

would only clarify that sponsors must include in their applications the information described in § 514.1 that is appropriate for their particular submission, the agency proposes to certify that the rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

## VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## VII. Paperwork Reduction Act of 1995

This proposed rule refers to previously approved collections of information found in FDA regulations. The proposed rule would amend these previously approved collections of information by clarifying that NADAs must contain the information appropriate for the particular submission. Further, this amendment is based upon the Center for Veterinary Medicine's previous experience with these submissions. Thus, § 514.1, as amended, does not constitute a new or additional paperwork burden requiring Office of Management and Budget (OMB) approval.

Collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in

§ 514.1 have been approved under OMB Control No. 0910–0032.

## VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 514 be amended as follows:

### PART 514—NEW ANIMAL DRUG APPLICATIONS

1. The authority citation for 21 CFR part 514 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 356a, 360b, 371, 379e, 381.

2. In § 514.1, revise the first sentence of paragraph (a) and the introductory text of paragraph (b) to read as follows:

#### § 514.1 Applications.

(a) Applications to be filed under section 512(b) of the act shall be submitted in the form and contain the information described in paragraph (b) of this section, as appropriate to support the particular submission. \* \* \*

(b) Applications for new animal drugs shall be submitted in triplicate and assembled in the manner prescribed by paragraph (b)(15) of this section, and shall include the following information, as appropriate to support the particular submission: \* \* \*

\* \* \* \* \*

Dated: October 19, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 648

RIN 0648–AW72

### Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast (NE) Multispecies Fishery; Amendment 16

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

**ACTION:** Notice of availability of a fishery management plan amendment; request for comments.

**SUMMARY:** NMFS announces that the New England Fishery Management Council (Council) has submitted Amendment 16 to the NE Multispecies Fishery Management Plan (FMP) and its associated draft Final Environmental Impact Statement (FEIS) for Secretarial review and is requesting comments from the public. Amendment 16 was developed by the Council as part of the biennial adjustment process in the FMP to update status determination criteria for all regulated NE multispecies or ocean pout stocks; to adopt rebuilding programs for NE multispecies stocks newly classified as being overfished and subject to overfishing; and to revise management measures, including significant revisions to the Sector management and allocation measures, necessary to end overfishing, rebuild overfished regulated NE multispecies or ocean pout stocks, and mitigate the adverse economic impacts of increased effort controls. Amendment 16 would also implement new requirements for establishing allowable biological catch (ABC), annual catch limits (ACLs), and accountability measures (AMs) for each stock managed by the FMP, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Finally, this action would add Atlantic wolffish to the list of species managed by the FMP. This action is necessary to address the results of the most recent stock assessment, which indicate that several additional NE multispecies regulated species are overfished and subject to overfishing and that some stocks currently classified as overfished require additional reductions in fishing mortality to rebuild by the end of their rebuilding periods.

**DATES:** Comments must be received on or before December 22, 2009.

**ADDRESSES:** You may submit comments, identified by 0648-AW72, by any of the following methods:

- Email: [MultsA16FEIS@noaa.gov](mailto:MultsA16FEIS@noaa.gov).

Include in the subject line RIN or text that identifies the subject **Federal Register** document open for comment.

- Federal eRulemaking Portal: <http://www.regulations.gov>.

- Fax: (978) 281-9135, Attn: Douglas Christel.

- Mail or hand-delivery: Paper, disk, or CD-ROM comments should be sent to Patricia A. Kurkul, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, "Comments on the NE Multispecies Amendment 16 FEIS."

Instructions: All comments received are part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (either N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Copies of Amendment 16, its Regulatory Impact Review (RIR), and the draft of the FEIS are available from Paul J. Howard, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950. Copies of the Initial Regulatory Flexibility Analysis (IRFA) are available from the Regional Administrator at the address above. The EIS/RIR/IRFA is also accessible via the Internet at <http://www.nefmc.org/nemulti/index.html>.

**FOR FURTHER INFORMATION CONTACT:**

Douglas Christel, Fishery Policy Analyst, phone: 978-281-9141, fax: 978-281-9135.

**SUPPLEMENTARY INFORMATION:**

Amendment 13 to the FMP, which became effective May 1, 2004 (April 27, 2004; 69 FR 22906), established two different strategies for rebuilding (an adaptive strategy and a phased rebuilding strategy), and a rebuilding plan for each overfished stock was developed in accordance with one of the two strategies. Under the "adaptive" rebuilding strategy, the fishing mortality

rate (F) is held at a level that would produce maximum sustainable yield ( $F_{MSY}$ ) from 2004 through 2008, and then is subsequently reduced to the level required to rebuild by the selected end-date of the rebuilding period. In contrast, under the "phased" rebuilding strategy, F was allowed to remain above  $F_{MSY}$  at the start of the rebuilding period in 2004, and then was reduced sequentially in 2006 and 2009. Eight stocks (Gulf of Maine (GOM) cod, Georges Bank (GB) haddock, GOM haddock, Southern New England (SNE)/Mid-Atlantic (MA) winter flounder, GB yellowtail flounder, redfish, windowpane flounder (southern stock), and ocean pout) are managed under the adaptive rebuilding strategy, while five stocks (GB cod, Cape Cod (CC)/GOM yellowtail flounder, SNE/MA yellowtail flounder, American plaice, and white hake) are managed under the phased rebuilding strategy.

Amendment 13 also established a biennial adjustment process whereby the Council reviews the FMP and makes any changes to management measures necessary to achieve the goals and objectives of the FMP. This adjustment process provides an update of the scientific information regarding the status of the stocks and an evaluation of the effectiveness of the regulations. The biennial review scheduled to occur in 2008, with necessary changes to the FMP implemented in 2009, included a peer-reviewed benchmark assessment and a review of the biological reference points (stock status determination criteria) for each stock. This planned assessment of the biological reference points (Groundfish Assessment Review Meeting, (GARM III)) was also part of the adaptive rebuilding strategy described above, which sought to evaluate the more fundamental scientific information mid-way through the rebuilding period for most stocks. GARM III, completed in August 2008, included a series of meetings over the course of one year. GARM III evaluated the underlying data and models utilized for assessment of the groundfish stocks, evaluated the biological reference points, established new reference points, assessed the biomass and fishing mortality status of the groundfish stocks in 2007, and provided examples of the Fs that would be expected to rebuild overfished stocks.

GARM III concluded that 11 stocks were still subject to overfishing (i.e., fishing above the  $F_{MSY}$ ) and that 12 stocks were overfished (i.e., biomass levels were less than one half of the biomass at  $MSY$  ( $B_{MSY}$ )), with 10 stocks classified as both overfished and subject to overfishing. A final determination on

the status of pollock could not be made until the fall 2008 survey data made available, as the status of this species is based on the 3-year centered average of the fall biomass indices. Such data became available in January 2009, and indicated that pollock is overfished.

The Council began development of Amendment 16 in 2006, with the intent of implementing any necessary revisions to management measures by the start of fishing year (FY) 2009 on May 1, 2009. On November 6, 2006, a notice of intent to prepare a supplemental EIS and hold scoping meetings designed to solicit public input on any revisions to management measures necessary to continue rebuilding overfished groundfish stocks was published in the **Federal Register** (71 FR 64941). The Council continued to develop Amendment 16 for implementation in FY 2009 until a presentation by the Northeast Fisheries Science Center NMFS (NEFSC) regarding preliminary estimates of 2006 stock size and F at the June 2008 Council meeting indicated that draft effort control measures under development for Amendment 16 were not targeting the correct stocks. Based on this information, the Council decided to wait until the receipt of the final GARM III assessment results in September 2008 to continue the development of appropriate management measures under Amendment 16. The Council subsequently developed a revised schedule of development for Amendment 16, which postponed implementation of Amendment 16 until the start of FY 2010 on May 1, 2010. In addition, the Council voted on September 4, 2008, to request that NMFS implement an interim action for the duration of FY 2009 (May 1, 2009–April 30, 2010), and recommended a specific suite of management measures for the interim action. A proposed rule to implement interim management measures published on January 16, 2009 (74 FR 2959), with final interim measures published on April 13, 2009 (74 FR 17030) and effective on May 1, 2009.

Based upon the final results of GARM III, the Council adopted draft management measures and an associated draft EIS (DEIS) at its February 2009 meeting. A notice of availability for the DEIS, which analyzed the impacts of all of the measures under consideration in Amendment 16, was published on April 24, 2009 (74 FR 18705), with public comments accepted through June 8, 2009. Final measures under Amendment 16 were adopted by the

Council at its June 2009 meeting. In addition to the implementing management measures to reduce F for overfished stocks, Amendment 16 contains changes to status determination criteria and other aspects of the management program, such as an ABC control rule and potential sector contributions, that are not reflected in regulations. The proposed measures include: Revisions to biological reference points for most stocks; incorporation of Atlantic wolffish into the list of NE multispecies managed by the FMP; new reporting measures to increase timeliness and accuracy of catch data; changes in the allocation of days-at-sea (DAS) between Category A DAS and Category B DAS; changes to the way NE multispecies DAS are allocated and counted; gear restricted areas; modifications to the DAS Leasing and Transfer Programs; changes in minimum fish size for two stocks; revisions to special access programs

(SAPs); modifications to existing trip limits, including increased trip limits for some stocks and landings prohibitions for other stocks; changes to Sector allocation procedures; modifications to Sector eligibility requirements; revisions to Sector operation plan requirements, including new and revised monitoring and reporting requirements and allowable exemptions; approval of 17 new Sectors; revisions to recreational gear, seasonal, and possession restrictions; establishment of a process to set and distribute ABCs and ACLs for all managed stocks among fishery subcomponents; and AMs for both commercial and recreational fisheries.

A proposed rule that would implement Amendment 16, if approved, will be published in the **Federal Register** for public comment, following NMFS's evaluation of the proposed rule under the procedures of the Magnuson-Stevens Act. Public comments on the proposed rule must be received by the

end of the comment period on Amendment 16 to be considered in the approval/disapproval decision on the amendment. All comments received by December 22, 2009, whether specifically directed to Amendment 16 or the proposed rule, will be considered in the approval/disapproval decision on the amendment. Any comments on the proposed rule received after that date will not be considered in the decision to approve or disapprove Amendment 16. To be considered, comments must be received by the close of business on the last day of the comment period; that does not mean postmarked or otherwise transmitted by that date.

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

Dated: October 19, 2009.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service*  
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