Agreement and wish to avoid the delays and expense which would accompany agency litigation concerning these penalty claims; and,

WHEREAS, Section ——— of the ——— Act ——— authorizes the Commission to collect and compromise civil penalties arising from the alleged violation(s) set forth and described above; and,

WHEREAS, the Respondent has terminated the practices which are the basis of the alleged violation(s) set forth herein, and has instituted and indicated its willingness to maintain measures designed to eliminate, discourage and prevent these practices by Respondent or its officers, employees and agents.

NOW THEREFORE, in consideration of the premises herein, and in compromise of all civil penalties arising from the violation(s) set forth and described herein that may have occurred between ——— (date) and ——— (date), the undersigned Respondent herewith tenders to the Federal Maritime Commission a bank cashier's check in the sum of $———, upon the following terms of settlement:

1. Upon acceptance of this agreement of settlement in writing by the Director of the Bureau of Hearing Counsel of the Federal Maritime Commission, this instrument shall forever bar the commencement or institution of any assessment proceeding or other claims for recovery of civil penalties from Respondent arising from the alleged violations set forth and described herein, that have been disclosed by Respondent to the

Commission and that occurred between ———— (date) and ———— (date).

2. The undersigned voluntarily signs this instrument and states that no promises or respresentations have been made to the Respondent other than the agreements and consideration herein expressed.

3. It is expressly understood and agreed that this Agreement is not to be construed as an admission of guilt by undersigned Respondent to the alleged violations set forth above.

4. Insofar as this agreement may be inconsistent with Commission procedures for compromise and settlement of violations as set out at 46 CFR Part 505, the parties hereby waive application of such procedures.

By ————
Title ————
Date ————

Approval and Acceptance

The above Terms and Conditions and Amount of Consideration are hereby Approved and Accepted:

By the Federal Maritime Commission.

(Hearing Counsel)

Director, Bureau of Hearing Counsel.

Date————

Appendix B—Example of Promissory Note To Be Used Under 46 CFR 540.36

Promissory Note Containing Agreement for Judgment

FMC File No.————

For value received, ———— promises to pay to the Federal Maritime Commission (the Commission) the principal sum of $———— ($————) to be paid at the offices of the Commission in Washington, D.C., by bank cashier's or certified check in the following installments:

$———— ($————) within — months of execution of the settlement agreement by the Director of the Bureau of Hearing Counsel;

$———— ($————) within — months of execution of the agreement;

$———— ($————) within — months of execution of the agreement;

[Further payments if necessary]

In addition to the principal amount payable hereunder, interest on the unpaid balance thereof shall be paid with each installment. Such interest shall accrue from the date of the execution of this Promissory Note by the Director of the Bureau of Hearing Counsel, and be computed at the rate of [———— percent (——%) per annum.]

If any payment of principal or interest shall remain unpaid for a period of ten (10) days after becoming due and payable, the entire unpaid principal amount of this Promissory Note, together with interest thereon, shall become immediately due and payable at the option of the Commission without demand or notice, said demand and notice being hereby expressly waived.

If a default shall occur in the payment of principal or interest under this Promissory Note, ———— (Respondent) does hereby authorize and empower any U.S. attorney, any of its assistants or any attorney of any court of record, Federal or State, to appear for him or her, and to enter and confess judgment against ———— (Respondent) for the entire unpaid principal amount of this Promissory Note, together with interest, in any court of record, Federal or State; to waive the issuance and service of process upon ———— (Respondent) in any suit on this Promissory Note; to waive any venue requirement in such suit; to release all errors which may intervene in entering up such judgment or in issuing any execution thereon; and to consent to immediate execution on said judgment.

———— (Respondent) hereby ratifies and confirms all that said attorney may do by virtue thereof.

This Promissory Note may be prepaid in whole or in part by Respondent by bank cashier's or certified check at any time, provided that accrued interest on the principal amount prepaid shall be paid at the time of the prepayment.

By ————
Title ————
Date ————

By the Commission.

Francis C. Hurney,

Secretary.

[FR Doc. 84-24313 Filed 9-13-84; 8:45 am]

BILLING CODE 6730-01-M

federal register

Friday
September 14, 1984

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 600, 803, 1002, and 1003
Medical Device Reporting; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 803, 1002, and 1003

[Docket No. 79N-0182]

Medical Device Reporting

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that requires manufacturers and importers of medical devices, including diagnostic devices, to report to FDA whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. FDA is taking this action under the Medical Device Amendments of 1976.

The final rule is intended to assure that FDA is informed promptly of all serious problems or potentially serious problems associated with marketed devices. FDA is the principal public health agency responsible for ensuring that devices are safe and effective. To carry out its responsibilities, the agency needs to be informed whenever a manufacturer or importer receives or otherwise becomes aware of information about device problems. Only if FDA is provided with such information will it be able to evaluate the risk, if any, associated with a device and take whatever action is necessary to reduce or eliminate the public's exposure to this risk. Depending on the facts and circumstances, these steps could include contacting the manufacturer or importer of the device and monitoring its voluntary actions to respond to the problem, initiating a consumer or user education program, or initiating regulatory action, such as injunction, seizure, or other enforcement action.

DATES: Comments on the conforming amendments by October 15, 1984. Effective November 13, 1984. For additional information concerning this effective date, see "Paperwork Reduction Act of 1980" appearing in the preamble of this document.

ADDRESS: 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: Robert A. Forst, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of November 18, 1980 (45 FR 76183), under the authority of sections 502(t), 519, 701(a), and 704(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(t), 360i, 371(a), and 374(e)), FDA issued a proposed rule that would have required device manufacturers, importers, and distributors to submit to FDA reports concerning devices that (1) may have caused a death or injury; (2) may have had a deficiency that could result in a death or injury or that could give inaccurate diagnostic information and, thereby, result in improper treatment; or (3) were the subject of a remedial action. Interested persons were given until February 17, 1981, to submit written comments on the proposal. FDA received more than 200 written comments. In addition, on February 2, 1981, FDA held a public hearing on the proposal at which 30 persons presented information and views. (The public hearing, announced in the proposal and originally scheduled for January 22, 1981, was rescheduled by notice published in the **Federal Register** of January 9, 1981 (46 FR 2364).)

Most of the comments on the 1980 proposal criticized its reporting requirements as being too broad in scope and claimed that the burden on manufacturers, importers, and distributors of complying with the requirements would outweigh any resulting benefits to the public health. Other comments, however, stated that to assure that devices are not adulterated or misbranded and are otherwise safe and effective, FDA needs to receive reports of death and serious injury, or at least death.

Subsequently, by a notice published in the **Federal Register** of November 24, 1981 (46 FR 57568), FDA placed the 1980 proposed rule in abeyance. FDA took this action to permit further review and evaluation of the comments recived on the proposal, to permit a review of the proposal in light of Executive Order 12291, which was issued on February 17, 1981, and to permit the initiation, completion, and analysis of an inspection program of complaint files maintained by manufacturers under the current good manufacturing practice (CGMP) regulations for medical devices (21 CFR Part 820). The inspection program was designed to provide FDA with data to determine, among other things, whether FDA inspection of manufacturers' complaint files could substitute for some or all of the proposed reporting requirements.

After publication of the notice of abeyance, FDA continued to review and evaluate the comments on the 1980 proposal. The agency concluded that the broad reporting requirements of the proposed rule were not appropriate. FDA tentatively concluded, however, that information regarding device-related deaths and serious injuries should be reported even if records of these events are maintained in the manufacturers' complaint files because the resources available to the agency for inspectional programs permit FDA to review most such files only once every 2 years. FDA also tentatively concluded that it needs, on a more timely basis, information about device-related deaths, serious injuries, and malfunctions that could cause deaths or serious injuries. For these reasons, in the **Federal Register** of May 27, 1983 (48 FR 24014), under the authority of sections 510 and 704(a) of the act (21 U.S.C. 360 and 374(a)), as well as the sections of the act cited in the November 1980 proposal, FDA issued a reproposed rule under which manufacturers and importers of medical devices would have been required to report to FDA whenever the manufacturer or importer had information that reasonably suggested, or a person made in allegation of which the manufacturer or importer was aware, that one of its marketed medical devices (1) caused or contributed to a death or serious injury or (2) malfunctioned, if a recurrence of the malfunction was likely to cause or contribute to a death or serious injury.

FDA acknowledged that the reporting requirements in the 1983 reproposal were narrower than those in the 1980 proposal, which would have required device manufacturers and distributors (including importers) to submit reports to FDA about devices that may have caused a death or injury or that may have a deficiency that could result in a death or injury. (For a complete discussion of the differences between the proposal and the reproposal, see 48 FR 24014.)

Since publication of the reproposal, FDA has completed its "Survey of Device Manufacturer Complaint Files" (Ref. 1) (the Survey) announced in the November 24, 1981, notice of abeyance, and has analyzed the data collected. The results of this analysis compel three conclusions. First, the results show that

FDA review of manufacturers' complaint files cannot substitute for a reporting rule; review of such files is not a timely or efficient way for the agency to learn of device problems and could not enable FDA to protect the public health adequately. Second, the results show that the reporting requirements of the final rule do not duplicate existing reporting systems and are not unduly burdensome. Third, the results show that under the 1980 proposal, FDA would have received more than 225,000 reports each year from manufacturers alone, and that less than 12 percent of these reports would have been related to incidents involving death, serious injury, or malfunctions that could have led to death or serious injury. Given the resources available to FDA to administer a device reporting program, the agency could not review more than 225,000 reports each year, determine which ones required further investigation and action by the agency, and proceed in a timely manner to protect the public from hazardous or potentially hazardous devices. A copy of the Survey is on file in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville MD 20857, under Docket No. 79N–0182 and is available for review by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

Statutory Authority and Legislative History

Section 519 of the act authorizes FDA to issue regulations to require device manufacturers, importers, and distributors to maintain such records, make such reports, and provide such information to FDA as may reasonably be necessary to assure that devices are not adulterated or misbranded and are otherwise safe and effective for human use. The legislative history of the Medical Device Amendments of 1976 (Pub. L. 94–295) (the amendments) reflects clear congressional intent to permit FDA to require under the authority of section 519 of the act that device manufacturers, importers, and distributors report to FDA product defects and adverse reactions to the firms' devices. H.R. Rep. No. 94–853, 94th Cong., 2d Sess. 23 (1976). In discussing the notification provisions of section 518 of the act (21 U.S.C. 360h), the House Report, the principal legislative document on the amendments, states:

> The notification provision is similar to, and to some extent patterned after, comparable authority contained in the National Traffic and Motor Vehicle Safety Act of 1966, the Radiation Control for Health and Safety Act of 1968, and the Consumer Product Safety Act of 1972. These statutes also include requirements that manufacturers provide notification of defects in their products to appropriate Federal agencies. The Committee determined that a comparable provision in new section 518(a) with respect to devices would be unnecessary since the Secretary could require the reporting of such information under the recordkeeping and reporting authority provided in new section 519 of the Act.

H.R. Rep. No. 94–853, *supra*, at 21.

Elsewhere, the House Report lists examples of reasonable reporting requirements, including reports of defects, adverse reactions, and patient injuries (*id.* at 23). That Congress intended FDA to use its authority under section 519 of the act to protect the public from potentially hazardous devices, as well as devices with confirmed hazards, is also clear from the legislative history (see *id.* at 24).

Among other things, section 519 of the act requires that any reporting requirement established under the authority of that section (1) may not be unduly burdensome (considering the cost of compliance and the need for the requirement); (2) shall state the purpose for any required report or information and identify to the fullest extent practicable such report or information; (3) may not, except in certain circumstances, require the disclosure of a patient's identity; and (4) may not, except in certain circumstances, require the manufacturer, distributor, or importer of a class I (general controls) device to maintain for such a device records respecting information not in its possession or to submit with respect to such device periodic reports or to submit with respect to such device information not in its possession. The House Report cautions, however, that these limitations "should not be construed * * * as limiting the Secretary's authority to obtain information needed to insure that the public is protected from potentially hazardous devices" (*id.* at 24).

Section 701(a) of the act authorizes FDA to promulgate substantive binding regulations for the efficient enforcement of the act. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); see also *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973); *National Ass'n of Pharmaceutical Manufacturers* v. *FDA*, 637 F.2d 877 (2d Cir. 1981); *National Confectioners Ass'n* v. *Califano*, 569 F.2d 690 (D.C. Cir. 1978); *National Nutritional Foods Ass'n* v. *Weinberger*, 512 F.2d 688 (2d Cir.), *cert. denied*, 423 U.S. 827 (1975). Section 502(t)(2) of the act deems a device to be adulterated, and thus prohibited from commerce under sections 301 and 304 of the act (21 U.S.C. 331 and 334), if there is a failure to furnish any material or information required under section 519 of the act respecting the device. Section 704(e) of the act provides that every person required under section 519 of the act to maintain records and every person who is in charge or custody of such records shall, upon request of any authorized FDA employee, permit such employee at all reasonable times to have access to, and to copy and verify, such records. Section 704(a) of the act provides that for purposes of enforcement of the act, any duly authorized FDA employee is authorized, among other things, (1) to enter, at reasonable times, any factory, warehouse, or establishment in which devices are manufactured, processed, packed, or held, or to enter any vehicle being used to transport or hold devices and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. Section 510 of the act requires every person who owns or operates any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device to register with FDA the person's name, places of business, and all such establishments and to list with FDA each device introduced by the person for commercial distribution. FDA's need for information about the safety and effectiveness of devices is implicit in other sections of the act, e.g., section 513 (21 U.S.C. 360c) on device classification, section 514 (21 U.S.C. 360d) on performance standards, and section 515 (21 U.S.C. 360e) on premarket approval. Thus, for example, reporting requirements may be a condition of approval under section 515.

Comments on the Reproposed Rule

In response to the 1983 reproposal, FDA received 84 written comments from interested persons. Comments were received from device manufacturers, industry trade associations, the Office of Management and Budget (OMB), and members of the public. The following is a summary of the significant comments received on the reproposal, including comments received from OMB (see paragraphs 39, 50, and 62 of this preamble), and the agency's response to them. The summary takes into account the significant comments on the proposed rule which are relevant to the reproposal and the final rule but which were not addressed in the preamble to the reproposal.

General Comments

1. Many comments assert that the proposed and reproposed rule would violate section 519 of the act, which prohibits the promulgation of reporting and recordkeeping requirements that are unduly burdensome. FDA also received comments that claim that the proposed and reproposed rule would not impose any undue burden on device manufacturers, importers, or distributors.

The reporting requirements included in the reproposed rule were considerably narrower than those included in the November 1980 proposal, which FDA concluded were unnecessarily broad (see 48 FR 24014). Whether or not the provisions of the proposed rule would have been unduly burdensome, FDA could not have processed in an effective manner all the information they would have captured (see the "Background" section of this preamble). FDA does not believe that the provisions of the reproposed rule would have been unduly burdensome (see 48 FR 24015). In any event, as explained throughout this preamble, in the final rule, FDA has made certain that manufacturers and importers are required to report to the agency only such information as may be reasonably necessary to assure the protection of the public health. Based on the Survey, FDA estimates that it will receive, 25,100 reports annually. FDA expects that most manufacturers and importers will not need to submit any reports under the final rule. FDA recognizes, however, that some manufacturers and importers will need to submit several reports to the agency. In short, the number of reports required will vary considerably from manufacturer to manufacturer and importer to importer. Given the nature of the events that are required to be reported—device-related deaths and serious injuries, and device malfunctions that are likely to lead to deaths or serious injuries—FDA has concluded that the final rule strikes the proper balance and protects the public health while avoiding undue burdens on industry. FDA notes that the submission of 25,100 reports to FDA each year under the final rule will represent less than 4 reports for every registered device establishment.

The purpose of the final rule is to assure that FDA is informed promptly of all serious problems or potentially serious problems associated with marketed devices. FDA is the principal public health agency responsible for ensuring that devices are safe and effective. To carry out its responsibilities, the agency needs to be informed whenever a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. (For the sake of convenience, information that is required to be reported under the final rule is referred to throughout this preamble as information about a reportable event.) Only if FDA is provided with information about reportable events will it be able to evaluate the risk, if any, associated with a device and take whatever steps are necessary to reduce or eliminate the public's exposure to this risk. Depending on the facts and circumstances, these steps could include contacting the manufacturer or importer of the device and monitoring its voluntary actions to respond to the problem, initiating a consumer or user education program, or initiating regulatory action, such as injunction, seizure, or other enforcement action. Moreover, the agency needs to receive information about reportable events promptly so that it can react rapidly to the problem and thereby prevent, to the extent possible, recurrence of any death or serious injury.

2. One comment states that FDA has not identified the occurrence of any death or serious injury of which the agency did not have timely notice. The comment also states that FDA has not identified any death or serious injury which would be prevented by the reproposed rule.

The results of the Survey show that reportable deaths and serious injuries do occur for which FDA does not receive timely notice. For example, following FDA's receipt of a complaint about an inter-aortic pump, an FDA inspection uncovered an additional 50 complaints. The firm subsequently recalled the pump. In another instance, following FDA's receipt of a complaint about an intravenous pump, an FDA inspection uncovered more than 94 additional complaints and resulted in major changes in the device's labeling.

FDA's experience in administering the amendments demonstrates that in these and similar instances, the agency could eliminate or reduce device-related deaths and serious injuries if FDA had timely notice of reportable events. In and of itself, of course, reporting under the final rule will not eliminate device-related deaths or serious injuries; however, such reporting will enable FDA to take action to reduce or prevent deaths and serious injuries associated with devices.

3. Many comments contend that FDA's existing voluntary reporting system provides adequate collection of and access to information concerning reportable events. The comments state that the purpose of the voluntary system is to encourage reports from users to manufacturers to enable manufacturers to correct any device problems; reporting to FDA will not improve this procedure. FDA also received comments stating that the existing voluntary system is not adequate to keep FDA informed of medical device problems.

FDA does not believe that reporting under the current voluntary system is an adequate substitute for this final rule. At present, FDA receives reports of device problems through its voluntary Device Experience Network (DEN) system. DEN consists of reports made to the Problem Reporting Program, which is coordinated by the United States Pharmacopeial Convention, Inc., and reports made to the Government Wide Quality Assurance Program (GWQAP) and the National Electronic Injury Surveillance System (NEISS).

Based on its experience, FDA does not believe that information about all reportable events is provided to FDA under DEN. As part of the Problem Reporting Program, from time to time FDA has actively encouraged the reporting of adverse device experiences to DEN through such organizations as the American Association of Critical Care Nurses, the American College of Pathologists, and the American College of Physicians. During these periods, the number of device experience reports has significantly increased. When there is no such encouragement, FDA believes that many incidents go unreported. Through the GWQAP program, FDA receives complaints only about those products purchased under contract by the Veterans Administration and the Department of Defense. Likewise, NEISS is limited in scope; the only device-related problems that are reported to NEISS, and subsequently, to FDA, are those medical problems that are treated in the emergency rooms of participating hospitals.

FDA acknowledges that the final rule does not require users to report to manufacturers, importers, or FDA. Voluntary reporting under DEN is not an adequate substitute for the requirements of the rule because DEN is not comprehensive and because, as the results of the Survey show, information that is provided by users to

manufacturers is not always provided by manufacturers to FDA.

4. One comment argues that any final rule should require device users to report directly to FDA.

Section 519 of the act authorizes FDA to issue regulations to require manufacturers, importers, and distributors to report to FDA product defects and adverse reactions to the firms' devices (see the "Statutory Authority and Legislative History" section and paragraph 51 of this preamble). For the reasons discussed in paragraphs 26a and 26b of this preamble, the final rule does not apply to a distributor other than a wholly owned distributor, which is considered to be an affiliate company under the control of the manufacturer. Accordingly, the final rule applies to a device user only if the user also is a manufacturer or importer.

FDA encourages device users to submit reports of device problems through the agency's voluntary DEN system (see paragraph 3 of this preamble). FDA plans to continue this voluntary system to complement the reporting requirements of the final rule.

5. One comment argues that the reproposed rule is unnecessary because it duplicates requirements under §§ 820.162 and 820.198 of the CGMP regulations to investigate device-related incidents of death and serious injury. The comment also argues that under § 7.46 (21 CFR 7.46) of FDA's guideline on policy, procedures, and industry responsibilities concerning recalls, a manufacturer is required to notify the appropriate FDA district office immediately if the manufacturer believes that one of its marketed devices is in violation of the act.

Under § 820.162, after a device has been released for distribution, a manufacturer is required to investigate any failure of a device or any of its components to meet its performance specifications and to establish and maintain a written record of the investigation, including the manufacturer's conclusions and followup. Under § 820.198, a manufacturer is required to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications and any complaint pertaining to injury, death, or any hazard to safety and to maintain a written record of the investigation. Under § 820.180, a manufacturer is required to retain records of such investigations. However, §§ 820.162, 820.198, and 820.180 do not require any report or other information about a failure or complaint to be transmitted to FDA. In many instances, FDA becomes aware of these failures and complaints only when the agency reviews a manufacturer's records. Generally, FDA conducts a CGMP inspection, including a records review, at a firm only every other year. The agency does not expect that such inspections will be conducted any more frequently in the future. If the agency were to rely on its inspection of manufacturer records for notification of reportable events, there could be as much as a 2-year period intervening between such an event and the time the agency became aware of it. During that intervening period, the agency would be able to do little to reduce or eliminate the risk presented by the device, simply because it would be unaware of the risk.

The results of the Survey show that reliance on §§ 820.162 and 820.198, as suggested by the comments, would require FDA to examine, during establishment inspections, more than 225,000 complaints to identify those that are reportable events under the final rule. As explained in the "Background" section and paragraph 17 of this preamble, FDA could not review 225,000 reports submitted to the agency to determine which ones required further investigation by FDA, and proceed in a timely manner to protect the public from hazardous or potentially hazardous devices. It follows that the agency could not effectively review and process, on site, more than 225,000 complaints annually.

In short, investigation of device failures and complaints of failures and maintenance of records of such investigations, required by the CGMP regulations, help achieve the public health objectives of those regulations but are not a substitute for the reporting requirements of this final rule. Also, the CGMP regulations do not apply to importers.

Likewise, FDA's recall guidelines do not require a device manufacturer or importer to submit any information to the agency. Under § 7.46, a firm is requested to notify FDA voluntarily whenever the firm removes or corrects a distributed product that the firm believes to be in violation of the act; any submission under § 7.46 is wholly voluntary and the failure to submit information under that section is not a violation of law. The final rule makes mandatory the submission of a report whenever a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

6. One comment argues that FDA should complete its survey of manufacturers' complaint files before establishing reporting requirements to ensure that only necessary requirements are imposed.

FDA does not believe that completion of the Survey was a prerequisite to the promulgation of this or any other medical device reporting rule. As stated in the "Background" section of this preamble, however, FDA has completed the Survey. The agency has concluded that this final rule imposes only those requirements necessary to enable FDA to carry out its responsibilities to protect the public health and that the data from the Survey support this conclusion.

7. One comment recommends that any final rule not require submission of a report of a device incident which could be construed as an admission that the death or serious injury was caused by the device.

The information required in the report is set forth in § 803.24(c) of this final rule. FDA does not believe that the submission of information that reasonably suggests that a device may have caused or contributed to a death or serious injury will be treated by the courts as an admission that the device actually caused or contributed to a death or serious injury. FDA advises, however, that whether the courts will treat the submission of this information as an admission is strictly within the authority of the courts to decide, on a case-by-case basis.

8. Two comments argue that the reproposed rule violates the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), because the requirement to report a malfunction, if, as a result of a recurrence of the malfunction, the device or any other device marketed by the manufacturer or importer is likely to cause or contribute to a death or serious injury, calls for speculation and will result in reports of minor device problems. A third comment argues that the reproposed rule violates section 3506(a) of the Paperwork Reduction Act of 1980, which provides that "[e]ach agency shall be responsible for carrying out its information management activities in an efficient, effective, and economical manner" because requiring reports based on mere allegation is speculative, inefficient, ineffective, and uneconomical.

FDA disagrees with the comments. The requirement to which the first two comments refer calls for the exercise of professional judgment rather than

speculation (see paragraphs 56 and 60 of this preamble). Further, if information reasonably suggests that a device has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, the device problem is not "minor." FDA has demonstrated the practical utility of and the need for the information required to be submitted under the final rule. The rule accordingly complies with the Paperwork Reduction Act of 1980.

The final rule does not require reports based on "mere allegation." For this reason, the third comment is not directly relevant. The final rule requires reporting whenever information "reasonably suggests" that a reportable event has occurred. As discussed in paragraph 38 of this preamble, if a health care professional informs a manufacturer or importer that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, such information reasonably suggests that a reportable event has occurred.

FDA believes that it is not speculative, inefficient, ineffective, or uneconomical for the agency to require the submission of information about reportable events before such events have been confirmed by the manufacturer or importer. Reasonable persons may differ as to whether a death or serious injury is device-related. Reasonable persons also may differ as to whether, as a result of recurrence of a malfunction, a device is likely to cause or contribute to a death or serious injury. FDA, as the public health agency responsible for protecting the public from unsafe devices, should make an independent evaluation of the device's role, if any, in a reportable event. It would be irresponsible for FDA to wait for confirmation of a reportable event by a manufacturer or importer before requiring reporting of any information about such event.

9. Two comments recommend that the final rule not become effective for 180 days after publication in the Federal Register to enable manufacturers and importers to establish internal procedures to administer the new reporting requirements.

FDA disagrees with the comments. FDA believes that 90 days is a reasonable period for manufacturers and importers to establish a procedure for complying with the provisions of the final rule. Manufacturers should already have in place procedures for investigating device failures under § 820.162, for reviewing, investigating, and evaluating device complaints under § 820.198, and for maintaining records under § 820.180 (see paragraph 5 of this preamble). (Those provisions of the CGMP regulations became effective on Dec. 18, 1978.) Thus, the only additional requirements that the final rule imposes on manufacturers are those of establishing procedures for preparing and submitting a report or additional information to the agency, and for retaining records under final § 803.31(d) (see paragraph 90 of this preamble).

FDA recognizes that importers are not subject to the requirements of §§ 820.162 and 820.180. FDA believes, however, that 90 days is a sufficient period for importers to establish a complaint file and procedures for maintaining such a file; to establish procedures for preparing and submitting a report or additional information to the agency, and to establish procedures for retaining records under final § 803.31 (a) and (b) (see paragraphs 89, 90, and 91 of this preamble).

To assure that device manufacturers and importers are aware of their responsibilities under this final rule, FDA will mail to every manufacturer and importer registered with FDA a copy of the rule as published in the Federal Register.

Economic Impact

10. Many comments claim that the reproposed rule would be too costly in comparison with any benefit to be derived from it.

FDA disagrees with the comments. As explained throughout this preamble, FDA has concluded that receipt of information about reportable events is necesssary to enable the agency to carry out its responsibilities to protect the public health. The threshold assessment of the cost impact of the final rule shows that the cost of the rule will be no more than $4 million based on the submission of 25,100 reports. The benefits from the final rule—the prevention or reduction of device-related deaths and serious injuries—justify the anticipated cost of the final rule to device manufacturers and importers.

11. Several comments state that, due to the definition of serious injury in the reproposed rule, FDA would require reporting of minor device problems and anticipated adverse experiences. These comments argue that FDA based its threshold assessment of the reproposed rule on an estimate of the number of reports of serious device problems which would be submitted, thereby underestimating the number of reports that would be submitted to the agency. The comments argue further that reporting of minor device problems and anticipated adverse reactions would not provide any benefit to the public health.

Under § 803.3(e) of the reproposed rule, a serious injury was defined as an injury that (1) is life threatening, (2) necessitates immediate medical or surgical intervention, (3) results in permanent impairment of a body function or permanent damage to body structure, or (4) results in unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure. FDA agrees that some device problems that led to such an injury could fairly be characterized as "minor" device problems. FDA, therefore, has revised the definition of "serious injury" to include an injury requiring medical or surgical intervention by a health care professional to (i) preclude permanent impairment of a body function or permanent damage to body structure or (ii) relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure (see final § 803.3(h) and paragraphs 39, 40, and 41 of this preamble). With this revision, FDA believes that the threshold assessment for the final rule does not include the cost of submitting reports of minor device problems because such reports are not required by the rule.

12. Several comments state that FDA has neglected to include in the threshold assessment for the reproposed rule any estimate of the cost of submitting additional information when required by FDA and of complying with FDA inspections initiated in response to the receipt of a report.

The cost of submitting additional information to FDA if required under § 803.24(e) is not significant. Under § 820.162 of the CGMP regulations, after a device has been released for distribution, a manufacturer already is required to investigate any failure of a device or any of its components to meet its performance specifications and to establish and maintain a written record of the investigation, including the manufacturer's conclusions and followup. Under § 820.198, a manufacturer already is required to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications and any complaint pertaining to injury, death, or any hazard to safety and to maintain a written record of the investigation.

Accordingly, any additional information required under § 803.24(e) should already have been gathered, reviewed, and evaluated under §§ 820.162 and 820.198. The cost of complying with an FDA inspection initiated in response to the receipt of a report cannot be estimated because any such cost would depend critically on the results of the inspection. For manufacturers, virtually the only costs imposed by the final rule are those of establishing procedures for, and preparing and submitting, a report or additional information to the agency and for retaining records under final § 803.31(d) (see paragraphs 90 and 91 of this preamble).

Under the final rule, importers are not required to review, evaluate, or investigate a reportable event. For importers, therefore, the only costs imposed by the final rule are those of establishing procedures for, and maintaining, complaint files; establishing procedures for, and preparing and submitting, a report or additional information to the agency; and establishing procedures for, and retaining, records under final § 803.31 (a) and (b) (see paragraphs 89, 90, and 91 of this preamble).

13. One comment states that FDA did not include in its threshold assessment the cost of legal review of a report before initial submission.

The per report cost used by FDA to determine the total cost of the final rule took into account 13 independent estimates submitted to FDA in comments on the November 1980 proposal. Although the estimates did not include data or information concerning the cost of legal review, they apparently include all costs that those preparing the estimates thought necessary in submitting a report to FDA, including legal review. FDA notes that the rule does not require those submitting reports to FDA to subject the reports first to legal review.

14. Several comments state that FDA failed to include in its threshold assessment for the reproposed rule the costs of more expensive product liability insurance and increased product liability litigation that would be caused by the reproposed rule.

FDA has no reason or evidence to believe that the final rule will result in increased product liability litigation and, therefore, did not include in its threshold assessment costs associated with such litigation (see paragraph 43 of this preamble). The cost of product liability insurance is determined primarily, though not exclusively, by the product liability experience of the insurance carrier. If an increase in product liability litigation does not occur as a result of the final rule, then an increase in product liability insurance will not occur as a result of the final rule.

FDA notes that none of the coments contains any data to substantiate the claims that product liability insurance premiums and litigation would increase as the result of the promulgation of any medical device reporting rule, nor do the comments include any basis for the statement that insurance carriers will raise the cost of product liability insurance in anticipation of increased product liability litigation.

15. Four comments contend that FDA has underestimated the number of reports that would be received under the reproposal.

FDA agrees with the comments. In the threshold assessment for the reproposed rule, FDA estimated that 7,050 reports would be submitted annually. This estimate was based on data from DEN, which as discussed in paragraph 3 of this preamble, is not comprehensive. Based on data from the Survey, FDA estimates that under the final rule no more than 25,100 reports will be submitted annually (see paragraph 1 of this preamble). FDA believes that the data collected under the Survey are valid and has used the 25,100 estimate in its threshold assessment for the final rule.

16. One comment claims that under the reproposed rule, the diagnostic device industry would be required to submit 2,000,000 reports each year.

FDA disagrees with the comment. Based on the Survey, FDA projected that 18,000 reports of failure to diagnose are received each year by manufacturers of diagnostic devices. FDA estimates that under the final rule, only a fraction of these failures to diagnose will be required to be reported.

Scope

17a. Several comments suggest that to protect the public health adequately, FDA return to the reporting requirements in the November 1980 proposal.

Under the 1980 proposal, manufacturers, distributors, and importers would have been required to submit to the agency reports concerning devices that (1) may have caused a death or injury; (2) may have had a deficiency that could result in a death or injury or that could give inaccurate diagnostic information and, thereby, result in improper treatment; or (3) were the subject of a remedial action by the manufacturer. FDA received more than 200 written comments on the proposed rule, and 30 persons presented information and views at a public hearing on the proposal. After reviewing these comments, FDA tentatively concluded that the requirements proposed in 1980 would have been unnecessarily broad, and might have resulted in reports not useful to the agency (48 FR 24014). The data from the Survey support this conclusion. Under the proposal, FDA would have received more than 225,000 reports annually from device manufacturers. Most of these reports would have been for minor device problems that now are adequately corrected without FDA involvement. This figure, moreover, does not include reports that would have been received from device distributors and importers. Given the resources available to FDA to administer a device reporting program, the agency could not review more than 225,000 reports each year, determine which ones required further investigation and action by the agency, and take whatever steps were necessary to reduce or eliminate the public's exposure to devices that proved hazardous or potentially hazardous (see the "Background" section and paragraphs 1 and 5 of this preamble). FDA believes that the reporting requirements of the final rule will ensure that the agency is informed of the more serious device problems that may require FDA involvement to protect the public health.

FDA advises that on its own initiative, it has revised final §§ 803.1(a) and 803.24 to require reporting whenever information reasonably suggests that a device "may have" caused or contributed to a death or serious injury, instead of whenever information reasonably suggests that a device "has" caused or contributed to a death or serious injury, as was reproposed in §§ 803.1(a) and 803.24. FDA revised the final rule in this manner because the agency needs to learn of instances in which there may be an association, as well as a causal connection, between the use of a device and a death or serious injury. If data or other information establish the existence of such an associated, relabeling of the device to disclose the association may be required under sections 502(a) and 201(n) of the act (21 U.S.C. 352(a) and 321(n)), as was the case when the occurrence of toxic shock syndrome was found to be associated with the use of menstrual tampons (see 47 FR 26982; June 22, 1982) (21 CFR 801.430). Data or other information establishing the existence of an association between the use of a device and a death or serious injury also could provide the basis for action by FDA under section 518 of the act to require notification and other remedies. In addition, regulatory action

under other provisions of the act, publicity, FDA-requested recalls under Part 7, or educational programs could be based on a finding that a death or serious injury is associated with a device.

17b. One comment argues that FDA should require manufacturers and importers to cease distribution of a marketed device upon receipt of information that reasonably suggests that a death or serious injury related to the device has occurred.

The requirement recommended by the comment is beyond the scope of this rulemaking proceeding. FDA believes, however, that imposition of an unqualified obligation to cease distribution upon receipt of information about a reportable death or serious injury, before the manufacturer, importer, or FDA had conducted any investigation of the event, would be unwise. The decision to cease distribution should be made on a case-by-case basis, taking into account such factors as the risks inherent in, and the benefits presented by, the use of the device, and the nature of the information that reasonably suggests that the device "may have caused or contributed to" the death or serious injury. FDA believes that where the facts and circumstances warrant, a responsible manufacturer or importer will voluntarily cease distribution of a marketed device. FDA notes that where the facts and circumstances are such that the device is in violation of the law, e.g., misbranded or adulterated within the meaning of section 501 or 502 of the act (21 U.S.C. 351 or 352), the agency will take whatever action is necessary to protect the public health.

18. One comment suggests that for class I (general controls), class II (performance standards), and class III (premarket approval) devices FDA adopt the reporting requirements currently imposed by FDA as a condition to premarket approval for class III devices that now require such approval.

FDA disagrees that the reporting requirements referred to in the comments should apply to all marketed devices. These requirements are specially designed to enable the agency to monitor the performance in the population-at-large of devices which, unlike class I and class II devices, and class III devices that do not now require premarket approval, do not have a history of marketing. For the reasons discussed in paragraph 96 of this preamble, however, manufacturers and importers of class III devices that now require premarket approval are subject to the provisions of the final rule, along with any specific requirements imposed on the approval orders for such devices.

19. One comment suggests that reports be required if a device does not meet its labeling specifications or a performance standard and, thereby, is ineffective. According to the comment, under the reproposed rule, a report would not be required unless such ineffectiveness falls under the definition of serious injury.

For the reasons discussed throughout this preamble, FDA has limited the reporting requirements under the final rule to instances in which information reasonably suggests that a device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Although the need for reports is not as great if the ineffectiveness of the device does not directly or indirectly pose a risk of death or serious injury, FDA strongly encourages voluntary reporting about ineffective devices.

20. One comment suggests that FDA exclude from the final rule any requirement to report adverse experiences disclosed in a device's labeling. The comment claims that this exclusion would be consistent with FDA's position stated in the preamble to the reproposed rule (48 FR 24019) "that FDA may notify a manufacturer or importer that a report of a particular type of event is no longer required (e.g., the injury reported becomes recognized by FDA as an inherent risk of using the device in which event it would become part of the product labeling)."

FDA recognizes that there are inherent risks associated with the use of certain devices and that the labeling for some of these devices properly informs the user of these risks. However, the comment misconstrued the statement cited by the comment. Even if the occurrence of a reportable event is disclosed in the device's labeling, a manufacturer or importer is subject to the obligation to report information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

In general, the agency reviews labeling for medical devices before marketing as part of its review of three types of documents, premarket approval applications, reclassification petitions, and premarket notification submissions. The largest category of documents is premarket notification submissions under section 510(k) of the act and Subpart E of Part 807 of FDA's regulations (21 CFR Part 807). FDA's review of these submissions is intended to permit the agency to determine the status of a postamendments device under section 513(f) of the act, which requires premarket approval or reclassification of any postamendments device that is not "substantially equivalent" to a preamendments or reclassified device. In determining whether a postamendments device is substantially equivalent to a preamendments or reclassified device, FDA considers whether the device presents risks and benefits not materially different from those of the preamendments or reclassified device. For a postamendments device to be "substantially equivalent," its intended use must be the same as, and its materials, design, and energy source, among other things, must not differ materially from, those of a preamendments or reclassified device. In addition, any variation between the postamendments device and the already marketed device must not materially affect safety or effectiveness. See H.R. Rep. No. 94–853, *supra*, at 36. Congress did not intend or authorize FDA to review a premarket notification submission for the purpose of determining whether the postamendments device that is the subject of the submission is safe or effective, except on a comparison basis. A determination by FDA that a postamendments device is "substantially equivalent" is thus not a determination that the device is not adulterated or misbranded and is otherwise safe and effective.

FDA's review of premarket notification submissions is not sufficiently comprehensive for the agency to state precisely how many reviewed devices have labeling that discloses, or adequately discloses, whatever risks are inherent in the use of the device. Furthermore, some devices have labeling that lists certain adverse experiences in the precautions or contraindications section of the labeling but that does not describe the frequency or expected severity of the adverse experiences. For these reasons, final § 803.24(a) requires that a manufacturer or importer report to FDA whenever information reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, regardless of the device's labeling, unless, under final § 803.24(d)(4), FDA notifies the manufacturer or importer, in writing, that a report of a particular type of event is no longer required (see paragraph 97 of this preamble).

FDA has included a narrow exception from reporting certain device malfunctions if, within 15 days of initial receipt of the information, certain conditions are met. When information reasonably suggests that a reportable malfunction has occurred, a manufacturer or importer is nevertheless not required to report if (i) the manufacturer or importer determines that a death or serious injury has not occurred; (ii) the device's labeling sets forth information concerning the potential for death or the type of serious injury that the malfunction may cause or contribute to; (iii) the device's labeling describes the malfunction, and the routine service, repair, or maintenance instructions to correct the malfunction; (iv) the malfunction has occurred or is occurring at or below the frequency and severity stated in the labeling or, if there is not any pertinent statement in the labeling, at or below the frequency and severity that are usual for the device; and (v) the malfunction does not lead the manufacturer or importer to undertake a remedial action involving any device other than the device product in which the malfunction occurrred (see the discussion beginning at paragraph 51 of this preamble and new § 803.24(d)(3)(iii) of the final rule).

21. One comment suggests that only reports of life-threatening occurrences be submitted. The comment explains that when first fitted, many orthotic and prosthetic devices may cause discomfort to the patient. This discomfort may require medical intervention or some adjustment that may result in temporary impairment of body function or structure, according to the comment.

The agency believes that it needs to be informed of events other than life-threatening events, e.g., those that cause permanent impairment of a body function or damage to body structure. Under the revised definition of serious injury in final § 803.3(h), however, an injury that is not life threatening or that does not result in permanent impairment is not "serious" unless the injury necessitates medical or surgical intervention by a health care professional to preclude permanent impairment of a body function or damage to body structure or to relieve unanticipated temporary impairment of a body function or damage to body structure (see paragraph 39 of this preamble). If the event described in the comment is not a "serious injury" as defined in § 803.3(h), then a report is not required.

22. One comment states that U.S. manufacturers should not be required to report incidents that occur in foreign countries. The comment states that foreign manufacturers are not required to submit reports to FDA concerning incidents that occur in foreign countries. The comment then argues that not requiring U.S. manufacturers to submit reports of incidents that occur in foreign countries would place U.S. manufacturers in the same competitive position as foreign manufacturers.

FDA disagrees with the comment. The agency is interested in information about any reportable event without regard to the location of the event because such information may enable FDA to assist in the protection of the public health. The rule applies equally to manufacturers and importers because both are required to register with FDA. If an importer receives information about a reportable event, a report is required regardless of the location of the event. FDA decided to exclude foreign manufacturers from the rule because, under section 519 of the act, FDA does not have authority to require a foreign manufacturer that does not offer a device for import into the United States to submit to FDA reports about the device. FDA does not believe that this lack of authority provides a competitive advantage to a foreign manufacturer whose device is not in commercial distribution in the United States.

23. Several comments argue that any final rule should not apply to class I devices. These comments argue that class I devices are not critical devices within the meaning of Part 820 or significant risk devices within the meaning of Part 812 of FDA's regulations governing investigational device exemptions (21 CFR Part 812), and that Part 820 and Part 812, respectively, contain different safeguards for these types of devices.

As noted in the preamble to the reproposal (48 FR 24017), FDA agrees that, in general, the lower the level of classification, the lower the risk posed by a device and the less likelihood that death or serious injury would be associated with such device. Consequently, even without an exemption, manufacturers or importers would receive, and subsequently report to FDA, fewer reports about deaths or serious injuries associated with class I devices than they would for class II or class III devices. Yet, if information reasonably suggests that a marketed device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, its level of classification is irrelevant. Regardless of the nature of a marketed device or its classification, FDA needs to be notified of all reportable events so that the agency can respond to them.

24. One comment argues that FDA should not impose any reporting requirements until the agency has promulgated final rules classifying all devices into class I, class II, or class III. Another comment argues that any final rule should not apply to hearing aids, which FDA has proposed to classify into class II (47 FR 3280; January 22, 1982), because there allegedly have not been any injuries associated with these devices.

FDA disagrees with these comments. As discussed in paragraph 23 of this preamble, if information reasonably suggests that one of a manufacturer's or importer's marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, FDA needs to be notified. Whether the device that is the subject of the reportable event has previously been associated with injuries or is the subject of a final classification rule is irrelevant, as is the classification of the device.

25. One comment suggests that the phrase "has information" in reproposed § 803.1(a) be changed to "has received or becomes aware of information." This comment claimed that, as reproposed, a report would be required if an employee of a firm read a journal article describing a device-related incident.

FDA advises that it intended the reproposed rule to apply in the circumstance described by the comment. FDA has revised § 803.1(a) in the final rule by substituting the phrase "receives or otherwise becomes aware of information" for the phrase "has information" to make clear this intent. FDA also has revised § 803.24 in the final rule to specify that a manufacturer or importer is required to report when the manufacturer or importer receives or otherwise becomes aware of information in a journal which reasonably suggests that a reportable event involving one of the manufacturer's or importer's marketed devices has occurred (see paragraph 53 of this preamble).

26a. Several comments suggests that independent distributors be required to report to manufacturers. The comments argue that, in many instances, the independent distributor rather than the

manufacturer of the device receives information about device problems. According to the comments, if the independent distributor does not provide this information to the manufacturer, FDA will remain uninformed and the manufacturer will be insulated from the reporting requirements, which will place in an unfair competitive position a manufacturer who sells directly to device users.

As noted in the preamble to the reproposed rule (48 FR 24016), FDA believes that manufacturers and importers generally are the most knowledgeable about their devices and are best able to evaluate any hazards or problems associated with their devices. In all likelihood, a manufacturer or importer whose identity is known will be informed by device users and independent distributors of reportable events due to the nature of these events. Therefore, under the final rule, only device manufacturers and importers are required to report. If, after implementing the final rule, FDA determines that requiring reports from independent distributors is necessary to be promptly informed of reportable events, the agency will propose such reporting requirements.

FDA does not believe that the final rule places at an unfair competitive advantage a manufacturer that has elected to sell directly to device users. FDA believes that the independent distributor has ample incentive to inform, and will inform, the manufacturer of reportable events and, accordingly, that such events will be reported to FDA.

26b. One comment asks whether a manufacturer is required to submit a report if information of a death or serious injury associated with the use of one of its devices is given to a distributor that is wholly owned by the manufacturer.

FDA advises that for the purpose of the final rule, a wholly owned distributor is considered to be an "affiliate company" under the control of the manufacturer. Accordingly, information received by a wholly owned distributor is deemed to be information received by a manufacturer. Thus, a manufacturer is required to report if information about a reportable event associated with one of the manufacturer's marketed devices is provided to a distributor that is wholly owned by the manufacturer.

27. One comment suggests that a distributor be permitted to submit reports on behalf of a manufacturer with the manufacturer's consent. The comment states that some distributors are much larger than some small manufacturers and better equipped to comply with the reporting requirements of any final rule.

FDA disagrees with the comment. A manufacturer is ultimately responsible for its devices and can easily furnish the information required in the report under final § 803.24(c). Under § 820.162 of the CGMP regulations, after a device has been released for distribution, a manufacturer is required to investigate any failure of a device or any of its components to meet its performance specifications and to establish and maintain a record of the investigation, including the manufacturer's conclusions and followup. Under § 820.198, a manufacturer is required to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications and any complaint pertaining to death, injury, or any hazard to safety and to maintain a written record of the investigation. Submission of this information to FDA pursuant to a request for additional information under final § 803.24(e) should be easily within the means and expertise of the manufacturer.

28. One comment requests that FDA clarify whether the reproposed rule applies to diagnostic devices. The comment notes that diagnostic devices were specifically identified as subject to the provisions of the November 1980 proposal and that the reproposal was unclear. Another comment states that reports of death or serious injury due to misdiagnosis should not be submitted because whether a diagnostic device has caused or contributed to a death or serious injury is speculative, at best.

FDA advises that, except for in vitro diagnostic products, manufacturers of which are required to be registered under Part 607 (21 CFR Part 607) of FDA's regulations governing establishment registration and product listing for manufacturers of human blood and blood products (see paragraph 94 of this preamble) and for general purpose articles (see paragraph 29 of this preamble), the final rule applies to all marketed devices, including diagnostic devices. FDA agrees that it may be difficult to determine whether a death or serious injury is a result of the failure of a diagnostic device to perform properly. However, if the information about the event reasonably suggests (see paragraph 38 of this preamble) that the event may have resulted from the failure of a diagnostic device to perform properly, a reportable event has occurred, and a report is required.

29. One comment requests clarification of the application of the reproposed rule to general purpose articles. The comment argues that general purpose articles should not be subject to the final rule even if a person manufactures other medical devices that are subject to the rule.

FDA agrees with the comment. General purpose articles are articles such as chemical reagents or laboratory equipment whose uses are generally known by a person trained in their use and which are not labeled or promoted for medical uses (see 21 CFR 807.65(c)). A manufacturer of general purpose articles is not required to submit reports concerning those products even if the manufacturer also markets other medical devices.

Definitions

30. Many comments request that FDA include a definition of "Malfunction" in the final rule. According to the comments, the statement in the preamble that "a device malfunction occurs whenever [the device] fails to perform its intended function" is inadequate and may result in numerous unnecessary reports (48 FR 24018).

FDA notes that a report about a malfunction is required only when information reasonably suggests that a device has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

FDA agrees that a definition of malfunction should be added to the final rule. FDA has defined "malfunction" in final § 803.3(c) and has redesignated reproposed § 803.3(c) as § 803.3(d). A "malfunction" is the failure of a device to meet any of its performance specifications or otherwise to perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the objective intent of the person legally responsible for labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It also may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used to perform a function for which it is neither labeled nor advertised. This definition was chosen to make the final rule consistent with §§ 820.162 and 820.198 and with the

meaning of "intended use" in section 201(h) of the act (21 U.S.C. 321(h)) and § 801.4 of FDA's regulations governing the labeling of devices (21 CFR 801.4). ("Malfunction" is discussed more completely in paragraphs 20, 51, and 56 through 60 of this preamble.)

31. One comment suggests changing the definition of manufacturer in reproposed § 803.3(c) (final § 803.3(d)) to exclude private label distributors other than those that set specifications for a device or are importers.

A person who does not perform any of the activities listed in § 807.20(a) (1) through (5), which specifies who is required to register, or who is exempted under § 807.65(e) from the requirement to register, is not subject to the requirements of this final rule. A private label distributor, i.e., a distributor that obtains a device from a manufacturer with the label already applied and that does not repackage or otherwise alter the device's package or label, is not required to register under Part 807 and, therefore, is not subject to the final rule. The agency advises that it intends to monitor closely the effect of this exclusion on the public health. If FDA determines that to protect the public health adequately it needs to make private label distributors or any other persons subject to the rule, FDA will propose appropriate amendments to the rule.

32. A comment argues that mail order firms and retailers should be excluded from the definition of manufacturer in any final rule.

FDA advises that only mail order firms or retailers that are required to register under § 807.20 and that are not exempted under § 807.65 from the requirement to register are subject to the final rule.

33. One comment suggests that a manufacturer be defined as any person who is required to list a medical device under Part 807, other than a person who initially distributes a device imported into the United States. The comment asserts that the definition of "manufacturer" in § 803.3(c) of the reproposal as "any person required to register under Part 807" includes contract manufacturers that manufacture a device according to another firm's specifications, as well as the firm that originally writes the specifications and markets the device. The comment argues that the definition is redundant and will result in duplicate reports from both the contract manufacturer and the "distributing" manufacturer. The comment concludes that by restricting the reporting requirements to those firms listing devices with FDA, duplicate reports will be eliminated.

FDA disagrees with the comment. The agency believes that the "distributing" manufacturer rather than the "contract" manufacturer (as these terms are used in the comment) will be the person contacted concerning a reportable event because the "distributing" manufacturer is listed on the labeling. Therefore, FDA does not believe that duplicate reporting will result from reproposed § 803.3(c) (final § 803.3(d)). FDA advises, however, that if the "contract" manfacturer receives information about a reportable event, the "contract" maufacturer is required to report to FDA. FDA notes that the "distributing" manufacturer is required to report because it is required to register as a manufacturer under § 807.20(a)(1).

34. One comment asks whether "person" includes a corporate entity.

It does. In response to this inquiry, FDA has added to the final rule new § 803.3(e), which defines the term "person" as any individual, partnership, corporation, association, scientific or academic establishment, Government agency, or organizational unit thereof, or any other legal entity.

35. Several comments object to the definition of "remedial action" in reproposed § 803.3(d) (final § 803.3(g)). The comments claim that, as defined, remedial action could include "communications" to insurance carriers, product liability attorneys, or employees who are subject to disciplinary actions. The comments argue that the definition should be limited to manufacturer actions concerning the labeling, manufacture, or distribution of a device.

FDA did not intend nor does the agency believe that the definition of "remedial action" includes the "communications" referred to in the comments. Generally, remedial actions include notification or other activities that are directed to devices, health institutions, health professionals, device users, manufacturers, importers, distributors, or retailers and that are intended to correct a reportable event. FDA believes that such activities may not be limited to actions concerning the labeling, manufacture, or distribution of a device, e.g., the repair of a device in the field.

36. One comment suggests that the definition of "remedial action" in reproposed § 803.3(d) (final § 803.3(g)) be made consistent with that of "recall" in § 7.3(g), which does not include withdrawals or stock recoveries. Another comment suggests that the term "remedial action" be changed to "corrective action" and defined as any action taken by a manufacturer or importer as a result of its investigation in response to information received concerning a potential or actual device-related death or serious injury.

FDA disagrees that the definition of "remedial action" should be made consistent with that of "recall" in § 7.3(g). Although not all market withdrawals or stock recoveries constitute "remedial actions," information about those initiated in response to reportable events is necessary to enable FDA to take action to protect the public health.

FDA does not believe that the suggested definition of "corrective action" differs significantly from that of "remedial action" or that changing the term "remedial action" to "corrective action" would serve any useful purpose.

37. One comment suggests that FDA define "person alleges."

FDA has deleted this phrase from the final rule. Therefore, a definition is not necessary (see paragraphs 8 and 38 of this preamble concerning reporting of "allegations").

38. Several comments argue that the phrase "information that reasonably suggests" in reproposed §§ 803.1(a) and 803.24(a) is vague and should be defined. One comment suggests that if the information known to the manufacturer or importer is such that "reasonable persons can differ as to whether a device has caused or contributed to a death or serious injury," than this information "reasonably suggests" that a reportable event has occurred.

FDA agrees that the phrase "information that reasonably suggests" should be defined. FDA has added to the final rule new § 803.3(f), which provides that "information that reasonably suggests" a conclusion means (1) information (such as professional, scientific, or medical facts or opinions) from which a reasonable person would reach the conclusion, and (2) a statement to a manufacturer or importer by a health care professional (e.g., a doctor of medicine, osteopathy, dental surgery, podiatry, or chiropractic, or an optometrist, pharmocist, registered nurse, or a hospital administrator), reaching the conclusion.

Under final §§ 803.3(f)(1) and 803.24(a), information that reasonably suggests a conclusion may be provided by any user of a device, e.g., a consumer, or any other person as defined in final § 803.3(e). Under final §§ 803.3(f)(2) and 803.24(a), if a physician, for example, informs a manufacturer or importer that he or she had to replace one of the firm's implanted devices because the device

malfunctioned and a serious injury occurred, the information provided by the physician reasonably suggests that a reportable event has occurred. The manufacturer or importer may not wait until it receives the device from the physician or until it has conducted its own analysis of the device before it reports under final § 803.24(b)(1). Similarly, if a serious injury did not occur, but the physician informs the manufacturer or importer that the device has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a serious injury (or death) if the malfunction were to recur, the information provided by the physician reasonably suggests that a reportable event has occurred. The manufacturer or importer may not wait until it receives the device from the physician or until it has conducted its own analysis of the device before it reports under final § 803.24(b)(2).

FDA recognizes that new § 803.3(f)(2) provides that information furnished by a health care professional is information that per se reasonably suggests that a reportable event has occured. FDA has concluded that this per se provision is warranted because of such persons' special education, training, experience, expertise, and knowledge with respect to medical devices.

FDA notes that even if information received from a health care professional or any other source initially appears to require a report, a report nevertheless is not required if, within the time period for reporting, the manufacturer or importer determines that certain conditions are met (see final § 803.24(d)(3) and paragraph 51 of this preamble).

39. Many comments, including comments from OMB, object to the definition of serious injury in reproposed § 803.3(e) (final § 803.3(h)) on the ground that it would result in the submission of reports of minor injuries. Some of these comments argue that only permanent impairment or damage should be reported; others argue that only unanticipated events should be reported. According to the comments, users accept the fact that some unavoidable risk may be associated with a device given the condition of the patient and the inherent nautre or function of the device. OMB recommends that the phrase "necessitates immediate medical or surgical intervention" in reproposed § 803.3(e)(2) (final § 803.3(h)(3)) be qualified by the phrase "by a health professional." OMB also recommends that FDA not include in the definition of serious injury unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure.

FDA advises that it intended the definition of serious injury in the reproposed rule to include those serious health problems that require prompt action to protect the public health (48 FR 24018). In the reproposal, FDA used the word "immediate" to modify "medical or surgical intervention" and the word "unanticipated" to modify "temporary impairment of a body function or damage to body structure" to eliminate reports of minor injury. The comments have persuaded FDA that the reproposed definition could be interpreted such that manufacturers and importers would be required to submit reports of minor injuries.

FDA has revised the definition of serious injury in reproposed § 803.3(e)(2) (final § 803.3(h)(3)) by providing that the medical or surgical intervention must be undertaken "by a health care professional" to preclude permanent impairment of a body function or permanent damage to body structure or to relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure. FDA made the revision because any medical or surgical intervention that is undertaken by other than a health care professional is likely to be undertaken in response to minor injuries, e.g., cuts or bruises caused by needle burrs on a defective syringe. FDA also has revised the definition by deleting the word "immediate" before the phrase "medical or surgical intervention" because FDA does not believe that an injury is "serious" only if it necessitates immediate, e.g., emergency or same day, medical or surgical intervention. If a cardiac pacemaker malfunctions, explanation may be indicated, but not always immediately. Thus, FDA has combined § 803.3(e) (2), (3), and (4) of the reproposal as § 803.3(h)(3) and has revised final § 803.3(h)(3) to read "necessitates medical or surgical intervention by a health care professional to (i) preclude permanent impairment of a body function or permanent damage to body structure or (ii) relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure."

FDA disagrees with the comments that argue that only permanent impairment or damage need be reported. Unanticipated temporary impairment or damage whose relief necessitates medical or surgical intervention by a health care professional is a significant event. Such impairment or damage cannot be successfully treated by a layperson. Further, if left untreated by a health care professional, unanticipated temporary impairment or damage could well result in permanent impairment or damage.

FDA disagrees with the comments that argue that only unanticipated injuries need be reported. FDA believes that a device-related incident that is life threatening, results in permanent health impairment, or requires medical or surgical intervention by a health care professional to preclude permanent health impairment should be reported to FDA whether or not anticipated. Such an incident is serious and FDA needs to know about it to determine, for example, whether the probable benefits to health from the use of the device outweigh the probable risks of injury from such use, and whether the agency needs to take any action to eliminate or reduce the public's exposure to these risks. The final rule requires a report of an incident involving temporary health impairment only if such impairment is unanticipated. The determination whether a temporary health impairment is unanticipated will be made by the manufacturer or importer. To make clear its intent, FDA has added to final § 803.3(h)(3), the following sentence: "Temporary impairment to a body function or temporary damage to body structure is unanticipated if reference to such impairment or damage is not made in the labeling for the device or, if such reference is made in the labeling for the device, the manufacturer or importer of the device determines that such impairment or damage has occurred or is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device."

40. Several comments argue that "unanticipated temporary impairment" is too vague to provide useful guidance. One of these comments suggests adding to the final rule language from the preamble to the reproposal (48 FR 24018) which stated that electrical shocks, severe lacerations, or broken bones are unanticipated events. Another comment asserts that the discussion in the preamble is inadequate because electrical shocks are not defined as to severity or duration, severe laceration is undefined, and all broken bones are considered of equal seriousness.

FDA believes that the changes to the definition of "serious injury" (final § 803.3(h)), discussed in paragraph 39 of this preamble, make clear the meaning

of "unanticipated temporary impairment." FDA does not believe that specifying in the final rule electrical shocks, severe lacerations, or broken bones will further define "unanticipated temporary impairment," or that these specific events need any definition.

41. One comment suggests that FDA delete reproposed § 803.3(e) (2) and (4) or add to the definition of serious injury the concept of significant medical intervention or significant temporary impairment. According to the comment, many minor injuries are corrected by medical intervention and, although unanticipated, are temporary and insignificant.

FDA disagrees with the suggestion. Under § 803.3(h) of the final rule, a serious injury is one that necessitates medical or surgical intervention by a health care professional to preclude permanent health impairment or to relieve unanticipated temporary health impairment. FDA believes that this and other changes in final § 803.3(h), as discussed in paragraph 39 of this preamble, will eliminate reports of minor injuries. Thus, there is no need to establish whether medical or surgical intervention is "significant" or whether an unanticipated temporary health impairment that requires such intervention is "significant."

42. One comment questions whether FDA intended that all four conditions under reproposed § 803.3(e) (final § 803.3(h)) be satisfied before a report is required or whether it is necessary that only one condition be met. Another comment suggests that FDA make each condition under reproposed § 803.3(e) (final § 803.3(h)) conjunctive rather than disjunctive. Other comments, however, argue that FDA needs to receive reports of an event that meets only one of the conditions.

Under final § 803.3(h), there are only three types of serious injury. If any one of these types occurs, then an injury is "serious" and a report is required. Making all provisions of § 803.3(h) conjunctive would mean that an event would have to be life threatening before a report could be required under the final rule, which would be inconsistent with the intent of Congress in enacting section 519 of the act (see "Statutory Authority and Legislative History" of this preamble) and would prevent FDA from adequately protecting the public from serious health risks that are less than life threatening.

Confidentiality

43. Many comments express concern that the public availability of unverified reports will lead to spurious product liability claims or unjustly damage a manufacturer's reputation and request that FDA add to the final rule a section on the confidentiality of reports. The comments suggest that the reports be considered trade secret or confidential commercial information and, as such, not available for public disclosure under § 20.61 of FDA's regulations governing public information (21 CFR 20.61). The comments also suggest that the name of the manufacturer or importer of the device, any patient or other device user, any health care professional, or any health care institution be deleted from a report before its public disclosure.

FDA has added to the final rule new § 803.9 *Public availability of reports.* FDA is generally required under the Freedom of Information Act (the FOIA) (5 U.S.C. 552) to make publicly available reports received under this final rule. The public availability of such reports is governed by the FOIA and Part 20. As specified in new § 803.9, in accordance with the FOIA and FDA's regulations, before a report is made publicly available, FDA will delete from the report information whose disclosure would constitute a clearly unwarranted invasion of personal privacy (see 5 U.S.C. 552(b)(6); § 20.63) or which constitutes trade secret or confidential commercial or financial information (see 5 U.S.C. 552(b)(4); § 20.61). However, FDA will make available to a patient who requests a report all the information in the report concerning that patient, except for trade secret or confidential commercial or financial information.

FDA notes that a good deal of information in reports of adverse reactions to approved new drugs (see 21 CFR 314.14) and in reports of device problems received under DEN is publicly available (see §§ 20.111 and 20.113). None of the comments* demonstrates that a spurious product liability claim or unjust damage to any manufacturer's reputation has resulted from the public availability of such reports.

44. One comment suggests that reports received under any final rule be kept confidential until after FDA's investigation of the incident has been completed. Another comment suggests that a report be released only if FDA determines that the incident is device related.

Under § 20.64, information submitted to FDA under the final rule may be considered an investigatory record compiled for law enforcement purposes and, therefore, not available for public disclosure until FDA's investigation is complete. FDA will determine on a case-by-case basis whether § 20.64 applies. FDA does not have the authority under the FOIA or Part 20 to withhold a report submitted under the final rule if the agency determines that the event that is the subject of the report is not device related.

45. One comment suggests that to ensure the confidentiality of reports FDA destroy them 1 year after the date of their receipt.

FDA disagrees with the comment. The agency believes that retention of the reports for an indeterminate period will enable the agency to undertake trend analyses and to determine the need for regulations, administrative or judicial enforcement actions, standards, guidelines, or educational programs.

46. One comment suggests that reports be kept confidential if there is ongoing litigation concerning the involvement of the device with a death or serious injury.

Under the FOIA and Part 20, FDA is without authority to withhold publicly available information because of ongoing litigation to which the government is not a party. If the government is a party to the litigation, the information would be withheld from public disclosure under § 20.64 as an investigatory record compiled for law enforcement purposes.

47. One comment suggests that reports submitted in response to a request for additional information under reproposed § 803.24(e) be kept confidential.

FDA lacks authority to categorize all such reports as confidential (see paragraphs 43 and 48 of this preamble). All reports and additional information, whether submitted under § 803.24 (b) or (e) of the final rule, are subject to the same statutes and regulations regarding public disclosure.

48. One comment suggests that before disclosing a report, FDA should provide the manufacturer or importer an opportunity to explain why public disclosure of information submitted in a report is not required for protection of the public health.

The comment's suggestion is inappropriate. Whether information is or is not required for protection of the public health is not relevant to whether the information is exempt from public disclosure under the FOIA and Part 20 (see paragraph 43 of this preamble). Under § 20.45, in situations where the confidentiality of data or information is uncertain and there is a request for public disclosure, FDA will consult with the person who has submitted or divulged the data or information or who would be affected by disclosure before determining whether or not such data or information is available for public disclosure.

49a. Many comments request that FDA add an express disclaimer to each report released, such as "Neither the submission of information by a manufacturer or importer pursuant to this rule, nor public release of such information, constitutes an admission that a device has malfunctioned or establishes the existence of any causal connections between a product and a death or serious injury."

FDA cannot accede to the request. Whether information submitted in a report or subsequently released by FDA constitutes an admission or establishes causation is for litigants to dispute, and the courts to decide, on a case-by-case basis. As explained in paragraph 7 of this preamble, however, FDA does not believe that the submission of the information required by the final rule will be treated by the courts as an admission.

49b. One comment suggests that the final rule recognize that a court order may prohibit release of information to FDA.

If a court order prohibits a manufacturer or importer from submitting certain information to FDA, the agency will respect the order. FDA accordingly does not believe that any provision concerning court orders needs to be included in the final rule.

When a Report Is Required

50. Several comments argue that the reproposal would require the submission of a report upon receipt by the manufacturer of a mere allegation that a death or serious injury had been caused by one of its devices. These comments claim that the legislative history of section 519 of the act does not authorize FDA to require reports of allegations that are unsubstantiated or known to be false. OMB states that requiring reporting of unverified or unsubstantiated allegations that a reportable event has occurred would be unreasonable. OMB recommends that manufacturers and importers be required to review all such "allegations" within 15 working days of initial receipt, but should not be required to report to FDA unless the manufacturer or importer determines that evidence suggests or could reasonably suggest that a device "caused or contributed to a death or serious injury."

FDA agrees that the reproposal would have required the submission of a report upon the receipt by a manufacturer or importer of an allegation that a death or serious injury had been caused by one of its devices. As noted in paragraph 8 of this preamble, however, the requirement to report allegations has been deleted from the final rule. For the reasons discussed in paragraph 38 of this preamble, FDA has provided in new § 803.3(f), which defines the phrase "information that reasonably suggests," that information furnished by a health care professional is information that per se reasonably suggests that a reportable event has occurred.

For the reasons discussed in paragraph 51 of this preamble, FDA does not agree that information about device-related deaths or serious injuries be confirmed before FDA may require that such information be reported to the agency. To carry out its responsibilities under the act, the agency needs to be informed whenever a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury. If the final rule applied only when information reasonably suggested that a device "had" caused or contributed to a death or serious injury, FDA would not learn of instances in which there could have been an association, as well as a causal connection, between the use of a device and a death or serious injury (see paragraph 17 of this preamble). FDA notes that under final § 803.24(d)(3), even if information initially appears to require a report, a report nevertheless is not required if, within the time period for reporting, the manufacturer or importer determining that certain conditions are met (see paragraph 51 of this preamble).

51. Many comments argue that a manufacturer or importer should be required to submit a report only if the manufacturer or importer confirms that a reportable incident is device related. These comments state that manufacturers and importers receive many complaints that upon investigation are determined not to involve the manufacturer's or importer's device. One comment suggests that manufacturers or importers be required to submit unconfirmed reports only if FDA can assist in the acquisition of information to determine whether the incident was device related. Other comments argue that manufacturers or importers should submit such reports regardless of whether the manufacturer or importer believes the incident to be device related.

The legislative history provides that reasonable reporting requirements include reports of defects, adverse reactions, and patient injuries (see the "Statutory Authority and Legislative History" section of this preamble). Nowhere in section 519 of the act or its legislative history is FDA's authority limited to requiring only information about reportable events that have been confirmed by the manufacturer or importer of the device. The legislative history clearly states that the limitations under section 519 of the act should not be construed as restricting FDA's authority to obtain information needed to ensure that the public is protected from potentially hazardous devices.

Where a device may have caused or contributed to a death or serious injury, FDA, as the public health agency responsible for protecting the public from unsafe devices, should make an independent evaluation of the device's role, if any, in the death or serious injury. So long as a reasonable person would conclude that a device may have caused or contributed to a death or serious injury, where there is such a difference of opinion, FDA should review and evaluate the role of the device. Requiring reports of death or serious injury, whether or not confirmed to be device related, is consistent with both the existing requirements (21 CFR 310.301) and recently proposed revisions for reporting adverse reactions associated with new human drugs (47 FR 46622; October 19, 1982).

FDA notes that there are cases in which a device malfunctions and the nature or severity of the malfunction is such that, although the device did not actually cause or contribute to a death or serious injury, the device or another device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. For example, an incubator thermostat malfunctions in such a way that the incubator could cause or contribute to a death or serious injury of a premature baby; however, at the time of the malfunction, the incubator is not in use and, thus, the device does not cause or contribute to a death or serious injury. Under a system of reporting only confirmed device-related deaths and serious injuries, this type of incident would not be reported simply because there would not have been a death or serious injury determined to have been device-related.

When a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its devices has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, the manufacturer or importer may not wait until the malfunction recurs or until a death or serious injury occurs before notifying the agency of the

malfunction. If FDA is to be able to prevent or reduce deaths or serious injuries from devices that malfunction, or is to be able otherwise to minimize the risk to the public health from such devices, the agency needs to receive this information in a timely manner from all manufacturers and importers.

FDA recognizes that a manufacturer or importer may receive information that erroneously attributes a reportable event to one of its devices. For this reason, FDA has revised § 803.24(d) in the final rule to enumerate the circumstances in which a report is not required even though the manufacturer or importer has received or otherwise become aware of information that initially appears to require a report under § 803.24(a). A report respecting a death or serious injury is not required if, within 5 calendar days of initial receipt of the information, the manufacturer or importer determines that a death or serious injury has not occurred (§ 803.24(d)(3)(i)). A report respecting a death, serious injury, or malfunction is not required if, within 5 calendar days of receipt of the information about the death or serious injury or within 15 working days of receipt of information about the malfunction, the manufacturer or importer determines that the information is erroneous in that the device that is the subject of the information was manufactured or imported by another manufacturer or importer (§ 803.24(d)(3)(ii)). In such circumstances, however, FDA strongly encourages the manufacturer or importer to report the event to FDA and, if known, to the manufacturer or importer that actually marketed the device.

A report respecting a malfunction is not required if, within 15 working days of receipt of information about the malfunction, (i) the manufacturer or importer determines that a death or serious injury has not occurred; (ii) the device's labeling sets forth information concerning the potential for death or the type of serious injury that the malfunction may cause or contribute to; (iii) the device's labeling describes the malfunction, and the routine service, repair, or maintenance instructions to correct the malfunction; (iv) the malfunction has occurred or is occurring at or below the frequency and severity stated in the labeling for the device or, if there is not any pertinent statement in the labeling, at or below the frequency and severity that are usual for the device; and (v) the malfunction does not lead the manufacturer or importer to undertake a remedial action involving any device other than the device product in which the malfunction occurred (§ 803.24(d)(3)(iii)).

52. One comment states that isolated reports of adverse occurrences from use of a device may be received by many manufacturers or importers and discarded in good faith as not device related; however, the reports aggregated by FDA may reveal a previously unsuspected device problem. Many comments state that manufacturers or importers receive a lot of complaints that, upon verification, are determined to be the result of user error, a failure to service or maintain the device properly, or use of the device beyond its labeled useful life. According to the comments, the submission of reports in these circumstances will not lead to any public benefit and, therefore, is an unnecessary cost to the manufacturer or importer and FDA. One comment states that user error may indicate improper instructions, inadequate labeling, or the need for an educational program.

FDA agrees that analysis by the agency of information from isolated reports submitted by many manufacturers and importers may result in the discovery of unsuspected device problems. FDA does not agree that reportable events attributable to user error, failure to service or maintain a device, or use of a device beyond its labeled useful life should not be reported. Reportable events determined by the manufacturer or importer to be the result of user error, improper service or maintenance, or improper use may indicate, for example, that the device is misbranded within the meaning of section 502(f) of the act (21 U.S.C. 352(f)) in that its labeling fails to bear adequate directions for use or to comply with § 801.109 of FDA's regulations governing labeling for devices. FDA agrees with the comment that states that reports of events attributable to user error also may indicate the need for an educational program for consumers and professional users.

53. One comment requests clarification as to when a manufacturer or importer has accumulated sufficient information to determine that the information "reasonably suggests" or "alleges" a death or serious injury. Another comment asks how allegations would arise, how a manufacturer or importer would be made aware of them, and how a mere allegation would be reported to FDA.

As noted in paragraph 8 of this preamble, the requirement to submit a report based on an "allegation" has been deleted from the final rule. The phrase "information that reasonably suggests" is defined in new § 803.3(f) of the final rule and discussed in paragraph 38 of this preamble. A manufacturer or importer is required to report whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Revisions in final § 803.24(a) describe more specifically the circumstances in which a report is required: the manufacturer or importer receives or otherwise becomes aware of information in the medical or scientific literature which reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (§ 803.24(a)(2)(i)); or the manufacturer or importer, through its own research, testing, evaluation, servicing, or maintenance of one of its devices, receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices malfunctions and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (§ 803.24(a)(2)(ii)).

54. Many comments suggest that the phrase "or a person alleges and the manufacturer or importer is aware of the allegation" be deleted from any final rule. The comments argue that any reasonable allegation would be included in the phrase "reasonably suggests," and that reporting unreasonable, irresponsible, or unlikely allegations would be an unnecessary expenditure of industry and FDA resources. The comments further argue that reports of allegations will be misleading to the public and unjustly damage a manufacturer's reputation, that disgruntled employees, competitors, or other persons with interests adverse to the manufacturer could trigger the submission of frivolous reports, and that the reproposal would require the submission of information that may be erroneous, vague, based upon idle rumor, or clearly absurd.

FDA has deleted from the final rule the phrase "or a person alleges and the manufacturer or importer is aware of the

allegation" (see paragraph 8 of this preamble), has added new § 803.3(f) (see paragraph 38 of this preamble), and has revised § 803.24(a) (see paragraphs 17, 25, and 53 of this preamble) to define more clearly when a report is required. FDA believes that these revisions, together with the revisions in final § 803.24(d) (see paragraphs 20 and 51 of this preamble), address each of the concerns raised by the comments without compromising FDA's ability to protect the public health.

55. One comment suggests that FDA not require the submission of allegations during litigation where the manufacturer or importer has a reasonable basis to believe that the allegation is not well founded.

Whether an allegation made in the course of litigation is required to be reported depends on whether the allegation reasonably suggests that one of the manufacturer's or importer's marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

56. Several comments argue that a report should be required only if a death or serious injury has occurred and that device malfunctions should not be reported. According to the comments, the reproposal would require that the manufacturer or importer determine whether the malfunction is likely to recur, and if it recurs, whether the device may cause or contribute to a death or serious injury. The comments believe that this standard is too subjective. Other comments strongly support requiring reporting of malfunctions before a death or serious injury has occurred.

As explained in paragraph 51 of this preamble, FDA disagrees that only incidents of death or serious injury should be reported. The purpose of a report is to enable FDA to take action that will eliminate unnecessary risks to health posed by medical devices. Such risks may be identified before a death or serious injury occurs. For example, in 1983 FDA learned of a report of a failure of a weld on the hood of an infant radiant warmer. The hood fell and would have struck the infant if a nurse had not been present and caught the hood. Similarly, in 1982 FDA learned of another instance in which a defect in an infusion pump in which a valve motor malfunction resulted in the occasional failure of the device to medicate the patient. As a result of the malfunction, the pump could have withdrawn the patient's own blood and reinfused him or her with it. The device was subsequently recalled.

The reproposed rule did not, and the final rule does not, require a manufacturer or importer to determine whether a malfunction is likely to recur. As explained in paragraph 57 of this preamble, FDA presumes that if a device malfunctions, the malfunction could recur. Thus, reproposed § 803.24(a) (final § 803.24(a)) requires that if information reasonably suggests that a marketed device has malfunctioned, the manufacturer or importer determine whether the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. In this context, the word "likely" means more probable than not and provides adequate guidance to manufacturers and importers.

FDA notes that if the information is received from a health care professional, the information reasonably suggests that a reportable malfunction has occurred (see § 803.3(f) of the final rule and paragraph 38 of this preamble), and the manufacturer or importer does not determine whether the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

57. Several comments suggest that to eliminate reports of routine service and maintenance, a device malfunction should not be required to be reported if such malfunction (i) has not recurred and is not likely to recur; (ii) did not occur during the performance of an intended therapeutic or diagnostic use of the device; or (iii) was corrected or is correctable by routine service or maintenance.

FDA agrees in part with the comments. FDA believes that agency resources allocated to the implementation of this final rule should not be spent monitoring device problems that can be corrected by routine service or maintenance. As discussed in paragraph 20 of this preamble, new § 803.24(d)(3)(iii) has been added to provide that a report is not required under certain specified circumstances. FDA believes that these changes in the final rule will eliminate reports of routine device service, repair, and maintenance.

FDA disagrees with the comment suggesting that the malfunction must recur or be likely to recur before the manufacturer or importer is required to report. FDA presumes that if a device malfunctions, another device marketed by the manufacturer or importer also could malfunction because, generally, all devices of the same type are produced under the same manufacturing practices. FDA also disagrees with the comment that the malfunction must occur during the performance of an intended therapeutic or diagnostic use of the device. A reportable malfunction under § 803.24(a) (1) or (2) of the final rule could occur when a device is not in use. FDA needs to know about such malfunctions so that it can take action to reduce or eliminate the risk of death or serious injury should the malfunction recur when the device is in use (see paragraphs 51 and 56 of this preamble).

58. One comment argues that a malfunction should not be required to be reported if it results from improper or inadequate maintenance by the user, unauthorized modification, or misuse or negligent handling.

FDA disagrees with the comment. For the reasons explained in paragraph 52 of this preamble, FDA does not believe the requirement to submit a report under final § 803.24(a) (1)(ii) or (2) should be determined by the manufacturer's or importer's assessment whether the malfunction is due to user error or misuse.

59. One comment asserts that a death or serious injury should not be required to be reported unless it is associated with or related to a device malfunction.

FDA disagrees with the comment. A device that performs to its specifications or otherwise performs as intended does not "malfunction" as defined in the final rule. However, because of flaws in its labeling or because of user error (see paragraph 52 of this preamble), such a device could cause or contribute to a death or serious injury. Therefore, FDA concludes that reporting should not be limited in the manner suggested by the comment.

60. One comment requests guidance about who determines the severity of a malfunction and whether it would generate a serious injury.

Under final § 803.24(a), the manufacturer or importer determines whether information "reasonably suggests" (see § 803.3(f) of the final rule and paragraph 38 of this preamble) that a malfunction has occurred and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. If a health care professional informs a manufacturer or importer that one of its marketed devices has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be

likely to cause or contribute to a death or serious injury if the malfunction were to recur, a reportable malfunction has occurred. In such circumstance, the manufacturer or importer does not determine the severity of the malfunction or whether the malfunction would generate a serious injury. In all other circumstances, the manufacturer or importer is required to make a determination with respect to the likelihood (see paragraph 56 of this preamble) that, as a result of a recurrence of the malfunction, the device or any other device marketed by the manufacturer or importer will cause or contribute to a death a serious injury. To the extent that this determination requires an assessment of the severity of the malfunction, the manufacturer or importer necessarily would have to make such assessment.

61. Three comments suggest that the phrase "or contributed to" in reproposed § 803.24(a) be eliminated because it is vague. The comments claim that the phrase will cause manufacturers or importers to submit a report for every service call or even when the device played only a minor role in the reportable event. One comment suggests the phrase "likely to cause or contribute to" be replace by "likely to be a determinant" in the case of a malfunction.

FDA disagrees in part with the comments. If a manufacturer or importer receives information that reasonably suggests that one of its devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, a report is required. In this context, the phrase "contribute to" means to play a part in the death or serious injury. As defined, FDA believes that the phrase "contribute to" is not vague, provides adequate guidance to manufacturers and importers concerning a reportable event, and will not result in the submissions of reports of every service call. Deaths or serious injuries in which a device played a part, however, are reportable events under the final rule.

FDA disagrees that the phrase "likely to cause or contribute to" should be replaced by the phrase "likely to be a determinant" in the case of a malfunction. The latter phrase would limit reportable events to those in which a malfunction likely was a cofactor, would be inconsistent with the legislative history of the amendments in general and section 519 in particular, and would preclude FDA from carrying out its statutory mandate to evaluate the risk, if any, associated with potentially hazardous devices.

Time Requirements

62. Several comments argue that the 15-working-day time period is too long. The comments recommend shortening the time period for reporting a death or serious injury. OMB notes that 15 working days is 3 weeks and suggests that FDA reassess whether device-related deaths should be reported earlier than 3 weeks after they occur. Several comments state that the time periods used in the November 1980 proposal (45 FR 76183), 72 hours for reports by telephone of death and 7 working days for written reports of injury, would be reasonable because under the reproposal FDA would not require much information in the telephone or written report.

FDA agrees that to enable timely involvement by the agency, FDA needs to receive reports of death and serious injury sooner than 15 working days after the manufacturer or importer receives or otherwise becomes aware of the information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury. As discussed in paragraph 39 of this preamble, FDA has revised the definition of "serious injury" in final § 803.3(h) to exclude minor injuries. For this reason, FDA believes that serious injuries and deaths should be subject to the same reporting requirements. Accordingly, FDA has revised final § 803.24(b) to require a telephone report as soon as possible but no later than within 5 calendar days of initial receipt, by the manufacturer or importer, of information that reasonably suggests that a device-related death or serious injury has occurred.

FDA recognizes that the 5-calendar-day time period for telephone reports of device-related deaths and serious injuries is shorter than the 15-working-day time period proposed for reports of any fatal or life-threatening adverse drug experience not mentioned in the product labeling (46 FR 46622; October 19, 1982). The shorter time period is warranted because the relationship between a device and a death or serious injury generally is easier to discern than is the relationship between a death or serious injury and a drug product; in the latter circumstance, but not the former, factors such a clinically significant drug/drug interactions or sensitivity reactions may make it difficult to determine whether there is any link between the product and the death or serious injury. For these reasons, FDA believes that the 5-calendar-day time period for providing FDA, by telephone, information about device-related deaths and serious injuries is reasonable.

Under final § 803.24(b)(1), the manufacturer or importer is also required to submit a followup written report within 15 working days of initial receipt of the information by the manufacturer or importer requiring a telephone report.

FDA recognizes that the 5-day time period for telephone reports of deaths and the 15-day time period for written reports of serious injuries are longer than those specified in the November 1980 proposal. FDA emphasizes, however, that under final § 803.24(b) telephone reports of device-related serious injuries are required to be submitted as soon as possible, but no later than within 5 calendar days of initial receipt of the information; under the proposal, information about such injuries would not have been required until 7 working days after receipt of the information. The change from 3 to 5 calendar days for reporting device-related deaths gives manufacturers or importers a reasonable time to gather the information specified in final § 803.24(c) and to determine under final § 803.24(d)(3) (i) or (ii) that a report is not required.

63. Many comments state that a manufacturer or importer should be deemed to be in compliance with any final rule based upon reproposed § 803.24(b) if the manufacturer or importer transmits the written report within the specified 15-day time period. Requiring receipt by FDA within the 15-day time period would discriminate against manufacturers and importers located on, for instance, the west coast, because transmittal time is longer for them than for manufacturers and importers located close to FDA in Maryland, where reproposed § 803.33 would require reports to be submitted.

FDA agrees with the comments and has revised final § 803.24(b) to require that the written report be submitted to FDA, i.e., postmarked or otherwise dated upon dispatch, to FDA within 15 working days of initial receipt of the information by the manufacturer or importer.

64. Several comments request clarification of whether the 15-working-day time period applies to the written report required under reproposed § 803.24(a) and to any additional information required by FDA under § 803.24(e).

The 15-working-day time period in final § 803.24(b) applies only to the written report. As FDA stated in the

preamble to the reproposal (48 FR 24020), if FDA requires a manufacturer or importer to submit additional information, FDA will state in the request the date by which the manufacturer or importer is required to submit the information. Final § 803.24(e) has been revised accordingly.

65. One comment requests clarification as to whether the 15-working-day time period applies if a telephone report is made.

The telephone report to which the comment refers was an option under reproposed § 803.24(b). If such a report was made, a confirming written report would have been required to be received by FDA within 15 working days of initial receipt of the information. As explained in paragraph 62 of this preamble, under final § 803.24(b)(1), a telephone report within 5 calendar days is required in certain circumstances. Within 15 working days of initial receipt of the information, a written report is required to be submitted to FDA. Thus, the 15-working-day time period still applies when a telephone report is made.

66. Several comments suggest that the 15-working-day time period in reproposed § 803.24(b) be extended to at least 30 days. The comments argue that such a time period would allow importers time to consult with the foreign manufacturers before submitting reports and would allow all manufacturers time to obtain the information required in the report by reproposed § 803.24(c). Other comments suggest that FDA permit manufacturers or importers to request extensions of time, if necessary, to obtain the required information.

FDA disagrees with the comments. FDA believes that it would be inconsistent with section 519 of the act and its legislative history and with FDA's responsibility to protect the public health for the agency to permit manufacturers or importers to wait 30 working days—a month and a half—before reporting to FDA that one of its marketed devices may have caused or contributed to a death or serious injury. In response to comments arguing that the 15-working-day time period in the reproposal would be too long, after reconsidering the appropriateness of that time period, especially in light of the minimal amount of information that is required to be included in the report, and as discussed in paragraph 62 of this preamble, FDA has concluded that it is reasonable to require the prompt submission of information that reasonably suggests that a device may have caused or contributed to a death or serious injury. Therefore, the final rule requires a manufacturer or importer to provide such information to the agency as soon as possible, but no later than within 5 calendar days of its initial receipt (see paragraph 62 of this preamble). FDA believes that manufacturers and importers should be able to assemble, process, and submit the information required in the report within the allotted time period. The final rule does not require that the manufacturer or importer provide in the report under final § 803.24(c) any information not in its possession (see paragraphs 12, 69, and 81 of this preamble). Therefore, an extension of time should not be necessary.

67. Several comments suggest that the phrase "essential information" in reproposed § 803.24(b) be eliminated because it is vague and that the phrase "the information in § 803.24(c)" be used.

FDA agrees with the comment and has revised final § 803.24(b) (1) and (2) accordingly.

68. Several comments argue that FDA should require only one submission concerning a reportable event, and that this information should be required to be submitted only after the manufacturer or importer has completed its investigation of the event.

FDA disagrees with the comment. Only a minimal amount of information about a reportable event is required in the report under final § 803.24(c). If information reasonably suggests that a marketed device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, FDA needs to be promptly advised to evaluate the possible risk to health posed by the device and to take whatever steps are necessary to reduce or eliminate the public's exposure to this risk. In some cases, FDA may conclude that the information provided in the report is adequate for FDA to take whatever additional action is necessary to protect the public health. In other cases, FDA may conclude that further action by FDA or the manufacturer or importer is not necessary. In still other cases, FDA may determine that to protect the public health the agency needs information in addition to that provided in the report. The submission of a report to FDA soon after the reportable event has occurred will enable the agency to initiate its own investigation, if deemed necessary, or to assist the manufacturer or importer in obtaining information from third parties. Thus, whether FDA will need information about a reportable event in addition to that provided under final § 803.24(c) will depend on the facts and circumstances of each matter. In any case, for the reasons discussed in paragraphs 50, 51, 53, and 57 of this preamble, FDA has concluded that it should not delay its review or any investigation of a reportable event until after a manufacturer or importer has completed its investigation of the same event.

69. One comment argues that FDA may require only the submission of information in the possession of the manufacturer or importer and that FDA does not have authority to require that a manufacturer or importer collect the additional information.

FDA disagrees with the comment. Section 519(a) of the act authorizes FDA to require manufacturers and importers to maintain such records, make such reports, and provide such imformation to FDA as may reasonably be necessary to assure that devices are not adulterated or misbranded and are otherwise safe and effective for human use. Nowhere in section 519 of the act or its legislative history is there any indication that Congress intended to limit FDA's authority in the manner claimed by the comment. Moreover, section 519(a)(5) of the act provides that the agency may not require the manufacturer or importer of a class I device to maintain for such a device records respecting information not in its possession or to submit with respect to such device information not in its possession, unless such report or information is necessary to determine if the device should be reclassified or is adulterated or misbranded. Thus, by negative implication, as well as its explicit language, section 519(a) of the act authorizes FDA to require the collection and submission of information not in the possession of manufacturer or importer, albeit with certain limitations on that authority insofar as class I devices are concerned.

FDA advises, however, that nothing in the final rule requires a manufacturer or importer to submit to FDA information not in the possession of the manufacturer or importer (see § 803.24 (c) and (e) of the final rule and paragraphs 12, 66, and 81 of this preamble). In any event, under § 820.162 of the CGMP regulations, after a device has been released for distribution, a manufacturer already is required to investigate any failure of a device or any of its components to meet its performance specifications and to establish and maintain a writtern record of the investigation, including the manufacturer's conclusions and followup. Under § 820.198, a

manufacturer already is required to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications and any complaint pertaining to injury, death, or any hazard to safety and to maintain a written record of the investigation. FDA believes that the information listed in § 803.24(e) which may be required by FDA is information that would be included in the written record of an adequate investigation under § 820.162 or § 820.198. As explained in paragraph 12 of this preamble, importers are not required to review, evaluate, or investigate a reportable event.

70. Many comments argue that reproposed § 803.24(c) should be revised to require in the report only information "to the extent known" by the manufacturer or importer when the report is due. Manufacturers and importers claim that this qualifying phrase is needed because the information necessary to evaluate a complaint often is in the hands of a third party, e.g., a physician or health care institution, that is reluctant to allow a manufacturer or importer access to the information until the third party has completed its own independent investigation, if at all.

FDA disagrees with the comments. FDA believes that the information listed under § 803.24(c) (1), (2), (3), (5), and (6) will be known by the manufacturer or importer and is critical to the agency's ability to initiate any investigation that needs to be conducted. FDA notes that, under the reproposed and final rule, the information listed in § 803.24(c)(4) is required to be submitted only "to the extent known." On its own initiative, FDA has added the following language to final § 803.24(c)(1): "and, to the extent known, the model, catalog, or other identification number or code of the device, and the manufacturing lot or serial number of the device."

71. Many comments argue that manufacturers and importers should be allowed to submit additional information concerning a reportable event at any time, regardless of whether the manufacturer or importer states in the report that additional information will be submitted.

FDA agrees with the comments and advises that it will accept, at any time, additional information submitted by a manufacturer or importer. Unless a manufacturer or importer notifies FDA in the report under final § 803.24(c) that it intends to submit additional information, however, FDA will presume that such information will not be submitted.

72. One comment suggests that reproposed § 803.24(c)(6) be deleted, arguing that a manufacturer or importer always will submit additional information to FDA because the report has placed the matter on public record. Another comment suggests that reproposed § 803.24(c)(6) be modified to state whether the report is complete, not whether additional information will be submitted. Still another comment objects to FDA requesting that a manufacturer or importer specify when the additional information will be submitted, arguing that this information often must be obtained from a third party. According to the comment, FDA should at most request an "expected [estimated] time frame."

Section 803.24(c)(6) of the reproposal provided that a medical device report was to "[s]tate, if the manufacturer or importer intends to submit additional information, when such information will be submitted." According to the preamble, however, § 803.24(c)(6) provided that a medical device report was to "state whether the manufacturer or importer intends to submit additional information, and, if so, when such information will be submitted" (48 FR 24019). The language in the preamble accurately reflected FDA's intent, and the comments responded to that language. Final § 803.24(c)(6) has been modified to be consistent with FDA's intent, as expressed in the preamble to the reproposal.

The agency does not believe that every manufacturer and importer always will submit, on a voluntary basis, additional information. The reason for requiring a statement of a manufacturer's or importer's intent to submit additional information is to assist FDA with the utilization of its resources to investigate reportable events. To reduce the reporting burden on the medical device indusrty, FDA is providing that manufacturers and importers may submit in the report under final § 803.24(c) a minimal amount of information about a reportable event. In certain instances, however, the protection of the public health will require that FDA initiate its own investigation of an event and may require that the agency obtain more information from the manufacturer or importer about the event. By providing that a manufacturer or importer state in the report under final § 803.24(c) whether it intends to submit additional information and, if so, to declare when such additional information will be submitted, FDA will be better able to determine whether its investigation can proceed on the basis of the report, and, where the manufacturer or importer states that additional information will be submitted, and when, whether it may defer such investigation pending receipt of the additional information. Revising § 803.24(c)(6) to require a statement from a manufacturer or importer about whether the report is complete would not provide FDA with the information it needs to allocate its resources properly.

FDA does not agree with the comment suggesting that FDA should at most request an "expected time frame" for the submission of additional information. Given the seriousness of the events required to be reported, FDA accepts an estimated time frame which the manufacturer or importer could change without notifying FDA.

73. On its own initiative, FDA has added to the final rule new § 803.24(c)(7), which requires that the manufacturer or importer state in the report FDA whether the reported event is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device, if such information is available. FDA needs this information to assist the agency in determining the significance of a reported event and whether to begin its own investigation.

On its own initiative, FDA also is adding to the final rule new § 803.24(e)(7), which provides that, if requested by FDA, the manufacturer or importer shall submit to FDA (1) all the information on the basis of which the manufacturer or importer determined that the reported event is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device; and (2) any evaluation or analysis available to or used by the manufacturer or importer in making this determination. In the final rule, FDA has redesignated reproposed § 803.24(e) (7) through (10) as § 803.24(e) (8) through (11).

74. One comment argues that requiring a manufacturer or importer to submit to FDA any of the evaluations specified in reproposed § 803.24(e) (final § 803.24(e)) would violate a manufacturer's or importer's constitutional rights because such information may be self-incriminating.

These requirements do not violate any privilege against compelled self-incrimination. That privilege attaches only to a person in his or her individual capacity, and is available neither to a collective entity, such as a business enterprise, nor to an individual acting in

a representative capacity on behalf of a collective entity. *California Bankers Ass'n* v. *Schultz*, 416 U.S. 21, 55 (1974); *Bellis* v. *United States*, 417 U.S. 85 (1974); *United States* v. *Kordel*, 397 U.S. 1, 8 (1970); *Curcio* v. *United States*, 354 U.S. 118, 122 (1957); *United States* v. *White*, 322 U.S. 694, 699 (1944); *Wilson* v. *United States*, 221 U.S. 361, 382–384 (1911); *Hale* v. *Henkel*, 201 U.S. 43, 74–75 (1906). Even for individuals, the privilege against compelled self-incrimination is inapplicable where a reporting requirement is applied to an "essentially noncriminal and regulatory area of inquiry," where self-reporting is the only feasible means of securing the required information, and where the requirement is not applied to a "highly selective group inherently suspect of criminal activities" in an "area permeated with criminal statutes." *California* v. *Byers*, 402 U.S. 424, 430 (1971); see *Marchetti* v. *United States*, 390 U.S. 39 (1968); *Albertson* v. *SACB*, 382 U.S. 70, 79 (1965); *Shapiro* v. *United States*, 335 U.S. 1 (1948). FDA concludes that each of these conditions is met here and therefore that the privilege against self-incrimination does not apply to individuals subject to the final rule.

75. One comment suggests that reproposed § 803.24(e) be revised to avoid duplication with any recordkeeping requirement under Part 820.

FDA does not believe that any provision of the final rule duplicates any provision of Part 820. The rule merely requires that in the case of a reportable event, some or all of the information required to be maintained under Part 820 be submitted to FDA.

76. Many comments argue that any additional information required under reproposed § 803.24(e) should be limited to information to the extent known by the manufacturer or importer. The comments claim that generally, the information needed to complete a report is in the possession of a third party, e.g., health care provider, and assert that the third party may be unwilling to allow the manufacturer or importer access to the information.

To the extent that the information listed under § 803.24(e) is not in the possession of the manufacturer or importer, and is not required to be obtained under §§ 820.162 and 820.198 of the CGMP regulations, the information is only required if available (§ 803.24(e)(4), (5), (6), and (10)). FDA acknowledges that a complete description of the reportable event may be unavailable to the manufacturer or importer. Therefore, FDA has revised § 803.24(e)(3) to provide that if a complete description of the reportable event is unavailable, the manufacturer or importer shall state the reason for its unavailability.

77. Many comments on reproposed § 803.24(e) argue that a request for additional information should be in writing and should state the basis for FDA's conclusion that such information is needed to protect the public health.

FDA agrees in part with the comments. In some cases, FDA may conduct an on-site inspection in response to information received about a reportable event. In such cases, section 704(e) of the act and final § 803.31 (c) and (d) require the manufacturer or importer to permit any authorized FDA employee at all reasonable times to have access to and to copy and verify records of reportable events. FDA agrees, however, that a request for additional information under final § 803.24(e) should be in writing and should state the reason or purpose such information is being required. The agency has revised § 803.24(e) to provide that any request for additional information under that section will be in writing, will state the reason or purpose for which the information is being requested, and will specify a due date for the submission of the information.

78. Several comments suggest that FDA include in any final rule criteria specifying when FDA will require the submission of additional information.

FDA will review each report submitted under final §803.24(b) and determine on a case-by-case basis whether the protection of the public health requires additional information. FDA believes that the agency needs to acquire some experience under the final rule before the agency can determine whether it is feasible to identify criteria for when additional information will be required under § 803.24(e). At this time, therefore, FDA is rejecting the suggestion.

79. One comment argues that FDA should set a time period after which it will not require additional information under reproposed § 803.24(e). The comments suggests 2 years, which is the retention period for records specified for importers in reproposed § 803.31(b).

FDA disagrees with the comment. Under final § 803.31(d), a manufacturer is required to retain copies of information received concerning a reportable event for a period of 2 years from the date that a report or additional information is submitted to FDA under § 803.24 (b) or (e), or for a period of time equivalent to the design and expected life of the device, whichever is greater (see paragraph 90 of this preamble). For the reasons discussed in paragraph 90 of this preamble, FDA reproposed in § 803.31(b) and is establishing in final § 803.31(b) a 2-year record retention requirement for importers. FDA believes, however, that the agency could reasonably require, at any time, whatever additional information the manufacturer or importer has retained.

80. One comment argues that a manufacturer or importer should have at least 30 days after receiving a request for additional information to submit it.

FDA has revised § 803.24(e) in the final rule to provide that an FDA request for additional information will specify a time period for the submission of such information. This time period will depend on a number of factors, including FDA's evaluation/assessment of the risk to health posed by the device. Therefore, FDA is not specifying in the final rule any preset time period within which manufacturers or importers are required to submit additional information.

81. One comment states that the phrase "whether a death or serious injury has occurred" should be deleted from proposed § 803.24(e)(3) because the information has been submitted under § 803.24(c)(4).

FDA disagrees with the comment. The report submitted under § 803.24(c)(4) is required to include only that information known by the manufacturer or importer at the time the report is submitted. FDA recognizes that when a manufacturer or importer submits its report under final § 803.24(b), the manufacturer or importer may not know whether a death or serious injury has, in fact, occurred. For this reason, final § 803.24(c)(4) requires that the manufacturer or importer describe in the report a reportable event "to the extent known" at that time. Under such circumstances, FDA expects that the additional information that the agency may subsequently require under § 803.24(e)(3) will be more complete and will likely confirm whether a death or serious injury has occurred. This is so because the manufacturer will have had more time to investigate the event in accordance with Part 820 and the importer, although not subject to Part 820 or required under the final rule to investigate the event, will have had more time to conduct a voluntary investigation of the event or obtain more information on the matter from the foreign manufacturer.

Content of a Report

82. Several comments on reproposed § 803.24(e)(5) state that the identity of an individual providing the information to the manufacturer or importer should not be routinely required by FDA.

FDA disagrees with the comment. In some cases, FDA may determine that it

should immediately begin an independent investigation of a reportable event. FDA will need to know the identity of the individual providing the information to the manufacturer or importer to begin such an investigation in a timely manner.

FDA recognizes that under section 519(a)(4) of the act, a rule promulgated under section 519 of the act may not mandate that the identity of any patient be disclosed in records, reports, or information submitted to the agency unless the identification is required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under the act. Given the scope of the final rule, FDA believes that disclosure of the identity of a patient providing information about a reportable event to a manufacturer or importer will be required to enable the agency to determine the safety or effectiveness of the device or to verify a record, report, or other information submitted under the rule. In most cases, however, FDA expects that the person providing the information to the manufacturer or importer will be a person other than a patient.

83. One comment claims that an evaluation may be publicly available and used as an admission against interest in a product liability proceeding.

The public availability of information submitted to FDA under the final rule is discussed in paragraphs 43 through 49 of this preamble. Whether an evaluation constitutes an admission against interest is for the courts to decide on a case-by-case basis (see paragraphs 7 and 49a. of this preamble). In any event, FDA needs the evaluations specified in final § 803.24(e) to carry out its statutory mandate to protect the public health.

84. Many comments urge that FDA revise reproposed § 803.24(e) (4), (5), and (6) to require the submission of an evaluation of a reportable event only if the evaluation is prepared for or used by the manufacturer of the device. One comment argues that it is unreasonable to require a manufacturer to submit unsubstantiated evaluations prepared by a third party regarding the manufacturer's device and submitted to or otherwise obtained by the manufacturer. Another comment suggested that after all information about a reportable event is collected, FDA should make its own determination as to whether the event is device related; FDA should not require the manufacturer to make such a determination.

FDA disagrees in part and agrees in part with the comments. Under §§ 820.162, 820.198, and 820.180 of the CGMP regulations, a manufacturer is required to maintain records of the evaluations referred to in the comments; under section 704(e) of the act, every person required under section 519 of the act to maintain records and every person who is in charge or custody of such records shall, upon request of any authorized FDA employee, permit such employee at all reasonable times to have access to, and to copy and verify, such reports. Final § 803.24(e) merely requires the manufacturer to submit evaluations to FDA rather than to have FDA go to the manufacturing facility to obtain it, and therefore is reasonable.

FDA agrees that it should make its own determination as to whether the reported event is device related. In making its determination, FDA will take into account evaluations prepared for or used by the manufacturer, or prepared by a third party and submitted to or otherwise obtained by the manufacturer. None of these evaluations is required by the final rule; each of them already is required to be made or maintained under §§ 820.162, 820.198, and 820.180, and each of them is required to be submitted to FDA under final § 803.24(e).

85. Several comments request clarification of the term "attributable" in reproposed § 803.24(e) (6) and (7) (final § 803.24(e) (6) and (8)).

FDA advises that the phrase "whether the event described in the medical device report is or is not attributable to the device" means an assessment of whether (1) the device caused or contributed to a death or serious injury or (2) as a result of a recurrence of a malfunction, the device or any other device marketed by the manufacturer or importer is likely to cause a death or serious injury.

86. Many comments argue that FDA should not require that manufacturers submit the information listed in reproposed § 803.24(e) (7) through (10) (final § 803.24(e) (8) through (11)) and, therefore, that these paragraphs should be deleted from any final rule. The comments state that manufacturers and importers do not make recall decisions for every complaint received. According to the comments, FDA should require that the agency be notified only if a manufacturer or importer has conducted a voluntary recall, and already has collected, pursuant to Part 7, the information listed in reproposed § 803.24(e) (7) through (10).

FDA disagrees with the comments. The final rule does not require a manufacturer or importer to make a recall decision for any complaint received. Under §§ 820.162 and 820.198 of the CGMP regulations, however, a manufacturer is required to make such a decision. Submission of the information specified in final § 803.24(e) (8) through (11) will be necessary, and will be required, whenever FDA determines that the protection of the public health demands that the agency conduct its own investigation of the reported event. Whether FDA will invoke these or any other provisions of final § 803.24(e) will depend on the facts and circumstances surrounding the event.

Under Part 7, reports of recalls are not required to be submitted to FDA, but rather are requested to be submitted voluntarily. In any event, information about recalls initiated in response to reportable events is necessary to enable FDA to take action to protect the public health and for the reasons discussed in paragraphs 5 and 68 of this preamble, FDA may not defer action, including investigation, with respect to every reportable event until after the manufacturer or importer has conducted a recall. FDA notes that if a remedial action is undertaken in response to information that is required to be reported under this rule, and such remedial action includes a significant change or modification to the device, a premarket notification may be required under 21 CFR 807.81.

87. Several comments state that reproposed § 803.24(e) (7) through (10) (final § 803.24(e) (8) through (11)) would require the submission of trade secret or confidential commercial information not generally available to FDA, and argue that such information can be required only for restricted and critical devices. One comment states that information required under reproposed § 803.24(e)(9) (final § 803.24(e)(10)) constitutes sales data, and argues that FDA does not have authority to require such data under section 704(a) of the act (21 U.S.C. 374(a)).

FDA disagrees with the comments, and directs attention to section 704(e) of the act. FDA acknowledges that the second sentence of section 704(a) of the act limits the agency's authority to examine, during an inspection, records relating to other than restricted devices. However, section 704(e) of the act provides that every person required to maintain records under section 519 of the act, and every person who is in charge or custody of such records, shall permit FDA at all reasonable times to have access to and to copy and verify such records. Section 704(e) of the act does not limit in any way the types of device records maintained under section 519 and 520(g) of the act that FDA may inspect. Moreover, nothing in section 519 of the act or its legislative history

precludes FDA from requiring the submission of trade secret or confidential commercial information. In addition, sections 301(j) and 520(c) of the act (21 U.S.C. 331(j) and 360j(c)), by explicitly protecting from public disclosure trade secret or confidential commercial information obtained under the authority of section 519, are evidence that Congress expected FDA to obtain such information under section 519.

88. One comment argues that reproposed § 803.24(e)(10) (final § 803.24(e)(11)) should be limited to information about the distribution of the affected lot or batch.

The extent to which FDA will require distribution information will be determined on a case-by-case basis. Any such request will be limited to that information necessary to protect the public health. FDA does not believe that a change in the language of the final rule is necessary.

Complaint Files

89. One comment suggests that a complaint file requirement for importers is unnecessary because all reports and additional information will be submitted to FDA.

FDA disagrees with the comment. The complaint file requirement is necessary to enable FDA to verify the accuracy of any report or additional information submitted to the agency under the final rule. The requirement also is necessary to enable FDA to determine whether, based on the information required to be maintained in the complaint file, an importer is reporting when it receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Absent the complaint file requirement, FDA could not be assured that device importers had fully complied with the requirements of the final rule.

90. One comment argues that the retention period for complaint files should be the same for manufacturers and importers, i.e., for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release by the manufacturer or importer for commercial distribution.

FDA disagrees with the comment. The record retention period should begin on the date of the submission to FDA of information about the reportable event. If FDA adopted the record retention period recommended by the comment, and, e.g., a reportable event occurred 3 years after the date of release for commercial distribution and within 10 days of the end of the expected life of the device, the manufacturer or importer could dispose of the records concerning the event immediately upon submission of a medical device written report under final § 803.24(b).

Final § 803.31(d) provides that a manufacturer is to retain copies of records of any information, including any written or oral communication, received by the manufacturer concerning a death, serious injury, or device malfunction that requires a report under § 803.24. The manufacturer also is required to retain a copy of any report submitted to FDA under § 803.24(b) and any additional information submitted to FDA under § 803.24(e). The manufacturer is to retain the records referred to in § 803.31(d) for a period of 2 years from the date that the report or additional information is submitted to FDA under § 803.24 (b) or (e) or for a period of time equivalent to the design and expected life of the device, whichever is greater. The manufacturer may maintain as part of its complaint file under § 820.198 the records referred to in this paragraph.

FDA believes that, unlike device manufacturers, importers generally do not maintain scientific or engineering staffs and, therefore, may be unable to determine the period of time equivalent to the design and expected life of the device. Therefore, FDA selected for importers a time period that the agency determined to be reasonable. The 2-year record retention period specified in final § 803.31(b) begins on the date that an importer submits to FDA under § 803.24 (b) or (e) a report or additional information about a reportable event and is the minimal period that a manufacturer is required to retain this type of information under new § 803.31(d).

91. One comment suggests that a manufacturer that also is an importer be permitted to maintain all its complaint files at one location.

FDA agrees with the comment. Final § 803.31(c) provides that an importer that also is a manufacturer may maintain the file at the same location as the manufacturer maintains its records under §§ 820.180 and 820.198.

Exemptions From Reporting

92. One comment suggests that FDA include in any final rule a provision noting a possible exemption under section 513(d)(2)(A) of the act (21 U.S.C. 360b(d)(2)(A)) from a requirement of section 519 of the act upon the recommendation of an FDA advisory committee. Two comments suggest that any final rule include a provision for manufacturers or importers to petition for an exemption from reporting in certain situations not already exempted, rather than to use the citizen petition provisions under Part 10.

FDA disagrees with the comments. There is no need to include in the final rule a provision that duplicates section 513(d)(2)(A) of the act or § 10.30. Section 513(d)(2)(A) speaks for itself, and § 10.30 is adequate for the purpose referred to in the comments. FDA notes that under § 803.24(d), FDA may notify a manufacturer or importer that reports of a particular type of event are no longer required.

93. One comment contends that FDA is required to exempt class I devices under section 519 of the act.

FDA disagrees with the comment. Under section 519 of the act, FDA is prohibited from requiring a manufacturer, importer, or distributor of a class I device to maintain for such a device records respecting information not in its possession or to submit reports of information not in its possession, or to submit reports on a periodic basis, unless such reports are necessary to determine if the device should be reclassified or is adulterated or misbranded. Nothing in section 519 of the act or its legislative history bars FDA from applying to manufacturers and importers of class I devices any of the provisions of the final rule. None of those provisions requires such a manufacturer or importer to maintain for its class I devices records respecting information not in its possession or to submit reports of information not in its possession, or to submit reports on a periodic basis.

94. Several comments argue that the reporting requirements in the reproposed rule are broader than the reporting requirements in several current FDA regulations (21 CFR 600.14, 606.170, 640.73, 812.150, 813.153, 1002.20, and 1003.10), which are cited in reproposed § 803.36(a) (1), (2), and (3). The comments contend that unless FDA has found that reporting under those regulations is inadequate, devices subject to those regulations should not be subject to any final medical device reporting rule.

The final rule applies to all manufacturers and importers of marketed devices other than general purpose articles. FDA has decided not to retain in the final rule the exemptions that were included in reproposed § 803.36(a) (1), (2), and (3).

FDA advises that §§ 606.170 and 640.73 do not apply to manufacturers or importers of medical devices. For this reason, the final rule does not duplicate either § 606.170 or § 640.73, and reproposed § 803.36(a)(1) insofar as it referred to §§ 606.170 and 640.73 is unnecessary. Because the final rule applies only to marketed devices, reproposed § 803.36(a)(3), which applied to investigational devices, also is unnecessary.

FDA needs a uniform reporting system for all marketed medical devices which captures, in a timely fashion, information about reportable events under the final rule. Accordingly, FDA is revising §§ 600.14, 1002.20, and 1003.10 to conform them to the final rule by providing that whenever a manufacturer or importer is required to report to FDA (1) under one of these sections and (2) under the final rule, the manufacturer is required to report only under the final rule. By establishing a uniform reporting system, FDA ensures that it will receive, in a prompt and efficient manner, the information it needs to protect the public from hazardous and potentially hazardous devices.

FDA finds for good cause that notice and public procedure are unnecessary in accordance with the Administrative Procedure Act (5 U.S.C. 553(b)(B)), considering the previous opportunities for comment afforded in the rulemaking and the resolution of the issues involved with the rule, as described in this paragraph. The agency, nevertheless, is providing a 30-day period during which it will accept comments on the conforming amendments. If FDA decides on the basis of comments received that any change to the conforming amendments is necessary, it will publish the change in the Federal Register.

FDA has redesignated reproposed § 803.36 (b) and (c) as final § 803.36 (a) and (b).

95. One comment suggests adding to any final rule exemptions for manufacturers and importers of devices which report to the Center for Drugs and Biologics, in accordance with § 310.301, § 310.302, § 312.1(a)(6), or § 431.60(b)(2).

FDA disagrees with the comment. Section 312.1(a)(6) applied to certain investigational devices before the effective date of FDA's regulations governing investigational device exemptions (21 CFR Part 812). Because the final rule applies only to marketed devices, there is no need to add an exemption for manufacturers and importers that report under § 312.1(a)(6) or Part 812.

In a notice published in the Federal Register of December 16, 1977 (42 FR 63472), FDA indicated that following enactment of the amendments, the Center for Drugs and Biologics would temporarily administer premarket approval and other requirements for transitional devices that previously were regulated as new drugs or antibiotic drugs. Thus, manufacturers of such devices have been required to provide information concerning experience with the devices to the Center for Drugs and Biologics in accordance with regulations applicable to new drugs or antibiotic drugs. In the December 16, 1977 notice, FDA also explained that the agency would gradually shift administrative responsibility for regulating transitional devices from the Center for Drugs and Biologics to the Center for Devices and Radiological Health at a pace consistent with the availability of manpower and administrative and technical capabilities. Consistent with that notice and in the interest of avoiding duplicative reporting requirements, FDA has concluded that on the effective date of the final rule, manufacturers and importers of transitional devices no longer need to report under § 310.301, § 310.302, or § 431.60(b)(2). This policy will be incorporated in any final rule governing the premarket approval of medical devices. Such a rule is under development.

96. Many comments argue that FDA should exempt from the requirements of any final medical device reporting rule adverse reactions that are required to be reported under the premarket approval regulations (when final) or pursuant to a condition to approval imposed in a premarket approval order for a class III device.

FDA disagrees with the comments. In the interest of uniformity of reporting requirements for all marketed medical devices (see paragraph 94 of this preamble), FDA affirms its tentative decisions, reflected in the November 1980 proposal and the May 1983 reproposal, not to exempt from the final rule manufacturers or importers that hold approved PMA's. To avoid duplicative reporting under both this final rule and approved PMA's, FDA advises that, upon the effective date of this final rule, any holder of an approved PMA for a device that is the subject of a reportable event will be required to report to FDA under this final rule. The holder shall continue to report to FDA under the terms or conditions to approval any information that is required under such terms or conditions and that is not a reportable event under this final rule. This policy will be incorporated in any final rule governing the premarket approval of medical devices. Such a rule is under development.

97. One comment suggests adding to any final rule exemptions for manufacturers and importers that submit information about reportable events under a voluntary program established by FDA, e.g., manufacturers of dialyzers are reporting hypersensitivity reactions on a quarterly basis.

FDA disagrees with the comment. Voluntary reporting, which by definition may cease at any time a manufacturer or importer chooses, cannot substitute for reporting under the final rule. FDA notes that there is not any specific program for manufacturers of dialyzers to report concerning hypersensitivity reactions to those devices.

Economic Assessment

FDA has assessed the economic impact of the final rule in accordance with Executive Order 12291 and concludes that the rule is not a major rule under the criteria included in the Executive Order. The agency also has considered the economic impact upon small business in accordance with the Regulatory Flexibility Act (Pub. L. 96–354) and certifies that there will not be a significant impact upon a substantial number of small medical device manufacturers or importers.

FDA estimates that under the final rule, approximately 25,100 medical device reports will be submitted each year. About 2,100 of these reports are expected to be for deaths and serious injuries. The remaining reports would be for device malfunctions which, if they recurred, could cause or contribute to a death or serious injury.

Using data provided by industry, FDA estimates that a cost of $600 for each report involving a death or serious injury will be incurred by the manufacturer or importer. (Even though these reportable events must be investigated by manufacturers under the CGMP regulations, FDA envisions that additional review by manufacturers may be undertaken before submission to FDA of this type of report. FDA also envisions that importers, although not subject to the CGMP regulations, will conduct voluntary investigations of device-related deaths and serious injuries.)

FDA believes that the cost of reports of device malfunctions will be proportional to the concern that the manufacturer or importer has over the potential for death or serious injury presented by the malfunction. FDA estimates that there will be 4,600 reports for which this concern will be the

greatest and for which some additional professional review might be necessary. FDA has assumed that a manufacturer or importer will incur an average cost of $300 for each such report. For the remaining reports of malfunctions, FDA assumes that a manufacturer or importer will incur a cost of only $60 for each report because these reports will entail only cursory review, photocopying, and mailing costs. Other costs attributable to the final rule include the cost of telephone calls for deaths and serious injuries, the cost to importers of establishing and maintaining complaints files, and the cost to manufacturers and importers of retaining records in accordance with final § 803.31. FDA estimates that the total cost of the final rule is approximately $4 million per year.

The agency also has examined the impact of the final rule upon small manufacturers. FDA estimates that most reports submitted under the final rule will be for critical devices within the meaning of Part 820 and that only about 43 percent of all establishments manufacturing such devices are small establishments. Also, small establishments typically manufacture only half as many types of medical devices as large establishments. Thus, neglecting differences in sales volume (larger establishments would sell more devices of each type) and assuming that the likelihood of a report on a device made by a small or large establishment would be the same, FDA expects that, at most, 22 percent (43 percent × 0.5) of the anticipated reports under the final rule will be from small establishments.

Therefore, FDA concludes that no more than 22 percent of the anticipated $4 million annual cost of the final rule (less than $0.9 million) should be ascribed to small establishments. Because there are between 5,000 and 6,000 such establishments subject to the final rule, the average impact on any one small establishment should be less than $200 annually.

Reference

1. "Survey of Device Establishment Complaint Files," March 1984, Center for Devices and Radiological Health.

Paperwork Reduction Act of 1980

In accordance with the Paperwork Reduction Act of 1980 and 5 CFR 1320.13(g) of OMB's regulations implementing the provisions of that act, FDA has submitted the final rule to OMB for approval of the collection of information requirements contained in §§ 803.24 and 803.31 of the rule. These requirements will not be effective until FDA obtains OMB approval. In accordance with 5 CFR 1320.13(j), prior to November 13, 1984, FDA will publish in the **Federal Register** a notice of OMB's decision to approve, modify, or disapprove these requirements.

List of Subjects

21 CFR Part 600

Biologics.

21 CFR Part 803

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 1002

Administrative practice and procedure, Electronic products, Radiation protection, Reporting requirements.

21 CFR Part 1003

Administrative practice and procedure, Defects, Electronic products, Noncompliance, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 502(t), 510, 519, 701(a), 704 (a) and (e), 52 Stat. 1055, 76 Stat. 792–795 as amended, 90 Stat. 564–565, 578, 581 (21 U.S.C. 352(t), 360, 360i, 371(a), 374 (a) and (e))) and under the Public Health Service Act (secs. 215, 351, 354–360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173–1186 as amended (42 U.S.C. 216, 262, 263b–263n)) and under 21 CFR 5.11, Title 21 of the Code of Federal Regulations is amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. Part 600 is amended in § 600.14 by designating the existing text as paragraph (a) and by adding new paragraph (b), to read as follows:

§ 600.14 Reporting of errors.

(a) * * *

(b) Manufacturers of licensed in vitro diagnostic products, and manufacturers of unlicensed in vitro diagnostic products which are required to be registered under Part 607 of this chapter, shall notify the Director in accordance with paragraph (a) of this section. Manufacturers of other in vitro diagnostic products which are required to be registered under Part 807 of this chapter, shall report in accordance with Part 803 of this chapter.

2. By adding new Part 803, to read as follows:

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.

803.1 Scope.
803.3 Definitions.
803.9 Public availability of reports.

Subpart B—Reports and Records

803.24 Reports by manufacturers and importers.
803.31 Complaint files.
803.33 Where to submit a report.
803.36 Exemptions from reporting.

Authority: (Secs. 502(t), 510, 519, 701(a), 704 (a) and (e), 52 Stat. 1055, 76 Stat. 792–795 as amended, 90 Stat. 564–565, 578, 581 (21 U.S.C. 352(t), 360, 360i, 371(a), 374 (a) and (e)).

Subpart A—General Provisions

§ 803.1 Scope.

(a) FDA is requiring a device manufacturer or importer to report to FDA whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. These reports will enable FDA to protect the public health by helping to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for their intended use. In addition, a device importer is required to establish and maintain a complaint file and to permit any authorized FDA employee at all reasonable times to have access to and to copy and verify the records contained in this file.

(b) This part supplements, and does not supersede, other provisions of this subchapter, including the provisions of Part 820, such as the requirements under § 820.162 that a manufacturer investigate the failure of a device or any of its components to meet its performance specifications and to establish and maintain a written record of the investigation, including the manufacturer's conclusions and followup, the requirements under § 820.198 that a manufacturer establish and maintain a complaint file, and the requirements under § 820.180 that a manufacturer allow access to, and copying of, these files by any authorized FDA representative.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 803.3 Definitions.

(a) "FDA" means the Food and Drug Administration.

(b) "Importer" means any person who imports a device into the United States

and is required to register under Part 807.

(c) "Malfunction" means the failure of a device to meet any of its performance specifications or otherwise to perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the objective intent of the person legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It also may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used to perform a function for which it is neither labeled nor advertised.

(d) "Manufacturer" means any person who is required to register under Part 807, other than a person who initially distributes a device imported into the United States.

(e) "Person" includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency, or organizational unit thereof, or any other legal entity.

(f) "Information that reasonably suggests" a conclusion means (1) information (such as professional, scientific, or medical facts or opinions) from which a reasonable person would reach the conclusion, and (2) a statement to a manufacturer or importer by a health care professional (e.g., a doctor of medicine, osteopathy, dental surgery, podiatry, or chiropractic, or an optometrist, pharmacist, or a registered nurse, or a hospital administrator), reaching the conclusion.

(g) A "remedial action" is any recall, repair, modification, adjustment, relabeling, destruction, inspection (including patient monitoring), notification, or any other action that is initiated by a manufacturer or importer in response to information that it receives or otherwise becomes aware of and that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(h) A "serious injury" is an injury that (1) is life threatening, (2) results in permanent impairment of a body function or permanent damage to body structure, or (3) necessitates medical or surgical intervention by a health care professional to (i) preclude permanent impairment of a body function or permanent damage to body structure or (ii) relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure. Temporary impairment of a body function or temporary damage to body structure is unanticipated if reference to such impairment or damage is not made in the labeling for the device or, if such reference is made in the labeling for the device, the manufacturer or importer of the device determines that such impairment or damage has occurred or is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device.

(i) Any term defined in section 201 of the Federal Food, Drug, and Cosmetic Act shall have that meaning, unless otherwise defined in this Part.

§ 803.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with Part 20.

(b) Before public disclosure of a report, FDA will delete from the report (1) any information that constitutes trade secret or confidential commercial or financial information under § 20.61; and (2) any personnel, medical, and similar information disclosure of which would constitute a clearly unwarranted invasion of personal privacy under § 20.63; provided, however, that except for the information that constitutes trade secret or confidential commercial or financial information under § 20.61, FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

Subpart B—Reports and Records

§ 803.24 Reports by manufacturers and importers.

(a) A manufacturer or importer shall submit to FDA a report containing the information listed in paragraph (c) of this section whenever the manufacturer or importer:

(1) Receives or otherwise becomes aware of oral or written information that reasonably suggests that:

(i) A death or serious injury has occurred and that one of the manufacturer's or importer's marketed devices may have caused or contributed to a death or serious injury; or

(ii) One of the manufacturer's or importer's marketed devices has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(2) Receives or otherwise becomes aware of information:

(i) In the medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices (*a*) may have caused or contributed to a death or serious injury or (*b*) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; or

(ii) Through its own research, testing, evaluation, servicing, or maintenance of one of its devices, that reasonably suggests that one of its marketed devices malfunctions and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(b)(1) Whenever a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, the manufacturer or importer shall report to FDA by telephone as soon as possible, but no later than within 5 calendar days of initial receipt of the information. The manufacturer or importer shall include in the telephone report the information listed in paragraph (c) of this section. The manufacturer or importer shall follow the telephone report with a written report submitted to FDA within 15 working days of initial receipt of the information.

(2) Whenever a manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, the manufacturer or importer shall report in writing or by telephone to FDA as soon as the information listed in paragraph (c) of this section has been obtained, but in no event later than 15 working days after initial receipt of the information. The manufacturer or importer shall follow any report made by telephone with a written report submitted to FDA within 15 working days of initial receipt of the information.

(c) A medical device telephone report or written report is required to:

(1) Identify the device, including its brand name and common or usual name and, to the extent known, the model, catalog, or other identification number or code of the device, and the manufacturing lot or serial number of the device.

(2) Identify the manufacturer or, in the case of an imported device, identify the importer and the foreign manufacturer;

(3) Identify, by name, address, and telephone number, the individual making the report to FDA;

(4) Describe, to the extent known, the event giving rise to the information received by the manufacturer or importer, including (i) whether any deaths or serious injuries have occurred and (ii) the number of persons who died or were seriously injured. (If the report is required under paragraph (a)(2)(i) of this section, the description of the event shall include a copy of the article.);

(5) Identify, by name and address, the person submitting the information to the manufacturer or importer;

(6) State whether the manufacturer or importer intends to submit additional information, and, if so, when such information will be submitted; and

(7) State whether the reported event has occurred or is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device, if such information is available.

(d)(1) A manufacturer or importer shall report to FDA as required under this part each time it receives or otherwise becomes aware of information described in paragraph (a) of this section, even if an event of the same or a similar nature has been reported previously to FDA. A medical device report is required under paragraph (a) of this section even if the manufacturer or importer believes that the event that requires a report is due to user error, the failure to service or maintain the device properly, the use of the device beyond its labeled useful life, or any other reason not listed under paragraph (d) (2) or (3) of this section.

(2) Only one medical device report is required under paragraph (a) of this section if the manufacturer or importer becomes aware, from more than one source, of information concerning the same patient and the same event.

(3) A medical device report is not required if within the time period specified under paragraph (b) of this section, the manufacturer or importer determines that:

(i) The information received under paragraph (a)(1)(i) of this section is erroneous in that a death or serious injury has not occurred; or

(ii) The information received under paragraph (a)(1)(i) or (ii) of this section is erroneous in that the device that is the subject of the information was manufactured or imported by another manufacturer or importer; or

(iii) Although the manufacturer or importer has received or otherwise became aware of information that reasonably suggests that a malfunction has occurred, each of the following applies:

(*a*) A death or serious injury has not occurred;

(*b*) The device's labeling sets forth information concerning the potential for death to the type of serious injury that the malfunction may cause or contribute to;

(*c*) The device's labeling describes the malfunction, and the routine service, repair, or maintenance instructions to correct the malfunction;

(*d*) The malfunction has occurred or is occurring at or below the frequency and severity stated in the labeling for the device or, if there is not any pertinent statement in the labeling, at or below the frequency and severity that are usual for the device; and

(*e*) The malfunction does not lead the manufacturer or importer to undertake a remedial action involving any device other than the device product in which the malfunction occurred.

(4) FDA may notify a manufacturer or importer, in writing, that medical device reports of a particular type of event are no longer required.

(e) If FDA determines that the protection of the public health requires information in addition to that included in the medical device report submitted to FDA under paragraph (b) of this section, a manufacturer or importer shall, upon FDA's request, submit such additional information. Any request by FDA under this paragraph will be in writing, state the reason or purpose for which the information is being requested, and specify a due date for the submission of such information. Additional items that may be requested include:

(1) Model, catalog, or other identification number or code of the device.

(2) Manufacturing lot or serial number of the device.

(3) A complete description of the event giving rise to the information received by the manufacturer or importer, including (i) whether any deaths or serious injuries have occurred and (ii) the number of persons who died or were seriously injured. If a complete description is unavailable, the manufacturer or importer shall explain the reason for the unavailability of such description.

(4) Any evaluation of the risk of death or serious injury, including failure analysis, and copies of any laboratory testing or analyses available to or used by the manufacturer or importer.

(5) Any available evaluation by a practitioner, such as a physician or dentist, licensed by law to use or order the use of the device, of the event described in the medical device report.

(6) Any evaluation or other determination available to or used by the manufacturer or importer as to whether the event described in the medical device report is or is not attributable to the device and the basis for such determination.

(7)(i) All the information on the basis of which the manufacturer or importer determined that the reported event has occurred or is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device; and (ii) any evaluation or analysis available to or used by the manufacturer or importer in making this determination.

(8) If the manufacturer or importer determines that the event described in the medical device report is attributable to the device, an outline of the plan for remedial action or, if the manufacturer or importer determines that a remedial action is unnecessary, the basis for such determination.

(9) A copy of any proposed remedial action communication and the names and addresses of recipients of the communication.

(10) Information concerning the device's manufacture, e.g., the total number manufactured or the number in the same batch, lot, or equivalent unit of production, the location and date of manufacture, and the device's expiration date, if any.

(11) Information concerning the device's distribution, e.g., the location and number of devices in inventory stock and distribution channels, a list of all consignees, and the dates of distribution.

(Information collection requirements approved by the Office of Management and Budget under number .)

§ 803.31 Complaint files.

(a) An importer shall establish a complaint file and maintain a record of any information, including any written or oral communication, received by the importer concerning a death, serious injury, or device malfunction that requires a report under § 803.24. The file

also is required to contain a copy of any medical device report submitted to FDA under § 803.24(b) and any additional information submitted to FDA under § 803.24(e).

(b) An importer shall retain copies of records maintained under paragraph (a) of this section for a period of 2 years from the date that the medical device report or additional information is submitted to FDA under § 803.24 (b) or (e), even if the importer has ceased importing the device that is the subject of the report or the additional information.

(c) An importer shall maintain the complaint file established under this section at the importer's principal business establishment. An importer that also is a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§ 820.180 and 820.198. An importer shall permit any authorized FDA employee at all reasonable times to have access to and to copy and verify the records contained in the complaint file.

(d) A manufacturer shall retain copies of records of any information, including any written or oral communication, received by the manufacturer concerning a death, serious injury, or device malfunction that requires a report under § 803.24. The manufacturer also shall retain a copy of any medical device report submitted to FDA under § 803.24(b) and any additional information submitted to FDA under § 803.24(e). The manufacturer shall retain the records referred to in this paragraph for a period of 2 years from the date that the report or additional information is submitted to FDA under § 803.24 (b) or (e) or for a period of time equivalent to the design and expected life of the device, whichever is greater. The manufacturer may maintain as part of its complaint file under § 820.198 the records referred to in this paragraph. The manufacturer shall permit any authorized FDA employee at all reasonable times to have access to and to copy and verify the records referred to in this paragraph.

(Information collection requirements approved by the Office of Management under number.)

§ 803.33 Where to submit a report.

(a) Any telephone report required under this part shall be provided to 301-427-7500.

(b) Any written report or additional information required under this part shall be submitted to the Device Monitoring Branch (HFZ-343), Center for Devices and Radiological Health, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910.

§ 803.36 Exemptions from reporting.

A manufacturer or importer otherwise subject to this part is exempt from reporting as required under this part, if the manufacturer or importer:

(a) Is a practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of that individual's professional practice.

(b) Is a person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale or under an investigational device exemption granted under Part 812 or Part 813.

PART 1002—RECORDS AND REPORTS

3. Part 1002 is amended in § 1002.20 by adding new paragraph (c), to read as follows:

§ 1002.20 Reporting of accidental radiation occurrences.

* * * * *

(c) If a manufacturer is required to report to the Director under paragraph (a) of this section and also is required to report under Part 803 of this chapter, the manufacturer shall report in accordance with Part 803. If a manufacturer is required to report to the Director under paragraph (a) of this section and is not required to report under Part 803, the manufacturer shall report in accordance with paragraph (a) of this section.

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

4. Part 1003 is amended in § 1003.10 by adding new paragraph (c), to read as follows:

§ 1003.10 Discovery of defect or failure of compliance by manufacturer; notice requirements.

* * * * *

(c) If a manufacturer is required to notify the Secretary under paragraph (a) of this section and also is required to report to the Food and Drug Administration under Part 803 of this chapter, the manufacturer shall report in accordance with Part 803. If a manufacturer is required to notify the Secretary under paragraph (a) of this section and is not required to report to the Food and Drug Administration under Part 803, the manufacturer shall notify the Secretary in accordance with paragraph (a) of this section.

Interested persons may, on or before October 15, 1984, submit to the Dockets Management Branch (address above) written comments regarding the amendments conforming §§ 600.14, 1002.20, and 1003.10 to this final rule. If FDA decides on the basis of comments received that any change to the conforming amendments is necessary, it will publish the change in the **Federal Register**. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. November 13, 1984.

(Secs. 502(t), 510, 519, 701(a), 704 (a) and (e), 52 Stat. 1055, 76 Stat. 792-795 as amended, 90 Stat. 564-565, 578, 581 (21 U.S.C. 352(t), 360, 360i, 371(a), 374 (a) and (e)); secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n))

Dated: August 27, 1984.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 84-23910 Filed 9-13-84; 8:45 am]

BILLING CODE 4160-01-M

federal register

Friday
September 14, 1984

Part VIII

Office of Management and Budget

Budget Rescissions and Deferrals; Cumultative Report

OFFICE OF MANAGEMENT AND BUDGET

Cumulative Report on Rescissions and Deferrals

September 1, 1984.

This report is submitted in fulfillment of the requirements of section 1014(e) of the Impoundment Control Act of 1974 (Pub. L. 93-344). Section 1014(e) provides for a monthly report listing all budget authority for this fiscal year for which, as of the first day of the month, a special message has been transmitted to the Congress.

This report gives the status as of September 1, 1984 of nine rescission proposals and 65 deferrals contained in the first twelve special messages of FY 1984. These messages were transmitted to the Congress on October 3, November 17, December 14 and December 21, 1983; and January 12, February 1 and 22, March 26, May 8 and 21, June 20, and July 20, 1984.

Rescissions (Table A and Attachment A)

As of September 1, 1984, there were no rescission proposals pending before the Congress. Attachment A shows the history and status of the nine rescissions proposed by the President in 1984.

Deferrals (Table B and Attachment B)

As of September 1, 1984, $1,946.0 million in 1984 budget authority was being deferred from obligation and $10.8 million in 1984 outlays was being deferred from expenditure. Attachment B shows the history and status of each deferral reported during FY 1984.

Information From Special Messages

The special messages containing information on the rescission proposals and deferrals covered by this cumulative report are printed in the **Federal Registers** listed below:

Vol. 48, FR p. 45730, Thursday, October 6, 1983
Vol. 48, FR p. 53060, Wednesday, November 23, 1983
Vol. 48, FR p. 56720, Thursday, December 22, 1983
Vol. 48, FR p. 57098, Tuesday, December 27, 1983
Vol. 49, FR p. 2076, Tuesday, January 17, 1984
Vol. 49, FR p. 4692, Tuesday, February 7, 1984
Vol. 49, FR p. 7342, Tuesday, February 28, 1984
Vol. 49, FR p. 13096, Monday, April 2, 1984
Vol. 49, FR p. 20234, Friday, May 11, 1984
Vol. 49, FR p. 22032, Thursday, May 24, 1984
Vol. 49, FR p. 26014, Monday, June 25, 1984
Vol. 49, FR p. 30155, Thursday, July 26, 1984

David A. Stockman,
Director, Office of Management and Budget.

TABLE A

STATUS OF 1984 RESCISSIONS

	Amount (In millions of dollars)
Rescissions proposed by the President	$ 636.4
Accepted by the Congress	-55.4 a/
Rejected by the Congress	-581.0
Pending before the Congress	$ -0-

a/ These amounts were available for obligation between March 28 and August 22, 1984 when the Second Supplemental Appropriations Act (P.L. 98-396) was enacted.

****

TABLE B

STATUS OF 1984 DEFERRALS

	Amount (In millions of dollars)
Deferrals proposed by the President	$ 7,434.5
Routine Executive releases through September 1, 1984 (OMB/ Agency Releases of $5,548.2 million and cumulative adjustments of -$86.5 million)	-5,461.7
Overturned by the Congress	-16.0
Currently before the Congress	$ 1,956.8 a/

a/ This amount includes $10.8 million in outlays for a Department of the Treasury deferral (D84-16).

Attachments

BILLING CODE 3110-01-M

Attachment A - Status of Rescissions - Fiscal Year 1984

As of September 1, 1984 Amounts in Thousands of Dollars Agency/Bureau/Account	Rescission Number	Amount Previously Considered by Congress	Amount Currently before Congress	Date of Message	Amount Rescinded	Amount Made Available	Date Made Available	Congressional Action
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT								
Public and Indian Housing Programs								
Payment for operation of low-income housing	R84-2		331,431	2-1-84		331,431	3-28-84	
DEPARTMENT OF THE INTERIOR								
National Park Service								
Land acquisition	R84-3		30,000	2-1-84	30,000	30,000	3-28-84	P.L. 98-396
DEPARTMENT OF LABOR								
Occupational Safety and Health Administration	R84-1		1,700	12-21-83		1,700	3-19-84	
OTHER INDEPENDENT AGENCIES								
Corporation for Public Broadcasting								
Public broadcasting fund	R84-9		20,000	2-1-84		20,000	3-28-84	
Delaware and Susquehana River Basin Commissions								
Salaries and expenses, Delaware River Basin Commission	R84-4		19	2-1-84		19	3-28-84	
Salaries and expenses, Susquehana River Basin Commission	R84-5		24	2-1-84		24	3-28-84	
Panama Canal Commission								
Operating expenses	R84-6A		17,750	2-1-84	17,750	17,750	3-28-84	P.L. 98-396
Capital outlay	R84-6B		7,625	2-1-84	7,625	7,625	3-28-84	P.L. 98-396
OFF-BUDGET FEDERAL ENTITIES								
DEPARTMENT OF AGRICULTURE								
Rural Electrification Administration								
Rural electrification and telephone revolving fund	R84-7		197,862	2-1-84		197,862	3-28-84	
Rural telephone bank	R84-8		30,000	2-1-84		30,000	3-28-84	
Rescissions, total BA			636,411		55,375	636,411		

NOTE:- Amounts rescinded in the Second Supplemental Appropriations Act (P.L.98-396) on August 22, 1984 were available between the date of release and the date of enactment.

Attachment B - Status of Deferrals - Fiscal Year 1984

As of September 1, 1984 Amounts in Thousands of Dollars Agency/Bureau/Account	Deferral Number	Amount Transmitted Original Request	Amount Transmitted Subsequent Change	Date of Message	Cumulative OMB/Agency Releases	Congressionally Required Releases	Congressional Action	Cumulative Adjustments	Amount Deferred as of 9-1-84
FUNDS APPROPRIATED TO THE PRESIDENT									
Appalachian Regional Development Programs									
Appalachian regional development programs	D84-1	10,000		10-3-83					10,000
International Security Assistance									
Foreign military sales credit	D84-30	1,315,000		1-12-84	-1315000				0
Economic support fund	D84-24	303,880		12-14-83					
	D84-24A		2,267,691	1-12-84	-2663571				0
	D84-60	102,000		5-8-84					10,000
Military assistance	D84-31	426,970		1-12-84	-426970				0
DEPARTMENT OF AGRICULTURE									
Soil Conservation Service									
Watershed and flood prevention operations	D84-49	8,138		2-1-84					8,138
Forest Service									
Construction	D84-37	10,814		2-1-84					10,814
Timber salvage sales	D84-2	6,211		10-3-83					
	D84-2A		9,210	1-12-84	-1950				13,471
Expenses, brush disposal	D84-3	42,674		10-3-83					
	D84-3A		12,398	1-12-84					
	D84-3B		778	5-8-84					55,850
DEPARTMENT OF COMMERCE									
International Trade Administration									
Participation in U.S. expositions	D84-32	550		1-12-84					550
National Oceanic & Atmospheric Administration									
Promote and develop fishery products and research pertaining to American fisheries	D84-4	33,600		10-3-83	-33600				0

Attachment B - Status of Deferrals - Fiscal Year 1984

As of September 1, 1984 Amounts in Thousands of Dollars Agency/Bureau/Account	Deferral Number	Amount Transmitted Original Request	Amount Transmitted Subsequent Change	Date of Message	Cumulative OMB/Agency Releases	Congressionally Required Releases	Congressional Action	Cumulative Adjustments	Amount Deferred as of 9-1-84
DEPARTMENT OF DEFENSE - MILITARY									
Operation and Maintenance									
Environmental restoration, defense	D84-33	75,000		1-12-84	-75000				0
Military Construction									
Military construction, all services	D84-5	414,597		10-3-83					
	D84-5A		488,340	12-14-83	-734902			129,648	297,683
Family Housing, Defense									
Family housing, Air Force	D84-6	53,000		10-3-83					
	D84-6A		20,131	12-14-83	-73131				0
DEPARTMENT OF DEFENSE - CIVIL									
Wildlife Conservation, Military Reservations									
Wildlife conservation	D84-7	777		10-3-83					
	D84-7A		385	1-12-84					1,162
DEPARTMENT OF EDUCATION									
Office of Postsecondary Education									
Higher education	D84-38	500		2-1-84	-500				0
DEPARTMENT OF ENERGY									
Atomic Energy Defense Activities									
Atomic energy defense activities	D84-62	1,050		6-20-84					
	D84-62A		206	7-20-84					1,256
Energy Programs									
General science and research activities	D84-63	700		6-20-84					700
Energy supply, research and development activities	D84-39	10,052		2-1-84					
	D84-39A		800	6-20-84	-1999				8,853
Uranium supply and enrichment activities	D84-8	130,000		10-3-83					130,000
Fossil energy research and development	D84-21	20,326		11-17-83	-20326				
	D84-21A		500	12-14-83					
	D84-21B		8,993	2-1-84					
	D84-21C		150	6-20-84					
	D84-21D		771	7-20-84					10,414
Fossil energy construction	D84-25	38,038	1,962	12-14-83				-26000	
	D84-25A		23,196	2-1-84					37,196
Naval petroleum and oil shale reserves	D84-40	41,500		2-1-84					
	D84-40A		50	6-20-84					41,550
Energy conservation	D84-41	10,077		2-1-84	-8577			1,218	2,718
Strategic petroleum reserve	D84-26	12,707		12-14-83					
	D84-26A		256	2-1-84					
	D84-26B		92	7-20-84					13,055
Alternative fuels production	D84-22	13,800		11-17-83					
	D84-22A		4,300	2-1-84	-12300			712	6,512
Power Marketing Administrations									
Operation and maintenance, Southwestern Power Administration	D84-42	7,000		2-1-84					
	D84-42A		60	6-20-84					
	D84-42B		41	7-20-84					7,101
Construction, rehabilitation, operation and maintenance, Western Area Power Administration	D84-64	100		6-20-84					
	D84-64A		514	7-20-84					614
Departmental Administration									
Departmental administration	D84-43	29,053		2-1-84					
	D84-43A		375	6-20-84					
	D84-43B		6,660	7-20-84					36,088
DEPARTMENT OF HEALTH AND HUMAN SERVICES									
Centers for Disease Control									
Disease control	D84-27	15,560		12-14-83					15,560

Attachment B - Status of Deferrals - Fiscal Year 1984

As of September 1, 1984 Amounts in Thousands of Dollars Agency/Bureau/Account	Deferral Number	Amount Transmitted Original Request	Amount Transmitted Subsequent Change	Date of Message	Cumulative OMB/Agency Releases	Congressionally Required Releases	Congressional Action	Cumulative Adjustments	Amount Deferred as of 9-1-84
National Institutes of Health									
Buildings and facilities	D84-65	8,006		7-20-84					8,006
Office of Assistant Secretary for Health									
Scientific activities overseas (special foreign currency program)	D84-9	6,463		10-3-83					
	D84-9A		571	1-12-84					7,034
Social Security Administration									
Limitation on administrative expenses (construction)	D84-10	10,571		10-3-83					
	D84-10A		10,490	12-21-83	-13				21,048
DEPARTMENT OF THE INTERIOR									
Minerals Management Service									
Payments for proceeds, sale of water, Mineral Leasing Act of 1920	D84-11	48		10-3-83					48
Bureau of Reclamation									
Construction program	D84-61	8,000		5-21-84	-8000				0
Bureau of the Mines									
Mines and minerals	D84-44	1,667		2-1-84					1,667
National Park Service									
Land acquisition and state assistance (contract authority)	D84-23	30,000		11-17-83					
	D84-23A		2,700	2-1-84				-30000	2,700
Construction (trust fund)	D84-50	14,000		2-22-84		-14000	98-332		0
Office of the Secretary									
Office of Water Policy	D84-51	300		2-22-84	-300				0
DEPARTMENT OF JUSTICE									
Interagency Law Enforcement									
Organized crime drug enforcement	D84-57	272		3-26-84					272
Federal Bureau of Investigation									
Salaries and expenses	D84-58	42,000		3-26-84					42,000
Federal Prison System									
Buildings and facilities	D84-28	22,025		12-14-83					
	D84-28A		23,752	1-12-84					45,777
Office of Justice Assistance, Research and Statistics									
Law enforcement assistance	D84-52	296		2-22-84					296
DEPARTMENT OF STATE									
International Organizations and Conferences									
Contributions to international organizations	D84-46	4,723		2-1-84					4,723
Contributions for international peacekeeping activities	D84-45	10,879		2-1-84					10,879
United States emergency refugee and migration assistance fund	D84-12	37,928		10-3-83					
	D84-12A		192	1-12-84	-192				37,928
United States bilateral science and technology agreements	D84-13	2,000		10-3-83					2,000
DEPARTMENT OF TRANSPORTATION									
Federal Railroad Administration									
Railroad research and development	D84-53	578		2-22-84					578
Federal Aviation Administration									
Facilities, engineering and development	D84-59	360		3-26-84					360
Construction, Washington Metropolitan Airports	D84-54	277		2-22-84					277

Attachment B - Status of Deferrals - Fiscal Year 1984

As of September 1, 1984 Amounts in Thousands of Dollars Agency/Bureau/Account	Deferral Number	Amount Transmitted Original Request	Amount Transmitted Subsequent Change	Date of Message	Cumulative OMB/Agency Releases	Congressionally Required Releases	Congressional Action	Cumulative Adjustments	Amount Deferred as of 9-1-84
Facilities and equipment (airport and airway trust)	D84-14	1,083,268		10-3-83	-153063				930,205
U.S. Coast Guard Retired pay	D84-55	13,350		2-22-84					13,350
Maritime Administration Ship construction	D84-47	7,000		2-1-84					7,000
Office of the Secretary Transportation planning, research and development	D84-56	160		2-22-84					160
DEPARTMENT OF THE TREASURY									
Office of Revenue Sharing State and local government fiscal assistance trust fund	D84-15	56,068		10-3-83	-3336			111	52,843
	D84-16	15,209		10-3-83	-15209			10,808	10,808
Bureau of the Mint Expansion and improvements	D84-29	256		12-14-83	-256				0
OTHER INDEPENDENT AGENCIES									
Pennsylvania Avenue Development Corporation Land acquisition and development fund	D84-17	13,148		10-3-83					13,148
Railroad Retirement Board Milwaukee Railroad restructuring, administration	D84-18	85		10-3-83					
	D84-18A		147	12-14-83					232
Tennessee Valley Authority Tennessee Valley Authority fund	D84-19	7,000		10-3-83					7,000
	D84-48	2,192		2-1-84					2,192
United States Information Agency Salaries and expenses	D84-34	2,400		1-12-84					2,400
Salaries and expenses (special foreign currency program)	D84-35	2,900		1-12-84					2,900
Acquisition and construction of radio facilities	D84-36	9,645		1-12-84					9,645
United States Railway Association Administrative expenses	D84-20	2,050		10-3-83		-2050	98-181		0
TOTAL, DEFERRALS		4,548,798	2,885,711		-5,548,195	-16,050		86,497	1,956,761

Notes: Deferral D84-25 was reported as part of D84-21 in the second special message. In the third special message the deferral was reported separately and adjusted upward slightly.

Of the amount deferred as D84-25, $26 million was transferred to Fossil energy research and development pursuant to the 1984 Interior and Related Agencies Appropriations Act.

All of the above amounts represent budget authority except one general revenue sharing deferral (D84-16) of outlays only.

The Soil Conservation Service deferral was erroneously transmitted as D84-36 in the sixth special message. It has been renumbered as D84-49.

[FR Doc. 84-24425 Filed 9-13-84; 8:45 am]

BILLING CODE 3110-01-C