

comment period to update comments and to receive any new information. Elsewhere in this issue of the **Federal Register**, FDA is also reopening the comment period on a notice of availability of a draft guidance document that would serve as the special control if FDA reclassifies this device.

**DATES:** Submit written or electronic comments on the proposed rule by October 14, 2008.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3638.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of October 31, 2006 (71 FR 63728), FDA published a proposed rule to reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket approval) to class II (special controls). FDA invited interested persons to comment on the proposed rule by January 29, 2007. In the **Federal Register** of May, 8, 2007 (72 FR 26011), FDA reopened the comment period for 30 days in response to two requests for additional time for preparation of comments.

On July 2, 2007, FDA received a petition under 21 CFR 10.30 and 10.35 requesting that the agency refrain from issuing a final regulation for the proposed reclassification and the draft special controls guidance for the absorbable hemostatic device until an updated and complete administrative record is made available to the public. The petitioner also requested that FDA reopen the rulemaking for the proposed reclassification to allow submission of comments based on the administrative record. FDA has updated the administrative record in the Division of Dockets Management (see **ADDRESSES**). FDA is also reopening the comment period for 30 days. Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on a notice of availability of a draft guidance document that would serve as the special control if the device is reclassified.

**II. How to Submit 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 to <http://www.regulations.gov> 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: September 4, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 301**

**[REG-160868-04]**

**RIN 1545-BF61**

**Section 6707A and the Failure To Include on Any Return or Statement Any Information Required To Be Disclosed Under Section 6011 With Respect to a Reportable Transaction**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking by cross-reference to temporary regulations.

**SUMMARY:** In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations under section 6707A of the Internal Revenue Code (Code), which provide the rules relating to the assessment of penalties under section 6707A for the failure to include on any return or statement any information required to be disclosed under section 6011 with respect to a reportable transaction. The text of those temporary regulations also serves as the text of these proposed regulations.

**DATES:** Written or electronic comments and requests for a public hearing must be received by December 10, 2008.

**ADDRESSES:** Send submission to: CC:PA:LPD:PR (REG-160868-04), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-160868-04), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS REG-160868-04).

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Matthew Cooper (202) 622-4940; concerning submissions of comments and requests for a public hearing, Richard Hurst (202) 622-2949 (TDD telephone) (not toll-free numbers) and his e-mail address is [Richard.A.Hurst@irs.counsel.treas.gov](mailto:Richard.A.Hurst@irs.counsel.treas.gov).

**SUPPLEMENTARY INFORMATION:**

**Background and Explanation of Provisions**

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Procedure and Administration Regulations (26 CFR part 301) relating to section 6707A. Section 811 of the American Jobs Creation Act of 2004, Public Law 108-357 (118 Stat. 1418) added section 6707A to the Code to provide a monetary penalty for the failure to include on any return or statement any information required to be disclosed under section 6011 with respect to a reportable transaction. The temporary regulations set forth the rules relating to the assessment of the penalty as well as the factors that the Commissioner (or the Commissioner's delegate) will consider in deciding whether the penalty should be rescinded based on promoting compliance with the Code and effective tax administration. The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments.

**Special Analyses**

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply

to these regulations, and because they do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

### Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and the Treasury Department request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be made available for public inspection and copying. A public hearing may be scheduled if requested by any person who timely submits comments. If a public hearing is scheduled, notice of the date, time and place for the public hearing will be published in the **Federal Register**.

### Drafting Information

The principal author of these regulations is Matthew Cooper, Office of the Associate Chief Counsel (Procedure and Administration).

### List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

### Proposed Amendments to the Regulations

Accordingly, 26 CFR part 301 is proposed to be amended as follows:

#### PART 301—PROCEDURE AND ADMINISTRATION

**Paragraph 1.** The authority citation for part 301 continues to read in part as follows:

**Authority:** 26 U.S.C. 7805 \* \* \*

**Par. 2.** Section 301.6707A-1 is added to read as follows:

**§ 301.6707A-1 Failure to include on any return or statement any information required to be disclosed under section 6011 with respect to a reportable transaction.**

[The text of proposed § 301.6707A-1 is the same as the text of § 301.6707A-

1T published elsewhere in this issue of the **Federal Register**].

**Linda E. Stiff,**

*Deputy Commissioner for Services and Enforcement.*

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 680

**RIN 0648-AW73**

#### Fisheries of the Exclusive Economic Zone Off Alaska; Allocating Bering Sea and Aleutian Islands King and Tanner Crab Fishery Resources

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

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

**SUMMARY:** The Bering Sea/Aleutian Islands (BSAI) Crab Rationalization Program (Program) allocates BSAI crab resources among harvesters, processors, and coastal communities. Amendment 27 would amend the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs (FMP) and the Program to include the statutory requirements of section 122(e) of the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006 and modify the methods used to determine individual processor quota share (IPQ) use caps when crab are processed under custom processing arrangements. Amendment 27 also would modify limits on the amount of Aleutian Islands golden and red king crab IPQ that could be processed at a facility. This action is intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act, the FMP, and other applicable laws.

**DATES:** Comments on the amendment must be submitted on or before November 10, 2008.

**ADDRESSES:** Send comments to Sue Salvesson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian. You may submit comments, identified by "RIN 0648-AW73", by any one of the following methods:

• **Electronic Submissions:** Submit all electronic public comments via the Federal eRulemaking Portal Web site at <http://www.regulations.gov>.

• **Mail:** P.O. Box 21668, Juneau, AK 99802.

• **Fax:** (907) 586-7557.

• **Hand delivery to the Federal Building:** 709 West 9th Street, Room 420A, Juneau, AK.

All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (e.g., name, address) 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 (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 portable document file (pdf) formats only.

Copies of Amendment 27, the Regulatory Impact Review (RIR)/Initial Regulatory Flexibility Analysis (IRFA), the categorical exclusion prepared for this action, and the Environmental Impact Statement (EIS) prepared for the Crab Rationalization Program may be obtained from the NMFS Alaska Region at the address above or from the Alaska Region Web site at <http://www.fakr.noaa.gov/sustainablefisheries.htm>.

**FOR FURTHER INFORMATION CONTACT:** Glenn Merrill, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** The Magnuson-Stevens Act requires that each regional fishery management council submit any fishery management plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval by the Secretary of Commerce (Secretary). The Magnuson-Stevens Act also requires that NMFS, upon receiving a fishery management plan amendment, immediately publish a notice in the **Federal Register** announcing that the amendment is available for public review and comment.

The king and Tanner crab fisheries in the exclusive economic zone of the BSAI are managed under the FMP. The FMP was prepared by the North Pacific Fishery Management Council (Council) under the Magnuson-Stevens Act as amended by the Consolidated Appropriations Act of 2004 (Pub. L. 108-199, section 801). Amendments 18 and 19 to the FMP amended the FMP to include the Program. Regulations