§ 522.970 Flunixin meglumine solution.

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(b) *Sponsors.* See Nos. 000061, 000856, and 059130 in § 510.600(c) of this chapter.

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Dated: October 17, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–26633 Filed 10–26–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 886

[Docket No. 91N–0063]

Immunology and Microbiology Devices; Revocation of the Exemption From Premarket Notification; Blood Culturing System Devices; Change of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; change of compliance date for certain manufacturers and distributors.

SUMMARY: The Food and Drug Administration (FDA) is changing the compliance date of the final rule published on July 27, 1995 (60 FR 38480), that revoked the exemption from the requirement of premarket notification for blood culturing system devices to allow a 60-day grace period for submission of premarket notifications and to change the April 22, 1996, deadline to a December 26, 1996, deadline for obtaining premarket clearance for manufacturers or initial distributors of the device that have already begun commercial distribution under the existing premarket notification exemption. This action is being taken in response to a request to reconsider the procedural requirements of the final rule.

DATES:

Effective date: The final rule is effective October 25, 1995.

Compliance dates: A premarket notification submission is required for any automated blood culturing system intended to be introduced or delivered for introduction into commerce on or after October 25, 1995, under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), and the procedures in subpart E of 21 CFR part 807. A manufacturer or an initial distributor of a blood culturing device that has already begun commercial distribution under the existing premarket notification exemption is required to submit a premarket notification on or before December 26, 1995, and must have a premarket notification cleared by FDA by December 26, 1996.

FOR FURTHER INFORMATION CONTACT: Lisa A. Rooney, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765, ext. 164.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 9, 1982 (47 FR 50814 at 50826), FDA published a final rule to classify blood culturing system devices into class I (21 CFR 866.2560). In the Federal Register of June 12, 1989 (54 FR 25042 at 25046), FDA published a final rule exempting microbial growth monitors, subject to certain limitations. In the Federal Register of April 26, 1991 (56 FR 19333), FDA proposed to revoke this exemption for blood culturing system devices because of safety and effectiveness considerations. In the proposed rule, FDA stated that a manufacturer or an initial distributor who has introduced blood culturing system devices into commerce since the premarket notification exemption became effective would be required to submit to FDA a premarket notification within 60 days after the final rule based upon the proposal became effective.

In the Federal Register of July 27, 1995 (60 FR 38480), FDA published a final rule to revise the microbial growth monitor classification regulation by revoking the exemption from the premarket notification requirements for automated blood culturing system devices used in testing blood and other normally sterile body fluids for bacteria, fungi, and other microorganisms. According to the final rule, a manufacturer or an initial distributor of a blood culturing device that had already begun commercial distribution under the existing premarket notification exemption would be required to submit a premarket notification on or before October 25, 1995, and have a premarket notification cleared by FDA by April 22, 1996.

In response to a letter requesting FDA to reconsider the procedural requirements of the final rule of July 27, 1995, FDA has decided to allow a 60-day grace period for submission of premarket notifications for manufacturers or initial distributors who have already begun introducing blood culturing system devices into commerce under the existing premarket notification exemption. However, a premarket notification submission is still required for any automated blood culturing system intended to be introduced or delivered for introduction into interstate commerce on or after October 25, 1995. Furthermore, in response to the correspondence, FDA has decided to change the April 22, 1996, deadline to a December 26, 1996, deadline for obtaining premarket clearance.

Dated: October 23, 1995,

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–26678 Filed 10–26–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8626]

RIN 1545–AT15

Continuity of Interest in Transfer of Target Assets After Qualified Stock Purchase of Target

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document prescribes final regulations under section 338 of the Internal Revenue Code regarding the transfer of target assets to the purchasing corporation or another member of the same affiliated group as the purchasing corporation after a qualified stock purchase (QSP) of target stock, if a section 338 election is not made. These regulations provide guidance to parties to such transfers.

DATES: These regulations are effective October 27, 1995.

These regulations are applicable to transfers of target assets that occur on or after October 26, 1995.

FOR FURTHER INFORMATION CONTACT: Steven M. Flanagan at (202) 622–7790 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Explanation of Provisions

Background

This document contains final regulations under section 338 that govern the treatment of an intragroup merger or similar transaction following a QSP of target stock, if a section 338 election is not made for the target.

Section 338 provides that, if a corporation makes a QSP of the stock of a target, the purchasing corporation may elect to have the target treated as having sold all of its assets at the close of the acquisition date in a single transaction and as a new corporation that purchased all such assets at the beginning of the following day. Under section 338(i), the

IRS and Treasury are authorized to prescribe such regulations as may be necessary or appropriate to carry out the purposes of section 338.

On February 17, 1995, proposed regulations under section 338 were published in the Federal Register (60 FR 9309). The proposed rules are based on the conclusion that the result in *Yoc Heating* v. *Commissioner*, 61 T.C. 168 (1973), is inconsistent with the legislative intent behind section 338 when there is a QSP of target stock.

Public Comments and the Final Regulations

The IRS received comments from the public on the proposed regulations, and a public hearing was held on June 7, 1995. Commentators generally support the proposed regulations. Accordingly, the final regulations adopt the proposed regulations with minor technical changes. The principal comments on the proposed regulations are discussed below.

Treatment of minority shareholders. The proposed regulations generally treat the purchasing corporation's target stock acquired in the QSP as an interest on the part of a person who is an owner of the target's business enterprise prior to the transfer that can be continued in a reorganization. Thus, if the purchasing corporation purchases the bulk of the stock of a target corporation in a QSP and subsequently merges the target into a subsidiary of the purchasing corporation in exchange for the subsidiary's stock, the continuity of interest requirement is treated as satisfied. However, this treatment does not extend to minority shareholders of the target whose stock is not acquired by the purchasing corporation.

Several commentators argue that the proposed regulations are inconsistent because they provide tax-free treatment to the purchasing corporation, but not minority shareholders who are the true historic owners of the target. Therefore, they suggest that the proposed regulations are contrary to traditional notions of shareholder continuity, and that the final regulations should extend tax-free treatment to minority shareholders who exchange their target stock for stock in the acquiring entity.

The final regulations do not adopt this suggestion. The legislative history of section 338 indicates a congressional intent to repeal the *Kimbell-Diamond* doctrine and protect the exclusivity of the section 338 election for obtaining a cost rather than a carryover basis in the target's assets after a QSP. See H.R. Conf. Rep. No. 760, 97th Cong., 2d Sess. 467, 536 (1982), 1982–2 C.B. 600, 632. The regulations apply the reorganization rules to the target corporation and purchasing group because the IRS and Treasury believe it is the simplest and most effective means of achieving this intent, as they provide a pre-existing set of rules with well-understood consequences.

The legislative history does not indicate any intention to provide reorganization treatment for all purposes to exchanges of stock incident to asset transfers after QSPs. Under general income tax rules, an exchange of shares is only accorded reorganization treatment if the continuity of interest requirement is satisfied with respect to the target shareholders generally. This requirement is not satisfied if the acquisition of the target in a QSP and the merger of the target into the purchasing corporation's subsidiary are pursuant to an integrated transaction in which the owner of the majority stake in the target receives solely cash. See, e.g., *Yoc Heating*, 61 T.C. 168; *Kass* v. *Commissioner*, 60 T.C. 218 (1973), *aff'd*, 491 F.2d 749 (3d Cir. 1974). Thus, extension of reorganization treatment to the minority shareholders in this case would inappropriately alter general reorganization principles, and would not be grounded in the policies of section 338.

Scope of minority shareholder exclusion provision. One commentator suggests that if the final regulations continue to deny reorganization treatment to the preexisting minority shareholders, the exclusion should expressly apply to both the continuity of interest and control rules, rather than only the continuity of interest rule (as proposed). The final regulations adopt the commentator's suggestion by moving the minority shareholder exclusion to the scope section. This change is intended to clarify that the minority shareholder exclusion applies to any transaction that qualifies as a tax-free reorganization by operation of these regulations.

Effect of section 338(h)(8). Section 338(h)(8) provides that stock and asset acquisitions made by members of the same affiliated group shall be treated as made by one corporation. One commentator suggests that the final regulations should specifically provide that section 338(h)(8) does not apply in determining whether the merger of target qualifies as a reorganization. Otherwise, the commentator contends, a transaction in which target ''sprinkles'' its assets among several members of the purchasing corporation's affiliated group would qualify as a reorganization, because section 338(h)(8) treats the purchasing corporation and its affiliates as one corporation.

The final regulations do not adopt this suggestion because section 338(h)(8) (including section 338(h)(8)), by its terms, only applies for purposes of section 338 (e.g., determining whether a transaction qualifies as a QSP). The final regulations only modify the continuity of interest and control requirements for reorganizations, and any transaction in which the target ''sprinkles'' its assets among several purchasing corporation affiliates would likely fail other reorganization requirements.

Guidance regarding mergers after a section 338 election. The Preamble to the proposed regulations requests comments on whether guidance is necessary on the proper treatment of post-QSP mergers if a section 338 election is made for target. Because this request did not receive a strong response, the IRS and Treasury have decided not to provide such guidance in this document.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f), the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Steven M. Flanagan, Office of Assistant Chief Counsel (Corporate), Internal Revenue Service. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

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

Par. 2. Section 1.338–0 is amended by adding contents entries for § 1.338–2(c)(3) in numerical order to read as follows:

§ 1.338–0 Outline of topics.

* * * * *

§ 1.338–2 Miscellaneous issues under section 338.

* * * * *

(c) * * *

(3) Consequences of post-acquisition elimination of target.

(i) Scope.

(ii) Continuity of interest.

(iii) Control requirement.

(iv) Example.

(v) Effective date.

* * * * *

Par. 3. Section 1.338–2 is amended by adding paragraph (c)(3) to read as follows:

§ 1.338–2 Miscellaneous issues under section 338.

* * * * *

(c) * * *

(3) *Consequences of post-acquisition elimination of target*—(i) *Scope.* The rules of this paragraph (c)(3) apply to the transfer of target assets to the purchasing corporation (or another member of the same affiliated group as the purchasing corporation) (the transferee) following a qualified stock purchase of target stock, if the purchasing corporation does not make a section 338 election for target. Notwithstanding the rules of this paragraph (c)(3), section 354(a) (and so much of section 356 as relates to section 354) cannot apply to any person other than the purchasing corporation or another member of the same affiliated group as the purchasing corporation unless the transfer of target assets is pursuant to a reorganization as determined without regard to this paragraph (c)(3).

(ii) *Continuity of interest.* By virtue of section 338, in determining whether the continuity of interest requirement of § 1.368–1(b) is satisfied on the transfer of assets from target to the transferee, the purchasing corporation's target stock acquired in the qualified stock purchase represents an interest on the part of a person who was an owner of the target's business enterprise prior to the transfer that can be continued in a reorganization.

(iii) *Control requirement.* By virtue of section 338, the acquisition of target stock in the qualified stock purchase will not prevent the purchasing corporation from qualifying as a shareholder of the target transferor for the purpose of determining whether, immediately after the transfer of target assets, a shareholder of the transferor is in control of the corporation to which the assets are transferred within the meaning of section 368(a)(1)(D).

(iv) *Example.* This paragraph (c)(3) is illustrated by the following example:

Example. (A) *Facts.* P, T, and X are domestic corporations. T and X each operate a trade or business. A and K, individuals unrelated to P, own 85 and 15 percent, respectively, of the stock of T. P owns all of the stock of X. The total adjusted basis of T's property exceeds the sum of T's liabilities plus the amount of liabilities to which T's property is subject. P purchases all of A's T stock for cash in a qualified stock purchase. P does not make an election under section 338(g) with respect to its acquisition of T stock. Shortly after the acquisition date, and as part of the same plan, T merges under applicable state law into X in a transaction that, but for the question of continuity of interest, satisfies all the requirements of section 368(a)(1)(A). In the merger, all of T's assets are transferred to X. P and K receive X stock in exchange for their T stock. P intends to retain the stock of X indefinitely.

(B) *Status of transfer as a reorganization.* By virtue of section 338, for the purpose of determining whether the continuity of interest requirement of § 1.368–1(b) is satisfied, P's T stock acquired in the qualified stock purchase represents an interest on the part of a person who was an owner of T's business enterprise prior to the transfer that can be continued in a reorganization through P's continuing ownership of X. Thus, the continuity of interest requirement is satisfied and the merger of T into X is a reorganization within the meaning of section 368(a)(1)(A). Moreover, by virtue of section 338, the requirement of section 368(a)(1)(D) that a target shareholder control the transferee immediately after the transfer is satisfied because P controls X immediately after the transfer. In addition, all of T's assets are transferred to X in the merger and P and K receive the X stock exchanged therefor in pursuance of the plan of reorganization. Thus, the merger of T into X is also a reorganization within the meaning of section 368(a)(1)(D).

(C) *Treatment of T and X.* Under section 361(a), T recognizes no gain or loss in the merger. Under section 362(b), X's basis in the assets received in the merger is the same as the basis of the assets in T's hands. X succeeds to and takes into account the items of T as provided in section 381.

(D) *Treatment of P.* By virtue of section 338, the transfer of T assets to X is a reorganization. Pursuant to that reorganization, P exchanges its T stock solely for stock of X, a party to the reorganization. Because P is the purchasing corporation, section 354 applies to P's exchange of T stock for X stock in the merger of T into X. Thus, P recognizes no gain or loss on the exchange. Under section 358, P's basis in the X stock received in the exchange is the same as the basis of P's T stock exchanged therefor.

(E) *Treatment of K.* Because K is not the purchasing corporation (or an affiliate thereof), section 354 cannot apply to K's exchange of T stock for X stock in the merger of T into X unless the transfer of T's assets is pursuant to a reorganization as determined without regard to § 1.338–2(c)(3). Under general income tax principles applicable to reorganizations, the continuity of interest requirement is not satisfied because P's stock purchase and the merger of T into X are pursuant to an integrated transaction in which A, the owner of 85 percent of the stock of T, received solely cash in exchange for A's T stock. See, e.g., *Yoc Heating* v. *Commissioner,* 61 T.C. 168 (1973); *Kass* v. *Commissioner,* 60 T.C. 218 (1973), *aff'd,* 491 F.2d 749 (3d Cir. 1974). Thus, the requisite continuity of interest under § 1.368–1(b) is lacking and section 354 does not apply to K's exchange of T stock for X stock. K recognizes gain or loss, if any, pursuant to section 1001(c) with respect to its T stock.

(v) *Effective date.* The provisions of this paragraph (c)(3) are effective for transfers of target assets on or after October 26, 1995.

* * * * *

Margaret Milner Richardson,

Commissioner of Internal Revenue.

Approved: October 3, 1995.

Leslie Samuels,

Assistant Secretary of the Treasury.

[FR Doc. 95–26739 Filed 10–26–95; 8:45 am]

BILLING CODE 4830–01–U

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26 CFR Part 301

[TD 8625]

RIN 1545–AS61

Seals of Office

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the authority contained within section 7514 of the Internal Revenue Code to prescribe or modify seals of office. These regulations provide an additional or alternative uniform seal for use by internal revenue offices throughout the country. In addition this regulation publishes what will be the newly reorganized regional and district offices, computing centers, submission processing centers, and customer service centers of the IRS.

EFFECTIVE DATE: October 27, 1995.

FOR FURTHER INFORMATION CONTACT: Robert A. Walker, (202) 622–3640 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

These final regulations amend the Procedure and Administration Regulations (26 CFR part 301) under section 7514 of the Internal Revenue Code (Code) and are issued under the