

Washington, DC, 20503 (Attention: ITA Desk Officer).

Dated: July 3, 2008.

David Spooner,

Assistant Secretary for Import Administration.

List of Subjects in 15 CFR Part 336

Imports, Quotas, Reporting and Record-keeping, Tariffs, Textiles. For reasons stated in the preamble, the Interim Final Rule, which was published on July 24, 2007 at 72 FR 40235, is adopted as final without change.

[FR Doc. E8-15754 Filed 7-9-08; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 902

50 CFR Part 648

[Docket No. 070817467-8744-03]

RIN 0648-AV90

Fisheries of the Northeastern United States; Atlantic Sea Scallop Fishery; Framework Adjustment 19; Announcing OMB Approval of Information Collection

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

ACTION: Final rule; effective date of OMB control numbers.

SUMMARY: The National Marine Fisheries Service (NMFS) announces that the Office of Management and Budget (OMB) has approved the following collection of information pursuant to the Paperwork Reduction Act of 1995: OMB 0648-0546, "Northeast Region Observer Providers Requirements." This rule publishes the OMB control number for these collections and makes effective the collection-of-information requirements published in a final rule to implement measures included in Framework Adjustment 19 (Framework 19) to the Atlantic Sea Scallop Fishery Management Plan (FMP).

DATES: This final rule is effective August 11, 2008. The amendments to 50 CFR 648.11(h)(5)(vii)(G) through (J), and the collection-of-information requirements published on May 29, 2008 (73 FR 30790), are effective August 11, 2008.

ADDRESSES: An environmental assessment (EA) was prepared for

Framework 19 that describes the action and other alternatives considered, and provides a thorough analysis of the impacts of the measures and alternatives. Copies of Framework 19, the EA, and the Initial Regulatory Flexibility Analysis (IRFA), are available upon request from Paul J. Howard, Executive Director, New England Fishery Management Council (Council), 50 Water Street, Newburyport, MA 01950. The Final Regulatory Flexibility Analysis (FRFA) was published in the Classification section of the final rule (73 FR 30790, May 29, 2008). Copies of the FRFA are available upon request from the Regional Administrator at the address listed in the next paragraph.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule may be submitted to the Regional Administrator at 1 Blackburn Drive, Gloucester, MA 01930 and by e-mail to David_Rostker@omb.eop.gov, or fax to (202) 395-7285.

FOR FURTHER INFORMATION CONTACT: Jamie Goen, Fishery Policy Analyst, phone 978-281-9220; fax 978-281-9135.

SUPPLEMENTARY INFORMATION: On May 29, 2008 (73 FR 30790), NMFS published a final rule to implement measures included in Framework Adjustment 19 (Framework 19) to the Atlantic Sea Scallop Fishery Management Plan (FMP), which was developed by the Council. Framework 19 included, in part, adjustments to the industry-funded observer program for the scallop fishery, which included a collection of information associated with regulations at 50 CFR 648.11(h)(5)(vii)(G) through (J). OMB's approval of NMFS PRA submission on the collection of information did not happen in time to publish their determination with the final rule on Framework 19.

The PRA and its implementing regulations require Federal agencies to display OMB control numbers and inform respondents of their legal significance after OMB has approved an Agency's information collection. An agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number, and no person is required to respond to a collection of information unless it displays a currently valid OMB control number. In accordance with the requirements of the PRA and its implementing regulations, NMFS notifies the public that the following information collection has been

approved by OMB following the Agency's submission of an information collection request (ICR):

OMB Control Number: 0648-0546.

OMB Approval Date: 06/03/08.

Expiration Date: 06/30/2011.

Title: Northeast Region Observer Providers Requirements.

This notice announces approval of the information collection listed above, publishes the OMB control number, and announces the effectiveness of the implementing regulations in 50 CFR 648.11(h)(5)(vii)(G) through (J).

Classification

NMFS determined that Framework 19 was necessary for the conservation and management of the Atlantic sea scallop fishery and was consistent with the Magnuson-Stevens Act and other applicable law. This rule announces OMB approval of a collection of information pursuant to the PRA and the effectiveness of regulations that were published in the final rule for Framework 19 dated May 29, 2008. Therefore, NMFS has also determined that this rule is necessary for the conservation and management of the Atlantic sea scallop fishery and is consistent with the Magnuson-Stevens Act and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

This rule contains a collection-of-information requirement subject to the PRA. The collection of this information was approved by OMB on June 3, 2008, under OMB Control Number 0648-0546. Public reporting burden for these collections of information are estimated to average as follows:

1. Service provider observer contact information reports, OMB # 0648-0546—5 min per response;
2. Service provider observer availability reports, OMB # 0648-0546—1 min per response;
3. Copies of service provider outreach materials, OMB # 0648-0546—30 min per response;
4. Copies of service provider contracts, OMB # 0648-0546—30 min per response.

More detail on these collections of information is available in the final rule for Framework 19 (73 FR 30790, May 29, 2008) and on the following website listing OMB approved PRA submissions: <http://www.cio.noaa.gov/itmanagement/prasubs.html>. Send comments regarding these burden estimates or any other aspect of this data collection, including suggestions for reducing the burden, to NMFS (see **ADDRESSES**) and by e-mail to

David Rostker@omb.eop.gov, or fax to 202-395-7285.

NMFS, pursuant to Section 604 of the Regulatory Flexibility Act (RFA), included a final regulatory flexibility analysis (FRFA) in the classification section of the Framework 19 final rule. This final rule only announces OMB approval of a collection of information and effectiveness of regulations contained in the Framework 19 final rule and analyses. Therefore, the FRFA is not repeated here. The FRFA described the economic impact the Framework 19 final rule will have on small entities. It incorporated the economic impacts and analysis summarized in the IRFA for the proposed rule to implement Framework 19, the comments and responses in the Framework 19 final rule, and the corresponding economic analyses prepared for Framework 19 (e.g., the EA and the RIR). A copy of the IRFA, the RIR, and the EA for Framework 19 is available upon request (see ADDRESSES).

List of Subjects in 15 CFR Part 902

Reporting and recordkeeping.

Dated: July 2, 2008.

John Oliver,

Deputy Assistant Administrator For Operations, National Marine Fisheries Service.

■ For the reasons stated in the preamble, 15 CFR part 902 is amended as follows:

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, the table in paragraph (b) under “50 CFR” is amended by revising the existing entry for § 648.11 to read as follows:

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

* * * * *

(b) Display.

CFR part or section where the information collection requirement is located	Current OMB control number (All numbers begin with 0648-)
* * * *	*
50 CFR * * * *	*
648.11	-0202,-0546, and -0555

CFR part or section where the information collection requirement is located	Current OMB control number (All numbers begin with 0648-)
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[FR Doc. E8-15610 Filed 7-9-08; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312, 314, 600, and 601

[Docket No. FDA-2004-N-0510] (formerly Docket No. 2004N-0267)

Applications for Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for approval to market new drugs and generic drugs (drugs for which approval is sought in an ANDA). The final rule discontinues FDA’s use of approvable letters and not approvable letters when taking action on marketing applications. Instead, we will send applicants a complete response letter to indicate that the review cycle for an application is complete and that the application is not ready for approval. We are also revising the regulations on extending the review cycle due to the submission of an amendment to an unapproved application and starting a new review cycle after the resubmission of an application following receipt of a complete response letter. In addition, we are adding to the regulations on biologics license applications (BLAs) provisions on the issuance of complete response letters to BLA applicants. We are taking these actions to implement the user fee performance goals referenced in the Prescription Drug User Fee Amendments of 2002 (PDUFA III) that address procedures and establish target timeframes for reviewing human drug applications.

DATES: This rule is effective August 11, 2008.

FOR FURTHER INFORMATION CONTACT: Brian L. Pendleton, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6304, Silver Spring, MD 20993, 301-796-3504; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

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I. Background

In the **Federal Register** of July 20, 2004 (69 FR 43351), we published a proposed rule to replace approvable and not approvable letters with complete response letters and to make other changes to our regulations on NDAs, ANDAs, and BLAs. Previous § 314.110 (21 CFR 314.110) set forth provisions on the issuance of and response to approvable letters; § 314.120 (21 CFR 314.120) addressed the issuance of and response to not approvable letters. The proposed rule proposed to replace those provisions with a revised § 314.110 regarding the issuance of complete response letters upon completion of our review of NDAs and ANDAs.

A. The Proposed Rule

The preamble to the proposed rule stated that the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) agreed to revise their regulations and procedures to provide for the issuance of complete response letters as part of our prescription drug