DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 902

50 CFR Part 600

[Docket No. 970304043–7105–02; I.D. 021997D]

RIN 0648–AJ59

Magnuson-Stevens Act Provisions; Foreign Fishing Vessels in Internal Waters; Reporting Requirements

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS implements new reporting requirements for foreign fishing vessels (FFV's) operating in the internal waters of a state. FFV's so authorized by the Governor of a state may engage in fish processing and support of U.S. fishing vessels within the internal waters of a state in compliance with the terms and conditions set by the authorizing Governor. The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), as amended by the Sustainable Fisheries Act (SFA), requires that FFV's report the tonnage and harvest location of fish received from vessels of the United States. The intent of this rule is to implement the new statutory requirements of the Magnuson-Stevens Act and collect landings information for management and conservation purposes.

DATES: Effective June 18, 1997.

ADDRESSES: Comments regarding burden-hour estimates for the collection-of-information requirements contained in this final rule should be sent to George H. Darcy, F/SF3, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910, and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, D.C. 20503 (Attention: NOAA Desk Officer).

FOR FURTHER INFORMATION CONTACT: George H. Darcy, 301–713–2341.

SUPPLEMENTARY INFORMATION: On October 11, 1996, the President signed into law the SFA (Pub. L. 104–297), which made numerous amendments to the Magnuson-Stevens Act (16 U.S.C. 1801 *et seq.*). Section 112(c) of the SFA amended section 306(c) of the Magnuson-Stevens Act to require that the owner or operator of a FFV engaged in fish processing and support of U.S. fishing vessels within the internal waters of a state submit reports on the tonnage of fish received from vessels of the United States and the locations from which such fish were harvested, in accordance with such procedures as the Secretary of Commerce, by regulation, shall prescribe.

On March 20, 1997, NMFS published a proposed rule at 62 FR 13360 revising § 600.508(f), to implement the SFA requirements. Comments on the proposed rule were requested through April 21, 1997; no comments were received and no changes to the proposed rule have been made, except to add the OMB control number for this approved collection of information to 15 CFR part 902. Section 3507(c)(B)(i) of the Paperwork Reduction Act (PRA) requires agencies to inventory and display a current control number assigned by the Director, OMB, for each agency information collection. Section 902.1(b) of 15 CFR identifies the location of NOAA regulations for which OMB control numbers have been issued. This final rule amends § 902.1(b) by adding the control number for this collection of information. Under NOAA Administrative Order 205–11, 7.01, dated December 17, 1990, the Under Secretary for Oceans and Atmosphere has delegated to the Assistant Administrator for Fisheries, NOAA, the authority to sign material for publication in the **Federal Register**.

Classification

This rule has been determined to be not significant for purposes of E.O. 12866.

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule would not have a significant economic impact on a substantial number of small entities. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not prepared.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

This rule contains a collection-of-information requirement subject to the PRA. This collection-of-information requirement has been approved by OMB under OMB control number 0648–0329. Public reporting burden is estimated to average 0.5 hours per response to fill out and submit each weekly report to the Regional Administrator, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding burden estimates, or any other aspect of this data collection, including suggestions for reducing the burden, to NMFS and OMB (see **ADDRESSES**).

List of Subjects

15 CFR Part 902

Reporting and recordkeeping requirements.

50 CFR Part 600

Fisheries, Fishing.

Dated: May 12, 1997.

C. Karnella,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 15 CFR chapter IX and 50 CFR chapter VI are amended as follows:

15 CFR Chapter IX

PART 902—NOAA INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT: OMB CONTROL NUMBERS

1. The authority citation for part 902 continues to read as follows:

Authority: 44 U.S.C. 3501 *et seq.*

2. In § 902.1, paragraph (b), the table is amended by adding in numerical order the following entry to read as follows:

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

* * * * *

(b) * * *

CFR part or section where the information collection requirement is located	Current OMB control number (all numbers begin with 0648–)
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50 CFR	
* * * * *	*
600.508	–0239
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50 CFR Chapter VI

PART 600—MAGNUSON ACT PROVISIONS

3. The authority citation for part 600 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

4. In § 600.508, paragraph (f) is revised to read as follows:

§ 600.508 Fishing operations.

* * * * *

(f) *Internal waters.* For FFV's authorized under section 306(c) of the Magnuson-Stevens Act:

(1) Each FFV may engage in fish processing and support of U.S. fishing vessels within the internal waters of that state in compliance with terms and conditions set by the authorizing Governor.

(2) The owner or operator of each FFV must submit weekly reports on the amount of fish received from vessels of the United States and the location(s) where such fish were harvested.

(i) Reports must include:

(A) Vessel identification information for the FFV.

(B) Date of each receipt of fish.

(C) Amount of fish received, by species.

(D) Location(s) from which the fish received were harvested.

(ii) Owners or operators of FFV's processing fish in internal waters under the provisions of this paragraph (f) must request, from the Regional Administrator, the requirements regarding timing and submission of the reports, at least 15 days prior to the first receipt of fish from a vessel of the United States. The Regional Administrator shall stipulate the timing and submission requirements in writing.

[FR Doc. 97–12988 Filed 5–16–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 806

[Docket No. 91N–0396]

Medical Devices; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to establish procedures for implementing the reports of corrections and removals provisions of the Safe Medical Devices Act of 1990 (the SMDA) by requiring that manufacturers, importers, and distributors report promptly to FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act (the act) caused by the device which may present a risk to health. FDA believes that this action is necessary to protect the public health by ensuring that the agency has current and complete information regarding those actions taken to reduce risks to health caused by the devices. Reports of such actions will improve the agency's ability to evaluate device-related problems and to take prompt action against potentially dangerous devices.

DATES: Effective November 17, 1997. Submit written comments on the information collection provisions of this final rule by July 18, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–827–2970.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's reporting and recordkeeping requirements for medical devices reflect a series of amendments to the act (21 U.S.C. 321–394) as follows: (1) The Medical Device Amendments of 1976 (Pub. L. 94–295) (the 1976 amendments) which amended the act to establish the first comprehensive framework for the regulation of medical devices; (2) the SMDA (Pub. L. 101–629), which amended the act to correct noted problems with the implementation and enforcement of the 1976 amendments; and (3) The Medical Device Amendments of 1992 (Pub. L. 102–300) (the 1992 amendments), which amended certain provisions of the act relating to devices.

Section 519(f) of the act (21 U.S.C. 360i(f)), as added by the SMDA, authorizes FDA to issue regulations to require reports and recordkeeping of correction and removal actions taken by device manufacturers, distributors, and importers. Under the final rule, a correction means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location. Removal means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

Under section 519(f)(1) of the act, device manufacturers, distributors, and importers are to report promptly to FDA any correction or removal of a device undertaken: (1) To reduce a risk to health posed by the device; or (2) to remedy a violation of the act caused by a device which may present a risk to health. Section 519(f)(1) of the act also requires manufacturers, distributors, and importers to keep records of those corrections and removals that are not required to be reported to FDA. Section 519(f)(2) of the act provides that no report of a correction or removal action under section 519(f)(1) may be required if a report of the correction or removal action is required and has been submitted to FDA under section 519(a), which prescribes rules for reporting and keeping records of certain significant device-related events. Section 519(f)(3) of the act states that the terms ''correction'' and ''removal'' do not include routine servicing.

The final rule provides a mechanism for FDA to receive timely information about potentially dangerous marketed devices by requiring device manufacturers, distributors, and importers to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of the act caused by the device which may present a risk to health. Section 519(f) of the act was enacted because Congress was concerned that device manufacturers, distributors, and importers were carrying out product corrections or removals without notifying FDA, or without notifying the agency in a timely fashion (H. Rept. 808, 101st Cong., 2d sess. 29 (1990)). Congress explained that industry's failure to report corrections and removals, particularly those undertaken to reduce risks associated with the use of a device, ''denies the agency the opportunity to fulfill its public health responsibilities by evaluating device-related problems and the adequacy of corrective actions'' (S. Rept. 513, 101st Cong., 2d sess. 23 (1990)), and ''has seriously interfered with FDA's ability to take prompt action against potentially dangerous devices'' (H. Rept. 808, 101st Cong., 2d sess. 29 (1990)).

The agency recognizes that Congress did not want to overburden industry or FDA with excessive reporting