

§ 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.

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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.

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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