

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 878**

[Docket No. 2006N-0362]

**General and Plastic Surgery Devices; Reclassification of the Absorbable Hemostatic Device; Reopening of Comment Period****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until June 7, 2007, the comment period for the proposed rule, published in the **Federal Register** of October 31, 2006 (71 FR 63278). The proposed rule would reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket approval) into class II (special controls). FDA is taking this action in response to two requests for an extension of the comment period for this rulemaking. 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in this issue of the **Federal Register**, FDA is also reopening the comment period on a notice of availability of a draft guidance document that would serve as the special control if FDA reclassifies this device.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 June 7, 2007.

**ADDRESSES:** You may submit comments, identified by Docket No. 2006N-0362, by any of the following methods:  
*Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
  - Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- 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 or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions:* All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090, ext. 141.

**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) into class II (special controls). FDA invited interested persons to comment on the proposed rule by January 29, 2007. Two companies requested FDA to extend the comment period by 90 days because the proposal presented complex medical and scientific issues that required the company to assemble a team of many different specialties in order to prepare their comments.

FDA was unable to respond to the request to extend the comment period before the comment period ended. Therefore, FDA is reopening the comment period for 30 days in order to allow the requestors and other interested persons to complete and prepare their comments. FDA believes that these 30 days in addition to the time that has already passed since the proposal was published allows for sufficient time for preparation of comments.

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.

**II. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the proposed rule. 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.

Dated: April 25, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-8784 Filed 5-7-07; 8:45 am]

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**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 1**

[REG-144859-04]

RIN 1545-BD72

**Section 1367 Regarding Open Account Debt; Correction**

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

**ACTION:** Correction to notice of proposed rulemaking.

**SUMMARY:** This document contains corrections to a notice of proposed rulemaking (REG-144859-04) that was published in the **Federal Register** on Thursday, April 12, 2007 (72 FR 18417) relating to the treatment of open account debt between S corporations and their shareholders.

**FOR FURTHER INFORMATION CONTACT:**

Stacy L. Short or Deanne M. Burke, (202) 622-3070 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:****Background**

The correction notice that is the subject of this document is under section 1367 of the Internal Revenue Code.

**Need for Correction**

As published, the notice of proposed rulemaking (REG-144859-04) contains errors that may prove to be misleading and are in need of clarification.

**Correction of Publication**

Accordingly, the publication of proposed rulemaking (REG-144859-04), which was the subject of FR Doc. E7-6764, is corrected as follows:

1. On page 18417, column 3, in the preamble, under the caption **DATES:**, first sentence of the paragraph, the language “Written or electronic comments and requests for a public hearing must be received by July 11, 2007.” is corrected to read “Written or electronic comments must be received by July 10, 2007.”.

2. On page 18418, column 1, in the preamble, under the caption **FOR FURTHER INFORMATION CONTACT:**, lines six through eleven, the language “attend the hearing, Richard Hurst at (202) 622-2949 (TDD Telephone) (not toll free numbers) and his e-mail address is *Richard.A.Hurst@irsounsel.treas.gov*, (202) 622-7180 (not toll-free numbers).” is corrected to read “attend the hearing, Richard Hurst at *Richard.A.Hurst@irsounsel.treas.gov*, (202) 622-7180 (not toll-free numbers).”.

3. On page 18420, column 2, in the preamble, under the paragraph heading “Comments and Public Hearing”, the second paragraph of the column, first line, the language “The rules of 26 CFR 606.601(a)(3)” is corrected to read “The rules of 26 CFR 601.601(a)(3)”.

**§ 1.1367-2 [Corrected]**

4. On page 18422, column 1, § 1.1367-2, first paragraph of the column, third line of the paragraph, the language “1. The section heading is revised.” is corrected to read “1. The section heading and paragraph are revised.”.

5. On page 18422, column 1, § 1.1367-2, first paragraph of the column, lines four through seven are removed.

**§ 1.1367-3 [Corrected]**

6. On page 18422, column 1, § 1.1367-3, second paragraph of the column, the language of the paragraph heading “§ 1.1367-3 Effective dates and transitional rules.” is corrected to read “§ 1.1367-3 Effective date.”.

**LaNita Van Dyke,**

*Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).*  
[FR Doc. E7-8705 Filed 5-7-07; 8:45 am]

**BILLING CODE 4830-01-P**

**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 1**

[REG-123365-03]

RIN 1545-BC94

**Guidance Regarding the Active Trade or Business Requirement Under Section 355(b)**

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document contains proposed regulations that provide guidance regarding the active trade or business requirement under section 355(b) of the Internal Revenue Code. These proposed regulations provide guidance on issues involving the active trade or business requirement under section 355(b), including guidance resulting from the enactment of section 355(b)(3). These proposed regulations will affect corporations and their shareholders.

**DATES:** Written or electronic comments and requests for a public hearing must be received by August 6, 2007.

**ADDRESSES:** Send submissions to: CC:PA:LPD:PR (REG-123365-03), room 5203, Internal Revenue Service, PO 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-123365-03), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) (IRS REG-123365-03).

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Russell P. Subin, (202) 622-7790; concerning submissions and the hearing, Kelly Banks, (202) 622-7180 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:****Background and Explanation of Provisions***A. Background and Overview of the Key Aspects of the Proposed Regulations***1. Background**

Section 355(a) of the Internal Revenue Code (Code) provides that, under certain circumstances, a corporation may distribute stock and securities of a corporation it controls to its shareholders and security holders

without causing either the corporation or its shareholders and security holders to recognize income, gain or loss. Sections 355(a)(1)(C) and 355(b)(1) generally require that the distributing corporation (distributing) and controlled corporation (controlled) each be engaged, immediately after the distribution, in the active conduct of a trade or business. Section 355(b)(2)(A) provides that a corporation shall be treated as engaged in the active conduct of a trade or business if and only if it is engaged in the active conduct of a trade or business, or substantially all of its assets consist of stock and securities of a corporation controlled by it (immediately after the distribution) which is so engaged. For this purpose, control is defined under section 368(c). All references to control in this preamble are references to control as defined in section 368(c).

Section 202 of the Tax Increase Prevention and Reconciliation Act of 2005, Public Law 109-222 (120 Stat. 345, 348) (TIPRA) amended section 355(b) by adding section 355(b)(3). Section 355(b)(3)(A), as amended by Division A, Section 410 of the Tax Relief and Health Care Act of 2006, Public Law 109-432 (120 Stat. 2922, 2963), provides that in the case of any distribution made after May 17, 2006, a corporation shall be treated as meeting the requirement of section 355(b)(2)(A) if and only if such corporation is engaged in the active conduct of a trade or business. Section 355(b)(3)(B) provides that for purposes of section 355(b)(3)(A) (and, consequently, section 355(b)(2)(A)), all members of such corporation’s separate affiliated group (SAG) shall be treated as one corporation (SAG rule). For purposes of the preceding sentence, a corporation’s SAG is the affiliated group which would be determined under section 1504(a) if such corporation were the common parent and section 1504(b) did not apply.

Thus, the separate affiliated group of distributing (DSAG) is the affiliated group that consists of distributing as the common parent and all corporations affiliated with distributing through stock ownership described in section 1504(a)(1)(B) (regardless of whether the corporations are includible corporations under section 1504(b)). The separate affiliated group of controlled (CSAG) is determined in a similar manner (with controlled as the common parent). Accordingly, unlike prior law, a corporation is not treated as engaged in the active conduct of a trade or business solely as a result of substantially all of its assets consisting of stock, or stock and securities, of one or more