

be exhibited, at any location other than their designated primary facility.

Estimated annual number of respondents: 300.

Estimated annual number of responses per respondent: 8.66.

Estimated annual number of responses: 2,600.

Estimated total annual burden on respondents: 650 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS Information Collection Coordinator, at (301) 851-2908.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS Information Collection Coordinator, at (301) 851-2908.

List of Subjects in 9 CFR Part 2

Animal welfare, Pets, Reporting and recordkeeping requirements, Research.

Accordingly, we propose to amend 9 CFR part 2 as follows:

PART 2—REGULATIONS

1. The authority citation for part 2 continues to read as follows:

Authority: 7 U.S.C. 2131-2159; 7 CFR 2.22, 2.80, and 371.7.

2. In § 2.126, the section heading is revised and a new paragraph (c) is added to read as follows:

§ 2.126 Access and inspection of records and property; submission of itineraries.

* * * * *

(c) Any person who is subject to the Animal Welfare regulations and who intends to exhibit any animal at any location other than the person's approved site(s) (including, but not limited to, circuses, traveling educational exhibits, animal acts, and petting zoos) shall submit a written itinerary to the Animal Care Regional Director. The itinerary shall be received by the Animal Care Regional Director no fewer than 2 days in advance of any travel and shall contain complete and accurate information concerning the whereabouts of any animal(s) intended

for exhibition at any location other than the person(s) approved site(s).

(1) The itinerary shall include the following:

(i) The name(s) of the person(s) who intends to exhibit the animal(s) and transport the animal(s) for exhibition purposes, including any business name(s) and current AWA license or registration number(s) and, in the event that any animal is leased, borrowed, loaned, or under some similar arrangement, the name of the person who owns such animal;

(ii) The name, identification number or identifying characteristics, species (common or scientific name), sex and age of each animal; and

(iii) The names, dates, and locations (with addresses), where the animals will travel, be housed, and be exhibited, including all anticipated dates and locations (with addresses) for any stops and layovers.

(2) The itinerary shall be promptly revised, as necessary, to account for any changes.

Done in Washington, DC, this 25th day of September 2009.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E9-23679 Filed 9-30-09; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

[Docket No. 0907301210-91239-01]

RIN 0648-AX83

Gulf of the Farallones and Monterey Bay National Marine Sanctuaries Regulations on Introduced Species

AGENCY: Office of National Marine Sanctuaries (ONMS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of proposed rulemaking; request for public comments.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) is proposing to revise its regulations on the introduction of introduced species into the Gulf of the Farallones and Monterey Bay national marine sanctuaries (GFNMS and MBNMS, respectively). This action is being taken in response to a letter received by the Governor of California on December 23, 2008. The Governor certified that the

terms of designation to regulate introduced species in these sanctuaries were unacceptable in State waters of the sanctuaries. In response to the Governor's letter, NOAA is proposing to modify its regulations to except all State-permitted aquaculture activities in the two sanctuaries.

DATES: Comments must be received by November 16, 2009.

ADDRESSES: You may submit comments by any of the following methods:

- *Electronic submission (preferred method):* <http://www.regulations.gov> (search for docket # NOAA-NOS-2009-0105).

- *Mail:* John Armor, Office of National Marine Sanctuaries, 1305 East-West Highway, Silver Spring, Maryland 20910.

Instructions: All comments received are a part of the public record and will be generally 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. NOAA will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: John Armor, Office of National Marine Sanctuaries, 1305 East-West Highway, Silver Spring, MD 20910, or by phone at 301-713-3125.

SUPPLEMENTARY INFORMATION:

I. Background

A. GFNMS and MBNMS Background

NOAA established the GFNMS in 1981 to protect and preserve a unique and fragile ecological community, including the largest seabird colony in the contiguous United States and diverse and abundant marine mammals. The GFNMS lies off the coast of California, to the west and north of San Francisco, and is composed of 1,279 square statute miles (966 square nautical miles) of offshore waters and submerged lands thereunder. The sanctuary boundary extends out to and around the Farallon Islands and nearshore waters (up to the mean high water line) from Bodega Head to Rocky Point in Marin. For more information about the GFNMS, see <http://farallones.noaa.gov>.

NOAA established the MBNMS in 1992 for the purposes of protecting and managing the conservation, ecological,

recreational, research, educational, historical, and esthetic resources and qualities of the area. The MBNMS is located offshore of California's central coast, adjacent to and south of the GFNMS. It encompasses a shoreline length of approximately 276 statute miles (240 nmi) between Rocky Pt. in Marin County and Cambria in San Luis Obispo County. The sanctuary spans approximately 6,094 square statute miles (4,602 square nautical miles) of ocean and coastal waters, and the submerged lands thereunder, extending an average distance of 30 statute miles (26 nmi) from shore. The Davidson Seamount is also part of the sanctuary, though it does not share a contiguous boundary. Supporting some of the world's most diverse marine ecosystems, the MBNMS is home to numerous mammals, seabirds, fishes, invertebrates, sea turtles and plants in a remarkably productive coastal environment. For more information about the MBNMS, please see <http://montereybay.noaa.gov>.

B. Regulatory Background

Pursuant to section 304(e) of the National Marine Sanctuaries Act (16 U.S.C. 1434 *et seq.*) (NMSA), the Office of National Marine Sanctuaries (ONMS) conducted a joint review of the management plans for the Gulf of the Farallones, Monterey Bay and Cordell Bank national marine sanctuaries. This review resulted in revised management plans, regulations, and terms of designation for all three sanctuaries. On November 20, 2008, NOAA published the associated final rule and terms of designation (73 FR 70488) and released the revised management plans.

Pursuant to section 304(b) of the National Marine Sanctuaries Act (NMSA), changes to a sanctuary's terms of designation and the associated regulations do not become effective until after forty-five days of continuous session of Congress. After forty-five days, in this case on March 9, 2009, the regulations would become final and take effect, except that any term of designation the Governor certified as unacceptable would not take effect in the area of a sanctuary lying within the seaward boundary of the State ("State waters"). If exercised, the effect of a gubernatorial objection is that the term(s) of designation do not become effective in State waters. Any regulations that rely on the change in terms of designation also do not become effective in State waters.

In the November 20, 2008 final rule, NOAA changed the terms of designation for the GFNMS and MBNMS to clearly allow regulation of introduced species.

Pursuant to section 304(b) of the NMSA, the Governor could accept or reject those changes to the terms of designation.

C. Certification by the Governor of California

On December 23, 2008, during the forty-five day review period under the NMSA, the Governor of the State of California certified by letter to the Secretary of Commerce that certain terms of designation regarding regulation of the introduction of introduced species in State waters were unacceptable. The following is the text of the December 23, 2008, letter from the Governor of California to the United States Secretary of Commerce.

December 23, 2008

Honorable Carlos M. Gutierrez
Secretary of Commerce
1401 Constitution Avenue Northwest
Washington, DC 20230.

Dear Mr. Secretary:

Since the designation of the Channel Islands National Marine Sanctuary in 1981, the National Oceanic and Atmospheric Administration's Office of National Marine Sanctuaries (ONMS) and the State of California have been working together to ensure the protection of our special and unique national marine sanctuaries. California very much appreciates the strong working relationship we have with our Federal partners, and I think we've done a lot of good work together to protect our coastal and ocean resources and to educate Californians about the importance of these resources.

In 2001, ONMS initiated a process to review and update the management plans and corresponding regulations of the three national marine sanctuaries off the California coast: Monterey Bay, Gulf of the Farallones and Cordell Bank. In October 2006, ONMS released the draft management plans and a draft environmental impact statement. In January 2007, the State of California submitted comments to ONMS. Since then, the State of California and ONMS have successfully resolved all concern regarding proposed regulations, with the exception of the following proposed regulations regarding introduced species:

For Gulf of the Farallones National Marine Sanctuary § 922.82(10):

Introducing or otherwise releasing from within or into the Sanctuary and introduced species except:

(A) Striped bass (*Morone saxatilis*) released during catch and release fishing activity; or
(B) Species cultivated by mariculture activities in Tomales Bay pursuant to a valid lease, permit, license or other authorization issued by the State of California and in effect on the effective date of the final regulation.

For Monterey Bay National Marine Sanctuary § 922.132(12):

Introducing or otherwise releasing from within or into the Sanctuary an introduced species, except striped bass (*Morone saxatilis*) released during catch and release fishing activity.

We agree with ONMS's assertion that introduced species can threaten our ocean and coastal ecosystems if not properly managed in the context of an aquaculture program. However, we object to the proposed regulations for several reasons:

1. There is no authority in either State or Federal law for the proposition that all non-native species are necessarily detrimental to native wildlife and must therefore be prohibited.

2. The California State legislature has not granted any submerged lands to the Federal government that would enable a sanctuary to assert authority over aquaculture operations in State waters.

3. The release of harmful non-native species is already controlled under State law, and any proposed introduction of non-native aquaculture species is subject to multiple agency review and to the California Environmental Quality Act.

In our January 2007 comment letter, the State of California suggested the following changes to the proposed regulations (deletions noted in *italics* and additions in UPPERCASE font):

For Gulf of the Farallones National Marine Sanctuary § 922.82(10):

Introducing or otherwise releasing from within or into the Sanctuary and introduced species, except:

(A) Striped bass (MORONE SAXATILIS) released during catch and release fishing activity; or

(B) Species cultivated by mariculture activities in Tomales Bay pursuant to a valid lease, permit, license or other authorization issued by the State of California *and in effect on the effective date of the final regulation.*

For Monterey Bay National Marine Sanctuary § 922.132(12):

Introducing or otherwise releasing from within or into the Sanctuary and introduced species, except striped bass (MORONE SAXATILIS) released during catch and release fishing activity OR THROUGH MARICULTURE OR RESEARCH ACTIVITIES CONDUCTED PURSUANT TO A VALID LEASE, PERMIT, LICENSE OR OTHER AUTHORIZATION ISSUED BY THE STATE OF CALIFORNIA.

These changes will allow us to protect sanctuary resources from introduced species without conflicting with State authority to manage aquaculture in State waters.

Despite the concerns expressed by the State of California, ONMS included these proposed regulations in the final environmental impact statement dated September 15, 2008, and the notice in the **Federal Register** dated November 20, 2008.

If ONMS is unable or unwilling to make the requested changes, I hereby use the authority given to me by the National Marine Sanctuaries Act (16 U.S.C. 1434(b)(1)) to certify that certain terms in the designation documents of the Gulf of the Farallones and Monterey Bay National Marine Sanctuaries are unacceptable. As a result, the unacceptable term of designation document shall not take effect in the area of the sanctuary lying within the seaward boundary of the State of California.

For the Gulf of the Farallones National Marine Sanctuary, I certify that Article IV,

section 1(e) of the designation document is unacceptable. Article IV, section 1(e) reads, "Introducing or otherwise releasing from within or into the Sanctuary an introduced species."

For the Monterey Bay National Marine Sanctuary, I certify that Article IV, section 1(l) of the designation document is unacceptable. Article IV, section 1(l) reads, "Introducing or otherwise releasing from within or into the Sanctuary an introduced species."

ONMS and the State of California have been working together for almost 30 years to ensure the protection of the national marine sanctuaries off California's coast. In the spirit of this ongoing partnership, I urge ONMS to respect the State of California's sovereign right to manage its resources in State waters, and I ask that ONMS make the requested changes in the Gulf of the Farallones and Monterey Bay National Marine Sanctuaries proposed regulations and designation documents. I look forward to continuing to work with you on this important issue.

Sincerely,

Arnold Schwarzenegger

D. NOAA's Response to the Governor

In his letter, the Governor indicated that the State of California's concerns were clearly articulated in its comments on the proposed rule (71 FR 59338, October 6, 2006). However, NOAA believes the State's position on the introduced species regulation was not clear. During the comment period on the proposed rule, NOAA received comments from the California Department of Fish and Game (CDFG), the California Department of Boating and Waterways (CDBW), the California Coastal Commission (CCC), and California State Lands Commission. The CDFG and CDBW both opposed NOAA's prohibition on the introduction of introduced species but the two commissions were either silent or explicitly supportive of it. To add further complexity to the State's position, the CCC—exercising its authority under the Federal consistency provisions of the Coastal Zone Management Act—specifically, rejected the CDFGs requested change and stated that NOAA must maintain the prohibition on introduced species as it was written in the proposed rule or else the final regulations would not be consistent with the enforceable policies of the California Coastal Management Program, which NOAA complies with. Therefore, NOAA did not anticipate the State of California's position on the matter when NOAA received the Governor's objection letter after the final rule was issued.

NOAA notes that the proposed and final regulations were drafted with a significant level of input from State agencies and commissions. The current

language was developed following numerous consultations with State personnel when NOAA first began the process of changing the terms of designation and regulations for the sanctuaries. For example, during consultations with the State of California, concern was expressed that striped bass would qualify as an introduced species and that an angler who catches and then releases a striped bass to comply with State imposed site restrictions would be in violation of the proposed regulation. Because prohibiting such activity was not the intent of the regulation, to address this concern, NOAA drafted the regulation to except striped bass, the only introduced species for which there is an active fishery.

After receiving the Governor's letter, NOAA worked with staff from the California Natural Resources Agency and the California Department of Fish and Game to find solutions to the Governor's concerns that would also meet NOAA's goals. As such, NOAA agreed to modify the regulations on introduced species to except State-permitted aquaculture in GFNMS. NOAA agreed to not enforce the invasive species provisions in the State waters of the GFNMS until NOAA could initiate a new rulemaking to consider the issue more closely and to consider public comment on the matter.

NOAA did not agree, however, to allow the research exception involving the introduction of introduced species in the MBNMS, as the Governor requested. In subsequent discussions with the State, NOAA was not provided with a reason why such an exemption would be needed. Neither the Governor nor the agencies with which NOAA worked at the State of California provided any description of how this exception would be used, what types of research activities would qualify, or what the effect of it would be on sanctuary resources.

NOAA noted to the State of California's Natural Resources Agency that if, in the future, there were a research proposal that involved the introduction of introduced species, the regulations would still allow NOAA to issue a permit, in coordination with the relevant State agencies, that would allow the research project to proceed. Therefore, NOAA explained to the State, the potential consequences to the sanctuary of excepting research from the introduced species regulation far outweighed the potential administrative consequences of issuing a regulation that would require researchers to obtain a permit from NOAA for the introduction of introduced species. The

State rejected this option and, because no compromise was attained, the Governor's objection to the term of designation for the regulation of introduced species in the State waters of the MBNMS stands. As indicated in the notice of effective date (March 23, 2009; 74 FR 12088), the regulation of the introduction of introduced species from within or into the MBNMS is valid and in effect in the area of the sanctuary lying beyond the seaward boundary of the State only.

II. Summary of the Proposed Revisions to the Regulation of Introduction of Introduced Species in GFNMS

The regulations for the GFNMS currently prohibit introducing or otherwise releasing from within or into the sanctuary (1) an introduced species, except striped bass (*Morone saxatilis*) released during catch and release fishing activity; and (2) species cultivated by mariculture activities in Tomales Bay pursuant to a valid lease, permit, license or other authorization issued by the State of California and in effect on the effective date of the final regulation. As proposed, the revised regulations for the GFNMS would remove the geographic reference to Tomales Bay and would revise the exception so as to allow the State-permitted mariculture activities in the area of the sanctuary that is within the seaward boundary of the State.

The term "introduced species" is defined as: (1) Any species (including, but not limited to, any of its biological matter capable of propagation) that is non-native to the ecosystems of the Sanctuary; or (2) any organism into which altered genetic matter, or genetic matter from another species, has been transferred in order that the host organism acquires the genetic traits of the transferred genes.

NOAA issued this regulation due to the threats introduced species pose to endangered species and native species diversity. For example, a number of non-native species now found in the Gulf of the Farallones and Monterey Bay regions were introduced elsewhere on the west coast but have spread through vectors such as vessel hull-fouling, ballast water discharge, and accidental introductions. NOAA also stated that introduced species are a major economic and environmental threat to the living resources and habitats of a sanctuary as well as the commercial and recreational uses that depend on these resources. Once established, introduced species can be extremely difficult, if not impossible, to eradicate. Introduced species have become increasingly common in recent decades, and the rate

of invasions continues to accelerate at a rapid pace. Threatened and endangered species are particularly vulnerable to invasion.

As such, NOAA continues to believe it is important to regulate the introduction of introduced species in a manner that is consistent with the sanctuary's and NMSA's goals. NOAA believes that the compromise language provided by the Governor of California would meet the objectives. Therefore, NOAA proposes to amend § 922.82(a)(10) as requested by the Governor, to expand the geographic and temporal scope of the exception for introduced species through State-permitted aquaculture in State waters. If adopted, these changes would change the geographic restriction of mariculture activities in Tomales Bay to all of the State waters. The new regulations would also remove the temporal component of the current regulations, allowing the State of California to issue additional permits for these activities.

III. Summary of the Revisions to MBNMS Regulations

In issuing the November 20, 2008 final rule, NOAA revised the MBNMS terms of designation to modify the list of activities that may be regulated. As revised, the terms of designation clearly authorize the regulation of "introducing or otherwise releasing from within or into the sanctuary an introduced species." This revision was intended to enable NOAA to more effectively and efficiently address new and emerging resource management issues, and was necessary in order to ensure protection, preservation, and management of the conservation, recreational, ecological, historical, cultural, educational, archeological, scientific, and esthetic resources and qualities of the MBNMS. However, this new term of designation does not apply to the State-waters part of the MBNMS due to the Governor's objection. NOAA indicated this in the notice of effective date (March 23, 2009; 74 FR 10488). As such, that specific term of designation should now read, "introducing or otherwise releasing from within or into the Federal waters of the sanctuary an introduced species." NOAA is proposing to modify the regulation associated with this term of designation to reflect the Governor of California's certification of this term as unacceptable.

NOAA proposes to update the regulations, at subpart M, § 922.132(a)(12), to conform with the Governor's objection so the scope of this portion of the JMPR's November 20, 2008 final rule will only apply to the area of the Sanctuary lying beyond the

seaward boundary of the State of California.

IV. Miscellaneous Rulemaking Requirements

A. National Marine Sanctuaries Act

Section 301(b) of the National Marine Sanctuaries Act (16 U.S.C. 1434) provides authority for comprehensive and coordinated conservation and management of national marine sanctuaries in coordination with other resource management authorities. Section 304(a)(4) of the National Marine Sanctuaries Act requires the procedures specified in section 304 for designating a national marine sanctuary be followed for modifying any term of designation. This action does not propose to revise the terms of designation for either sanctuary.

B. National Environmental Policy Act

NOAA prepared a final environmental impact statement (FEIS) to evaluate regulating the introduction of introduced species off the California coast. NOAA identified a preferred action in that FEIS, but is now proposing to implement a different action based on the Governor's letter of December 23, 2008. NOAA has analyzed the impacts of this action in the FEIS for the joint management plan review for the three national marine sanctuaries on the central California coast (availability of which was announced in the **Federal Register** on September 26, 2008; 73 FR 55843). NOAA intends to issue a new record of decision (ROD) with regard to this action. Copies of the FEIS are available at <http://sanctuaries.noaa.gov/jointplan/feis/feis.html>, or by contacting NOAA at the address listed in the Address section of this proposed rule.

C. Executive Order 12866: Regulatory Impact

This proposed rule has been determined to be not significant within the meaning of Executive Order 12866.

D. Executive Order 13132: Federalism Assessment

NOAA has concluded that this regulatory action falls within the definition of "policies that have federalism implications" within the meaning of Executive Order 13132. The changes will not preempt State law, but will simply update sanctuary regulations to comply with the Governor's action. In keeping with the intent of the Executive Order, the NOAA consulted with a number of entities within the State which participated in development of the initial rule, including but not limited to, the California Department of Fish and

Game, and the California Natural Resources Agency.

E. Regulatory Flexibility Act

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration this rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this certification is as follows:

Using the SBA's Small Business Size Standards, NOAA determined that the small business concerns operating within the both of the sanctuaries include: Commercial fishermen who vary in number seasonally and annually from approximately 300 to 500 boats; twelve mariculture leaseholders in Tomales Bay (in GFNMS); approximately 25 recreational charter-fishing businesses; and approximately 7 recreational charter businesses engaged in wildlife viewing. The small organizations, as defined under 5 U.S.C. 601(4), that would be impacted by this rule include approximately 3 small organizations operating within the GFNMS, which include non-governmental organizations (NGOs) and/or non-profit organizations (NPOs) dedicated to environmental education, research, restoration, and conservation concerning marine and maritime heritage resources. The small governmental jurisdictions, as defined under 5 U.S.C. 601(5), that would be impacted by this rule are the Bodega, Bolinas and Tomales Bay settlements that are directly adjacent to the GFNMS.

The prohibition on releasing or otherwise introducing from within or into the GFNMS and in the area of the MBNMS lying beyond the seaward boundary of the State an introduced species is not expected to significantly adversely impact small entities because this activity is not part of the business or operational practices associated with most of the small entities that would be impacted by this rule. Small entities whose operational practices may include catch and release of striped bass (*Roccus saxatilis*), (*i.e.*, consumptive recreational charter businesses), would not be affected because the prohibition would not apply to the catch and release of fish already present in the sanctuaries. In fact, the prohibition against introduced species may result in indirect benefits for certain small entities since their activities could potentially be negatively impacted by the spread of introduced species.

The mariculture leaseholders located adjacent to the GFNMS may, however, be potentially impacted by this

proposed rule. Under the current regulations, existing leaseholders are excepted from the introduced species prohibition if they have active lease agreements at the time of implementation of the regulation (the regulation took effect on March 9, 2009). Under the proposed rule for the GFNMS, this exemption will no longer contain a geographic restriction of Tomales Bay, and will no longer restrict new permits from being issued through the State (as opposed to through the ONMS). This prohibition would not put any current operations out of business, because they will not need to change anything about their current procedures to continue in their operations. A beneficial effect from this proposed action may result for existing and future lease holders, such as reduced administrative burden for issuance or renewal of a lease permit. Comments received on the economic impacts of this proposed rule will be summarized and responded to in the final rule.

F. Paperwork Reduction Act

This proposed rule does not contain information collections that are subject to the requirements of the Paperwork Reduction Act. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any 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.

V. Request for Comments

NOAA requests comments on this proposed rule for 45 days after publication of this notice.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Environmental protection, Fish, Harbors, Marine pollution, Marine resources, Natural resources, Penalties, Recreation and recreation areas, Research, Water pollution control, Water resources, Wildlife.

Dated: September 24, 2009.

William Corso,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

Accordingly, for the reasons set forth above, 15 CFR part 922 is amended as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM REGULATIONS

1. The authority citation for Part 922 continues to read as follows:

Authority: 16 U.S.C. 1431 *et seq.*

Subpart H—Gulf of the Farallones National Marine Sanctuary

2. Section 922.82(a)(10) is amended to read as follows:

§ 922.82 Prohibited or otherwise regulated activities.

(a) * * *

(10) Introducing or otherwise releasing from within or into the Sanctuary an introduced species, except:

(i) Striped bass (*Morone saxatilis*) released during catch and release fishing activity; or

(ii) Species cultivated by a mariculture activity within the area of the sanctuary lying within the seaward boundary of the State of California and authorized by a valid lease, permit, license or other authorization issued by the State.

* * * * *

Subpart M—Monterey Bay National Marine Sanctuary

3. Section 922.132(a)(12) is amended to read as follows:

§ 922.132 Prohibited or otherwise regulated activities.

(a) * * *

(12) Introducing or otherwise releasing from within or into the area of the Sanctuary lying beyond the seaward boundary of the State of California an introduced species, except striped bass (*Morone saxatilis*) released during catch and release fishing activity.

* * * * *

[FR Doc. E9-23576 Filed 9-30-09; 8:45 am]

BILLING CODE 3510-NK-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 4

[Docket No. FDA-2008-N-0424]

RIN 0910-AF82

Postmarketing Safety Reporting for Combination Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the combination product regulations to set forth postmarketing safety reporting requirements for combination products. Specifically, the rule will clarify the postmarketing safety

reporting requirements that apply when regulated articles (drugs, devices, and biological products) are combined to create a combination product. The proposed rule is intended to promote and protect the public health by clarifying requirements for postmarketing safety reporting for combination products, and is part of FDA's ongoing effort to ensure the consistency and appropriateness of the regulatory requirements for combination products.

DATES: Submit written or electronic comments on the proposed rule by December 30, 2009. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by November 2, 2009, (see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2008-N-0424 and/or RIN number 0910-AF82, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For