

attributable to one broker-dealer. This broker-dealer informed the NYSE that the fail positions were not being closed out because it was relying on the options market maker exception.

○ Prior to the Commission's Proposal, the Commission's Office of Compliance and Inspections ("OCIE") conducted some examinations for Regulation SHO compliance and found that some broker-dealers were still carrying a significant amount of fails to deliver in securities that they were not closing out because they were relying on the grandfather provision. One broker-dealer indicated that it had not closed out several persistent fails in threshold securities because it was relying on the options market maker exception.

Therefore, the Commission is reopening the comment period for Exchange Act Release No. 54154 from the date of this release through April 30, 2007.

By the Commission.

Dated: March 26, 2007.

Nancy M. Morris,

Secretary.

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BILLING CODE 8010-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

21 CFR Parts 211, 226, 300, 500, 530, 600, 895, and 1271

[Docket No. 2005N-0373]

RIN 0910-AF54

#### Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants; Reopening of the Comment Period

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

**ACTION:** Proposed rule; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until May 14, 2007, the comment period for the proposed rule published in the *Federal Register* of January 12, 2007 (72 FR 1582). The proposed rule would prohibit the use of certain cattle material in, or in the manufacture (including processing) of, drugs, biologics, and medical devices intended for use in humans and human cells, tissues, and cellular and tissue-based products (HCT/Ps) (collectively, medical products for humans), and in

drugs intended for use in ruminant animals (drugs for ruminants) and would also require new recordkeeping provisions for medical products for humans and drugs for ruminants that are manufactured from or otherwise contain material from cattle. The agency is reopening the comment period in response to a request for more time to enable industry to generate more information on products that might be affected by the rule.

**DATES:** Submit written or electronic comments on the proposed rule by May 14, 2007.

**ADDRESSES:** You may submit comments, identified by Docket No. 2005N-0373 and RIN number 0910-AF54, 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(s) and Regulatory Information Number (RIN) 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 section II "Comments" in 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/>

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:

*For information concerning products regulated by the Center for Drug Evaluation and Research:* Audrey A. Thomas, Center for Drug Evaluation and Research (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5533, e-mail: [audrey.thomas@fda.hhs.gov](mailto:audrey.thomas@fda.hhs.gov).

*For information concerning products regulated by the Center for Biologics Evaluation and Research:* Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210, e-mail: [stephen.ripley@fda.hhs.gov](mailto:stephen.ripley@fda.hhs.gov).

*For information concerning products regulated by the Center for Devices and Radiological Health:* Scott G. McNamee, Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., rm. 230, Rockville, MD 20850, 240-276-0105, e-mail: [scott.mcnamee@fda.hhs.gov](mailto:scott.mcnamee@fda.hhs.gov).

*For information concerning products regulated by the Center for Veterinary Medicine:* Michael J. Popek, Center for Veterinary Medicine (HFV-144), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6462, e-mail: [michael.popek@fda.hhs.gov](mailto:michael.popek@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the *Federal Register* of January 12, 2007 (72 FR 1582), FDA published a proposed rule that, if finalized, would prohibit the use of certain cattle material in, or in the manufacture (including processing) of, medical products for humans and drugs for ruminants. FDA also proposed new recordkeeping requirements for medical products for humans and drugs for ruminants that are manufactured from or otherwise contain material from cattle.

Interested persons were given until March 13, 2007, to submit written or electronic comments to the agency on the proposal. On February 12, 2007,

FDA received a request to extend the comment period. FDA believes that extending the comment period by 45 days is appropriate to allow industry to generate information on products that might be affected by the rule. Therefore, FDA is extending the comment period until May 14, 2007. This extension will provide the public with a total of 105 days to submit comments.

## II. 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 No. 2005N-0373. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 23, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-5894 Filed 3-29-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG-156779-06]

RIN 1545-BG27

#### Determining the Amount of Taxes Paid for Purposes of Section 901

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

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

**SUMMARY:** These proposed regulations provide guidance relating to the determination of the amount of taxes paid for purposes of section 901.

The proposed regulations affect taxpayers that claim direct and indirect foreign tax credits. This document also provides notice of a public hearing.

**DATES:** Written or electronic comments must be received by June 28, 2007. Outlines of topics to be discussed at the public hearing scheduled for July 30, 2007, at 10 a.m. must be received by July 9, 2007.

**ADDRESSES:** Send submissions to CC:PA:LPD:PR (REG-156779-06), 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-156779-06), 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-156779-06). The public hearing will be held in the Auditorium of the Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

#### FOR FURTHER INFORMATION CONTACT:

Concerning submission of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Kelly Banks (202) 622-7180; concerning the regulations, Bethany A. Ingwalson, (202) 622-3850 (not toll-free numbers).

#### SUPPLEMENTARY INFORMATION:

##### Background

Section 901 of the Internal Revenue Code (Code) permits taxpayers to claim a credit for income, war profits, and excess profits taxes paid or accrued (or deemed paid) during the taxable year to any foreign country or to any possession of the United States.

Section 1.901-2(a) of the regulations defines a tax as a compulsory payment pursuant to the authority of a foreign country to levy taxes, and further provides that a tax is an income, war profits, or excess profits tax if the predominant character of the tax is that of an income tax in the U.S. sense. Section 1.901-2(e) provides rules for determining the amount of tax paid by a taxpayer for purposes of section 901. Section 1.901-2(e)(5) provides that an amount paid is not a compulsory payment, and thus is not an amount of tax paid, to the extent that the amount paid exceeds the amount of liability under foreign law for tax. For purposes of determining whether an amount paid exceeds the amount of liability under foreign law for tax, § 1.901-2(e)(5) provides the following rule:

An amount paid does not exceed the amount of such liability if the amount paid is determined by the taxpayer in a manner that is consistent with a reasonable interpretation and application of the substantive and procedural provisions of foreign law (including applicable tax treaties) in such a way as to reduce, over time, the taxpayer's reasonably expected liability under foreign law for tax, and if the taxpayer exhausts all effective and practical remedies, including invocation of competent authority procedures available under applicable tax treaties, to reduce, over time, the taxpayer's liability for foreign tax (including liability pursuant to a foreign tax audit adjustment).

Section 1.901-2(e)(5) provides further that if foreign tax law includes options or elections whereby a taxpayer's liability may be shifted, in whole or

part, to a different year, the taxpayer's use or failure to use such options or elections does not result in a noncompulsory payment, and that a settlement by a taxpayer of two or more issues will be evaluated on an overall basis, not on an issue-by-issue basis, in determining whether an amount is a compulsory amount. In addition, it provides that a taxpayer is not required to alter its form of doing business, its business conduct, or the form of any transaction in order to reduce its liability for tax under foreign law.

#### A. U.S.-Owned Foreign Entities

Commentators have raised questions regarding the application of § 1.901-2(e)(5) to a U.S. person that owns one or more foreign entities. In particular, commentators have raised questions concerning the application of the regulation when one foreign entity directly or indirectly owned by a U.S. person transfers, pursuant to a group relief type regime, a net loss to another foreign entity, which may or may not also be owned by the U.S. person. Certain commentators have expressed concern that foreign taxes paid by the transferor in a subsequent tax year might not be compulsory payments to the extent the transferor could have reduced its liability for those foreign taxes had it chosen not to transfer the net loss in the prior year. This concern arises because the current final regulations apply on a taxpayer-by-taxpayer basis, obligating each taxpayer to minimize its liability for foreign taxes over time, even though the net effect of the loss surrender may be to minimize the amount of foreign taxes paid in the aggregate by the controlled group over time.

Similar questions and concerns arise when one or more foreign subsidiaries of a U.S. person reach a combined settlement with a foreign taxing authority that results in an increase in the amount of one foreign subsidiary's foreign tax liability and a decrease in the amount of a second foreign subsidiary's foreign tax liability.

#### B. Certain Structured Passive Investment Arrangements

The IRS and Treasury Department have become aware that certain U.S. taxpayers are engaging in highly structured transactions with foreign counterparties in order to generate foreign tax credits. These transactions are intentionally structured to create a foreign tax liability when, removed from the elaborately engineered structure, the basic underlying business transaction