should be subject to part 803 of this chapter to protect the public health. For Class I and certain Class II devices you must submit reportable malfunctions on a quarterly basis using a summary format. You must also submit any required followup reports to a ''malfunction report'' required by § 803.56 of this chapter.

(3) If your combination product contains a drug or a biological product constituent part, you must submit a postmarketing 15-day ''alert report'', for each adverse experience associated with the use of a drug or biological product constituent part of the combination product, whether or not considered drug or biological product related, that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the reporter, as required by § 314.80(c)(1)(i) or § 600(c)(1)(i) of this chapter. You must also promptly investigate and submit any required followup reports to a postmarketing 15-day ''alert report'' as required by § 314.80(c)(1)(ii) or § 600(c)(1)(ii) of this chapter.

(4) If your combination product contains a drug constituent part, you must submit a field alert report within 3 working days of your receipt to the FDA district office that is responsible for the facility involved, by telephone or other rapid communication means and prompt written followup, information concerning:

(i) Any incident that causes the drug constituent part of a distributed combination product or its labeling to be mistaken for, or applied to, another article; or

(ii) Any bacteriological contamination or any significant chemical, physical, or other change or deterioration in the drug constituent part of a distributed combination product, or any failure of one or more distributed batches of a drug constituent part of a combination product to meet the specification established for it in the application.

(5) If your combination product contains a biological product constituent part containing blood or a blood component, and a complication of blood collection or transfusion is confirmed to be fatal as described in § 606.170(b) of this chapter, you must submit a blood fatality report by telephone, facsimile, express mail, or e-mail as soon as possible, and a written report within 7 days after the fatality.

(c) *Periodic reports.* (1) If your combination product is approved under an NDA, ANDA, or BLA, you must also include information in reports submitted in accordance with paragraphs (b)(1), (b)(2), and (b)(5) of this section in the periodic reports you submit under §§ 314.80(c)(2)(ii)(a) and 600.80(c)(2)(ii)(a) of this chapter. Information on these additional reports should be treated as 15-day alert reports, i.e., included in narrative summary and analysis of the information in the report and an analysis of the 15-day alert reports submitted during the reporting interval (all 15-day alert reports being appropriately referenced by the applicant's patient identification number, adverse reaction term(s), and date of submission to FDA). The history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated) should include information on the combination products as a whole (i.e., all of its constituent parts).

(2) If your combination product is approved under a PMA, you must also include information in reports submitted in accordance with paragraphs (b)(3), (b)(4), and (b)(5) of this section in the periodic reports you submit under §814.82(a)(7) of this chapter.

§ 4.104 How do I report if another reporter is responsible for a constituent part of my combination product?

(a) If another person holds an application used to approve or clear a constituent part of your combination product, or legally markets a constituent part of your combination product without an approved or cleared marketing application, in addition to the requirements of § 4.103(a), you must submit the information you received about the event to FDA or the other person within 5 calendar days of your receipt of the information.

(b) If you receive information from the other person that holds an application used to approve or clear a constituent part of your combination product, or legally markets a constituent part of your combination product without an approved or cleared marketing application, you must investigate and, if required, report the event in accordance with § 4.103(a) and (b).

§ 4.105 How, where, and when do I submit postmarketing safety reports for combination products?

(a) You must submit the field alert reports described in § 4.103(b)(4) to the FDA district office that is responsible for the facility involved within 3 working days of receipt of the information.

(b) You must submit all other postmarketing safety reports required under this subpart (i.e., required under § 4.103(a), (b)(1), (b)(2), (b)(3), (b)(5), and (c)) using the submission methods and timeframes identified in the regulations applicable under § 4.103(a), (b), and (c) for your combination product or your constituent part.

§ 4.106 What are the postmarketing safety reporting recordkeeping requirements?

(a) You must maintain records of postmarketing safety reports required by § 4.103(a) in accordance with the recordkeeping requirements of the underlying regulation(s) identified in § 4.103(a) that are applicable to your combination product or your constituent part.

(b) You must maintain records of reportable events required by § 4.103(b) and (c) for the time period specified as follows:

(1) 5-day and malfunction reports described in § 4.103(b)(1) and (b)(2): for 2 years or the expected life of the combination product, whichever is longer;

(2) Postmarketing 15-day 'alert reports' field alert reports, and blood fatality reports described in § 4.103(b)(3), (b)(4), and (b)(5), and periodic reports as described in § 4.103(c): for 10 years.

Dated: September 24, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23519 Filed 9–30–09; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–139068–08]

RIN 1545–BI31

Modification to Consolidated Return Regulation Permitting an Election To Treat a Liquidation of a Target, Followed by a Recontribution to a New Target, as a Cross-Chain Reorganization; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to a notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: This document contains corrections to a notice of proposed rulemaking by cross-reference to temporary regulations (REG–139068–08) that were published in the **Federal Register** on Friday, September 4, 2009 (74 FR 45789) modifying the election under which a consolidated group can avoid immediately taking into account

an intercompany item after the liquidation of a target corporation. This modification was made necessary in light of the regulations under section 368 that were issued in October 2007 addressing transfers of assets or stock following a reorganization.

FOR FURTHER INFORMATION CONTACT: Mary W. Lyons, (202) 622–7930 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

A notice of proposed rulemaking by cross-reference to temporary regulations that is the subject of this document is under section 1502 of the Internal Revenue Code.

Need for Correction

As published, a notice of proposed rulemaking by cross-reference to temporary regulations (REG–139068–08) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of a notice of proposed rulemaking by cross-reference to temporary regulations (REG–139068–08), which was the subject of FR Doc. E9–21323, is corrected as follows:

§ 1.1502–13 [Corrected]

1. On page 45791, column 1, paragraph (f)(5)(ii)(B)(*1*), lines 2 and 3, the language ''amendments to § 1.1502–13(B)(*1*) is the same as the text of § 1.1502–13T(B)(*1*)'' is corrected to read ''amendments to § 1.1502–13(f)(5)(ii)(B)(*1*) is the same as the text of § 1.1502–13T(f)(5)(ii)(B)(*1*)''.

2. On page 45791, column 1, paragraph (f)(5)(ii)(B)(*2*), lines 2 and 3, the language ''amendments to § 1.1502–13(B)(*2*) is the same as the text of § 1.1502–13T(B)(*2*)'' is corrected to read ''amendments to § 1.1502–13(f)(5)(ii)(B)(*2*) is the same as the text of § 1.1502–13T(f)(5)(ii)(B)(*2*)''.

3. On page 45791, column 1, paragraph (f)(5)(ii)(F), lines 2 and 3, the language ''amendments to § 1.1502–13(F) is the same as the text of § 1.1502–13T(F)'' is corrected to read ''amendments to § 1.1502–13(f)(5)(ii)(F) is the same as the text of § 1.1502–13T(f)(5)(ii)(F)''.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E9–23645 Filed 9–30–09; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 0909011267–91269–01]

RIN 0648–AY19

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS is proposing to implement a regulatory amendment to modify the fishing vessel permit regulations to include specific terms and conditions for Federal fishing vessel permits obtained through the purchase of fishing vessels using Federal grant awards. The terms and conditions would authorize the NMFS Administrator, Northeast Region (Regional Administrator), to suspend, cancel, fail to renew, modify, or otherwise rescind any Federal fishing vessel permit, or the rights thereto, if the terms and conditions of any Federal grant award used to obtain said permit, or an associated memorandum of understanding, are violated by the grant recipient.

DATES: Written comments must be received no later than 5 p.m., eastern standard time, on November 2, 2009.

ADDRESSES: You may submit comments, identified by RIN 0648–AY19, by any of the following methods:

- Electronic submissions: Submit all electronic public comments via the Federal e-Rulemaking portal *http://www.regulations.gov*.
- Fax: (978) 281–9135, Attn: Michael Pentony.
- Mail: Patricia A. Kurkul, Regional Administrator, NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope: ''Comments on Vessel Permit Regulatory Amendment.''

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. Attachments to electronic comments will be accepted via Microsoft Word, Microsoft Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the Regulatory Impact Review (RIR) are available upon request from Patricia A. Kurkul, Regional Administrator, NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930.

FOR FURTHER INFORMATION CONTACT: Michael Pentony, Senior Fishery Policy Analyst, phone (978) 281–9283.

SUPPLEMENTARY INFORMATION:

Background

This proposed rule would implement changes to the Northeast (NE) fisheries regulations at 50 CFR part 648 to authorize the Regional Administrator to suspend, cancel, fail to renew, modify, or otherwise rescind any Federal fishing vessel permit, including the rights thereto, held by a person, corporation, non-profit organization, or government entity if the terms and conditions of any Federal grant award used to obtain said permit, or an associated memorandum of understanding, are violated by the grant recipient. The intent of this proposed action is to establish a new regulatory mechanism through which NOAA would be able to enforce the terms and conditions of any Federal grant award used to obtain Federal fishing vessel permits in the NE Region.

As several fisheries in the NE Region begin to transition to catch-share management strategies, various fishing organizations, conservations groups, and states are exploring alternatives to the traditional vessel-permit ownership model. Traditionally, an individual or corporation invests in a fishing vessel and obtains the appropriate vessel permits necessary to participate in the target fishery. An individual or corporation may own multiple vessels, but each of these vessels is generally associated with a unique vessel permit (or, a unique set of permits to operate in different fisheries may be associated with each vessel). An alternative model known as ''permit banking'' is developing in the Northeast, whereby an organization obtains a suite of permits in a particular fishery, with the option to lease out the fishing rights associated with those permits.

Permit banks hold promise for addressing two important issues related to the development and implementation of effective catch-share management programs: First, permit banks can be