5. The proposed prohibitions against using an NDC number to represent a different drug than the drug to which the NDC number was assigned, and against using a different NDC number if marketing is resumed for a drug that was discontinued earlier (see 71 FR 51276 at 51305).

6. The proposal to exempt from public disclosure the NDC number assigned to the drug immediately before the drug is received by the repacker or relabeler. The reason for the proposed exemption is that this information may disclose a business relationship between the manufacturer, repacker, relabeler, or drug product salvager and the business from which they obtained the drug, and may constitute commercial or financial information that is exempt from public disclosure (see 71 FR 51276 at 51320).

7. The possibility of adding one or more digits to the NDC code in the future (see 71 FR 51276 at 51300).

*C. Registration, Agenda, and Transcript*

There is no fee to register for the meeting, but registration is required and space is limited. Interested parties are therefore encouraged to register early. Limited visitor parking is available for a fee, and the Twinbrook Metro Stop is within walking distance of the meeting site. Early arrival is encouraged, as there will be security screening. You will be asked for government-issued picture identification by the security officers. If you need special accommodations due to a disability, please include this information when registering.

*Registration for General Attendees.* Registration is required to attend the public meeting. If you wish to attend the meeting, you must register by November 24, 2006, via e-mail to: *CDER_330CATS@cder.fda.gov*. Please indicate ''National Drug Code (NDC) system'' in the SUBJECT line and provide complete contact information for each attendee (including name, title, affiliation, e-mail address, and phone number(s)). Upon receipt and review for adequacy of information, an e-mail will be sent to confirm registration.

*Registration for Speaking Attendees.* If you wish to speak at the meeting, you must register by November 24, 2006, via e-mail to: *CDER_330CATS@cder.fda.gov*. Please indicate ''Speaker-National Drug Code (NDC) system'' in the SUBJECT line. When registering, speakers must provide the following information: (1) The NDC-related topic or issue to be addressed; (2) the speaker's name, title, company or organization, address, phone number, and e-mail address; and (3) the approximate length of time requested to speak. We encourage consolidation of like minded presentations to enable a broad range of views to be presented.

*Agenda and Transcript.* The agenda for the public meeting will be available on FDA's Center for Drug Evaluation and Research (CDER) Web site at: *www.fda.gov/cder/ndc/database/default.htm*. After the meeting, the agenda, presentations, and transcript will be placed on file in the Division of Dockets Management under Docket No. 2005N–0403 and on CDER's Web site identified previously.

Copies of the transcript may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the meeting at a cost of 10 cents per page, or on compact disc at a cost of $14.25 each. You may also examine the transcript at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*.

## III. Extension of the Comment Period for the Proposed Rule

By letter dated September 25, 2006, the Compressed Gas Association and the Gases and Welding Distributors Association requested an extension of 60 days to comment on the proposed rule because their member companies do not have sufficient time to evaluate the economic impact of the proposal and report their findings to FDA. By letter dated September 26, 2006, the Animal Health Institute (AHI) also requested a 60–day extension of the comment period to provide AHI additional time to review the proposed rule, analyze the impact on its industry, and provide comments to FDA. In addition, by letter dated October 12, 2006, the Consumer Healthcare Products Association (CHPA) requested a 60–day extension of the comment period to provide CHPA additional time to obtain and review opinions and responses from its member companies.

FDA has considered these extension requests and is extending the comment period to January 26, 2007. We believe that extending the comment period is reasonable in light of the complexity and scope of the issues in the proposed rule and that it will not significantly delay resolution of this rulemaking.

## IV. Request for Comments

We are interested in obtaining public comment on the NDC-related issues identified in this document. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document and the proposed rule (see **DATES**). Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with Docket No. 2005N–0403. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 25, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–18310 Filed 10–30–06; 8:45 am]

**BILLING CODE 4160–01–S**

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## 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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket approval) into class II (special controls). FDA is proposing this reclassification in accordance with the Federal Food, Drug, and Cosmetic Act (the act). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document that would serve as the special control if FDA reclassifies this device.

**DATES:** Submit written comments by January 29, 2007. See section X of this document for the proposed effective date of a final rule based on this proposed rule.

**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 in the *Electronic Submissions* portion of this paragraph.

*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 ''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. Regulatory Authorities

The act, as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

The 1976 amendments broadened the definition of ''device'' in section 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified all transitional devices, i.e., those devices previously regulated as new drugs, including the absorbable hemostatic device, into class III. SMDA amended section 520(l) of the act (21 U.S.C. 360j(l)) to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices still remaining in class III to determine whether the devices should be reclassified into class II (special controls) or class I (general controls). The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated in class III (H. Rept. 808, 101st Cong., 2d sess. 26–27 (1990); S. Rept. 513, 101st Cong., 2d sess. 27 (1990)).

Accordingly, in the **Federal Register** of November 14, 1991 (56 FR 57960), FDA issued an order under section 520(l)(5)(A) of the act, requiring manufacturers of transitional devices, including the absorbable hemostatic device (21 CFR 878.4490), to submit to FDA a summary of and a citation to any information known or otherwise available to them respecting the devices, including adverse safety or effectiveness information, which had not been submitted under section 519 of the act (21 U.S.C. 360i).

Manufacturers were to submit the summaries and citations to FDA by January 13, 1992. However, because of misunderstandings and uncertainties regarding the information required by the order, and whether the order applied to certain manufacturers' devices, many transitional class III device manufacturers failed to comply with the reporting requirement by January 13, 1992. Consequently, in the **Federal Register** of March 10, 1992 (57 FR 8462), FDA extended the reporting period to March 31, 1992.

Section 520(l)(5)(B) of the act provides that, after the issuance of an order requiring manufacturers to submit any information known or otherwise available respecting the devices, but before December 1, 1992, FDA was to publish regulations either leaving transitional class III devices in class III or reclassifying them into class I or II. Subsequently, as permitted by section 520(l)(5)(C) of the act, in the **Federal Register** of November 30, 1992 (57 FR 56586), the agency published a notice extending the period for issuing such regulations until December 1, 1993. Due to limited resources, FDA was unable to publish the regulations before the December 1, 1993, deadline.

## II. Regulatory Background of the Device

In the **Federal Register** of December 16, 1977 (42 FR 63472), FDA identified the absorbable hemostatic agent and dressing as a transitional device that is a class III device that FDA previously regulated as a drug and for which premarket approval was immediately required. Since enactment of the 1976 amendments, FDA has approved numerous premarket approval (PMA) applications and PMA supplements authorizing the commercial distribution of new absorbable hemostatic agents and dressings in the United States.

Absorbable hemostatic products that include biological products or drug components are combination products as defined in 21 CFR 3.2(e). When the device component is responsible for the primary mode of action of the absorbable hemostatic product, it is assigned to CDRH for premarket review and regulation. If the absorbable hemostatic device is reclassified, these combination products will be subject to premarket notification [510(k)] requirements.

## III. Description of the Device

The current identification of the device states that an ''absorbable hemostatic agent or dressing is a device intended to produce hemostasis by accelerating the clotting process of blood. It is absorbable.'' Absorbable hemostatic devices are primarily applied during surgical procedures in order to control bleeding that is not readily controlled via conventional means, such as cautery or ligation. At other times, an absorbable hemostatic device may be applied due to the inaccessibility of a site to conventional hemostatic methods.

FDA is proposing the following device name and identification based on the agency's review to more accurately identify the device: An absorbable hemostatic device is an absorbable device that is placed in the body during surgery to produce hemostasis by accelerating the clotting process of blood.

## IV. Recommendation of the Panel

At a July 8, 2002, public meeting of FDA's General and Plastic Surgery Devices Panel (the Panel), the Panel requested that the agency provide information on the potential content of a class II special controls guidance document for the absorbable hemostatic device. The Panel requested this information to enable them to make an appropriate recommendation on possible reclassification of the device (Ref. 1).

At a July 24, 2003, public meeting of the Panel, the agency presented the possible content of a class II special controls guidance for the absorbable hemostatic device (Ref. 2). The Panel unanimously recommended that the absorbable hemostatic device be reclassified from class III into class II and recommended that a class II guidance document be the special control for the device. The Panel based the recommendations on the information provided by FDA, the presentations to the panel by manufacturers and FDA, the Panel's deliberations at the meeting, and their personal experience with the device.

**V. Risks to Health**

After considering the information in the panel's recommendation, as well as the published literature and Medical Device Reports, FDA has evaluated the risks to health associated with use of the absorbable hemostatic device and determined that the following risks to health are associated with its use.

*A. Uncontrolled Bleeding*

The absorbable hemostatic device is intended for use during surgical procedures as an adjunct to hemostasis when conventional means fail to produce hemostasis or are impractical. Patients receiving antiplatelet/anticoagulation therapy have increased blood clotting times. This increase in blood clotting time occurs even when an absorbable hemostatic device is used during the surgical procedure to control bleeding. Failure to completely control bleeding can lead to death or severe injury.

*B. Hematoma*

If small amounts of bleeding persist following the application of an absorbable hemostatic device, the accumulation of blood behind the device will form a hematoma. The hematoma may press on soft tissue and cause soft tissue or nerve damage. A hematoma may also result in infection (see section V.C of this document).

*C. Infection*

An absorbable hemostatic device may serve as a nidus for infection and abscess formation. Absorbable hemostatic devices are manufactured from collagen, gelatin, or oxidized regenerated cellulose; some collagen and gelatin hemostatic devices may contain FDA-licensed bovine thrombin. Bacteria can grow on these device materials. For example, the use of absorbable hemostatic devices in nasal surgery has caused toxic shock syndrome.

*D. Wound Dehiscence*

The use of an absorbable hemostatic device near sites of skin incision closures has interfered with the healing of the incision. This interference is due to mechanical interposition of the device and is not due to intrinsic interference with the wound healing process.

*E. Foreign Body Reactions*

The absorbable hemostatic device has been associated with foreign body reactions involving fluid accumulation due to encapsulation of the device. Such encapsulated devices have resulted in granuloma formation, inflammation, and edema, which may require surgical removal.

*F. Immunologic Reactions*

Absorbable hemostatic devices are composed of animal or plant derived proteins and/or polysaccharides. These devices are made of bovine collagen, porcine and bovine gelatin, and regenerated oxidized cellulose; some may also include FDA-licensed bovine thrombin as a combination product component. Some patients are allergic to these animal or plant-derived materials. Patients allergic to bovine thrombin containing hemostatic devices may form antibodies to bovine Factor $V_a$ that may cross react with human Factor $V_a$ resulting in a potentially fatal coagulopathy.

*G. Adhesion Formation*

An absorbable hemostatic device, in the presence of coagulated blood and tissue fluid, often leads to scarring and adhesion formation in the weeks and months following the surgical procedure. The surgical procedure itself may result in scarring and adhesion formation.

*H. Failure to be Absorbed*

Absorbable hemostatic devices are readily degraded by enzymatic and hydrolytic action. Occasionally, an absorbable hemostatic device may lodge in an area with low enzymatic and hydrolytic activity. In such instances, it may not be efficiently absorbed. Subsequently, it may become encapsulated and exert pressure on soft tissue requiring surgical removal.

*I. Interference With Methylmethacrylate Adhesives*

Some types of absorbable hemostatic devices have been reported to reduce the strength of methylmethacrylate adhesives used to fixate orthopedic prosthetic devices to bone.

*J. Aspiration Into Blood Salvage System Filters*

Fragments of an absorbable hemostatic device may pass through blood salvage system filters and occlude the systems or the patient's vasculature.

*K. Embolization*

Absorbable hemostatic devices used near moderate to large blood vessels may result in embolization of the blood vessel. Such embolization has been associated with severe adverse effects, including fever, duodenal and pancreatic infarct, embolization of lower extremity vessels, pulmonary embolization, splenic abscess, necrosis, asterixis, and death.

*L. Paralysis/Nerve Damage/Tissue Necrosis*

Absorbable hemostatic devices absorb liquid and swell to varying degrees, up to 35 to 40 times their weight in liquid. This absorption of liquid is accompanied by a concomitant swelling of the device.

**VI. Summary of the Reasons for the Reclassification**

FDA believes that the absorbable hemostatic device should be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device and because there is sufficient information to establish special controls to provide such assurance.

In addition to the potential risks to health associated with use of the absorbable hemostatic device described in section V of this document, there is reasonable knowledge of the benefits of the device. Specifically, the absorbable hemostatic device may prevent extended bleeding, reduce surgical morbidity due to blood loss, and reduce the need for transfusions.

**VII. Special Controls**

In addition to general controls, FDA believes that the draft guidance document entitled ''Class II Special Controls Guidance: Absorbable Hemostatic Device'' (the class II special controls guidance document) is an adequate special control to address the risks to health associated with the use of the device described in section V of this document. FDA believes that the class II special controls guidance document, which incorporates voluntary consensus standards and describes labeling recommendations, addresses the Panel's concerns. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft class II special

controls guidance document that the agency would use as the special control for this device.

The draft class II special controls guidance document sets forth the information FDA believes should be included in premarket notification submissions (510(k)s) for the absorbable hemostatic device. FDA has identified the risks to health associated with the use of the device in the first column of table 1 of this document and the recommended mitigation measures identified in the class II special controls guidance document in the second column of table 1. FDA believes that addressing these risks to health in a 510(k) in the manner identified in the class II special controls guidance document, or in an acceptable alternative manner, is necessary to provide reasonable assurance of the safety and effectiveness of the device.

TABLE 1.

| Identified Risk | Recommended Mitigation Measures |
|---|---|
| Uncontrolled Bleeding | Material and performance characteristics, Animal testing, Clinical testing, Labeling |
| Hematoma | Animal testing, Clinical testing, Labeling |
| Infection | Animal testing, Sterility, Labeling |
| Wound Dehiscence | Labeling |
| Foreign Body Reactions | Animal testing, Biocompatibility, and Labeling |
| Immunological Reactions | Animal testing, Biocompatibility, Labeling |
| Adhesion Formation | Animal testing, Clinical testing |
| Failure to be Absorbed | Material and performance characteristics, Animal testing, Biocompatibility |
| Interference with Methylmethacrylate Adhesives | Animal testing, Labeling |
| Aspiration Into Blood Salvage System Filters | Labeling |
| Embolization | Labeling |
| Paralysis/Nerve Damage/Tissue Necrosis | Labeling |

## VIII. FDA's Findings

As discussed previously in this document, FDA believes the absorbable hemostatic device should be reclassified into class II because special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device and because there is sufficient information to establish special controls to provide such assurance. FDA, therefore, is proposing to reclassify the device into class II and establish the draft class II special controls guidance document as a special control for the device.

Section 510(m) of the act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the act, if the agency determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA believes that premarket notification is necessary to provide reasonable assurance of safety and effectiveness and, therefore, does not intend to exempt the device from the premarket notification requirements.

## IX. Effective Date

FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

## X. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed reclassification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## XI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–602), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, the agency certifies that the proposed 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 $118 million, using the most current (2004) 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.

## XII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would 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 tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

## XIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the draft special control guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance document entitled ''Class II Special Controls Guidance Document:

Absorbable Hemostatic Device''; the notice contains an analysis of the paperwork burden for the draft guidance.

**XIV. 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.

**XV. References**

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. General and Plastic Surgery Devices Panel, Transcript, pp. 80–177, July 8, 2002.

2. General and Plastic Surgery Devices Panel, Transcript, July 24, 2003.

**List of Subjects in 21 CFR Part 878**

Medical devices.

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 878 be amended as follows:

## PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR Part 878 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 878.4490 is revised to read as follows:

**§ 878.4490 Absorbable hemostatic device.**

(a) *Identification.* An absorbable hemostatic device is an absorbable device that is placed in the body during surgery to produce hemostasis by accelerating the clotting process of blood.

(b) *Classification.* Class II (special controls). The special control for the device is FDA's ''Class II Special Controls Guidance Document: Absorbable Hemostatic Device.'' See § 878.1(e) for the availability of this guidance document.

Dated: October 19, 2006.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. E6–18324 Filed 10–30–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[REG–124152–06]**

**RIN 1545–BF73**

### Definition of Taxpayer for Purposes of Section 901 and Related Matters; Correction

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

**ACTION:** Notice of proposed rulemaking and notice of public hearing; Correction.

**SUMMARY:** This document contains corrections to notice of proposed rulemaking and notice of public hearing that was published in the **Federal Register** on Friday, August 4, 2006 (71 FR 44240) relating to the determination of who is considered to pay a foreign tax for purposes of sections 901 and 903.

**FOR FURTHER INFORMATION CONTACT:** Bethany A. Ingwalson, (202) 622–3850 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

The notice of proposed rulemaking and notice of public hearing (REG–124152–06) that is the subject of these corrections are under sections 901 and 903 of the Internal Revenue Code.

**Need for Correction**

As published, the notice of proposed rulemaking and notice of public hearing (REG–124152–06) contains errors that may prove to be misleading and are in need of clarification.

**Correction of Publication**

Accordingly, the notice of proposed rulemaking and notice of public hearing (REG–124152–06) that was the subject of FR Doc. E6–12358 is corrected as follows:

**§ 1.901–2 [Corrected]**

1. On page 44246, column 1, § 1.901–2(f)(6), paragraph (i) of *Example 4.*, line 4, the language ''county Y. A accrues interest income on the'' is corrected to read ''country Y. A accrues interest income on the''.

2. On page 44246, column 2, § 1.901–2(f)(6), paragraph (i) of *Example 4.*, first paragraph of the column, line 1, the language ''pay over to country X 10 percent of the'' is corrected to read ''pay over to country Y 10 percent of the''.

3. On page 44247, column 1, § 1.901–2(f)(6), paragraph (i) of *Example 8.*, the language ''tax purposes. New D also has a short U.S.'' is corrected to read ''tax purposes. ''New'' D also has a short U.S.''.

4. On page 44247, column 1, § 1.901–2(f)(6), paragraph (ii) of *Example 8.*, line 11, the language ''years of terminating D and new D. See'' is corrected to read ''years of old D and new D. See''.

5. On page 44247, column 1, § 1.901–2(f)(6), paragraph (ii) of *Example 8.*, line 13, the language ''allocation of terminating D's country M taxes'' is corrected to read ''allocation of old D's country M taxes''.

6. On page 44247, column 1, § 1.901–2(h), the language ''(h) *Effective Date.* Paragraphs (a)'' is corrected to read ''(h) *Effective date.* Paragraphs (a)''.

**LaNita Van Dyke,**

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

[FR Doc. E6–18205 Filed 10–30–06; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 3

**RIN 2900–AM17**

### Notice and Assistance Requirements

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) proposes to amend its regulation governing VA's duty to provide a claimant with notice of the information and evidence necessary to substantiate a claim and VA's duty to assist a claimant in obtaining the evidence necessary to substantiate the claim. The purpose of these proposed changes is to clarify when VA has no duty to notify a claimant of how to substantiate a claim for benefits, to make the regulation comply with statutory changes, and to streamline the development of claims.

**DATES:** Comments must be received by VA on or before January 2, 2007.

**ADDRESSES:** Written comments may be submitted through *http://www.Regulations.gov;* by: mail or hand-delivery to the Director, Regulations Management (00REG), Department of Veterans Affairs, 810 Vermont Ave.,