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Briefing on How To Use the Federal Register
For information on a briefing in Washington, DC, see
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Tylosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions reflecting approval of two new animal drug applications (NADA's), one held by Cargill, Inc.-Nutrena Feed Div., and the other by Tyson Foods, Inc. The NADA's provide for the use of what is now called tylosin Type B medicated feed to make Type C medicated swine feed. In a notice published elsewhere in this issue of the *Federal Register*, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: May 14, 1990.

FOR FURTHER INFORMATION CONTACT:

Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the *Federal Register*, FDA is withdrawing approval of NADA 102-717, held by Cargill, Inc.-Nutrena Feed Div., and NADA 121-290, held by Tyson Foods. Both NADA's provide for the use of what is now called tylosin Type B medicated feed for making Type C medicated swine feed. This document removes the sponsor entries in 21 CFR 510.600 (c)(1) and (c)(2) for Cargill, Inc.-Nutrena Feeds Div., and Tyson Foods, Inc. Neese & Sons, Inc., the original sponsor, is removed from the sponsor entries in 21 CFR 510.600 (c)(1) and (c)(2) because it was never removed after the transfer of its NADA to Cargill, Inc. (October 5, 1979; 45 FR 57389). § 558.625 (b)(47) and (b)(75) (21 CFR 558.625 (b)(47) and (b)(75)) are removed and reserved to reflect the withdrawal of these NADA's.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 708 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing entries "Cargill, Inc.-Nutrena Feed Div.," "Neese & Sons, Inc.," and "Tyson Foods, Inc.," and in the table in paragraph (c)(2) by removing the entries "024761," "035221," and "039502".

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.625 [Amended]

4. Section 558.625 Tylosin is amended by removing and reserving paragraphs (b)(47) and (b)(75).

Dated: April 26, 1990.

Richard H. Teske,
Deputy Director, Center for Veterinary Medicine.

[FR Doc. 90-10158 Filed 5-1-90; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 61

(AD-FRL-3761-6)

National Emission Standards for Hazardous Air Pollutants; Benzene Emissions From Chemical Manufacturing Process Vents, Industrial Solvent Use, Benzene Waste Operations, Benzene Transfer Operations, and Gasoline Marketing System; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; Correction.

SUMMARY: This notice corrects errors and makes clarifications in the regulatory text of the General Provisions and the final National Emission

Standard for Benzene Waste Operations which appeared in the *Federal Register* on March 7, 1990 (55 FR 8292).

FOR FURTHER INFORMATION CONTACT:

Ms. Shirley Tabler at (919) 541-5256, Standards Development Branch, Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

SUPPLEMENTARY INFORMATION: On March 7, 1990 (55 FR 8292), EPA promulgated regulations limiting benzene emissions from benzene waste operations and benzene transfer operations and incorporated by reference some materials in the General Provisions of 40 CFR part 61. The paragraph designation for the incorporation by reference material in the General Provisions is being corrected, and a few editorial corrections to the National Emission Standard for Benzene Waste Operations are being made by this notice.

Also, many inquiries have been received requesting clarification of the date for compliance with the control requirements of the benzene waste operations standard. The indirect manner in which the standard provides the 2-year waiver of compliance for installation of controls has created confusion regarding the compliance date. Consequently, EPA is clarifying that existing sources, as provided by the statute, need not comply until 90 days after the effective date of the standard, and that sources needing to install controls need not come into compliance until 2 years from the effective date. Thus, the compliance date becomes March 7, 1992. Paragraph (b) of § 61.342 is therefore revised to require compliance with control requirements by March 7, 1992. This change is solely intended to clarify the compliance date and does not alter the control requirements.

Dated: April 24, 1990.

Michael Shapiro,

Acting Assistant Administrator for Air and Radiation.

The following corrections are being made in FRL 3706-1; National Emission Standards for Hazardous Air Pollutants; Benzene Emissions from Chemical Manufacturing Process Vents, Industrial Solvent Use, Benzene Waste Operations, Benzene Transfer Operations, and Gasoline Marketing System published in the *Federal Register* on March 7, 1990 (55 FR 8292).

1. The amendatory instruction 2, on page 8341, column 1, is corrected to read "Section 61.18 is amended by adding paragraph (d) to read as follows:"

§ 61.18 [Corrected]

1a. Paragraph (c) of § 61.18 on page 8341, column 2, is correctly redesignated as paragraph (d).

§ 61.342 [Corrected]

2. On page 8348, column 2, in paragraph (b) of § 61.342, in line 9, change "1990" to "1992."

§ 61.356 [Corrected]

3. In paragraph (j)(9) of § 61.356 on page 8359, column 2, line 5 from the bottom of the page, change "the owner or operator shall each" to "the owner or operator shall record each"

[FR Doc. 90-10196 Filed 5-1-90; 8:45 am]

BILLING CODE 6580-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 405

[BERC-473-F]

RIN 0936-AD52

Medicare Program; Protocol for the Reuse of Dialysis Bloodlines

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements section 1881(f)(7) (B) and (C) of the Social Security Act, added by sections 9335(k) and 4036(c) of the Omnibus Budget Reconciliation Acts of 1986 and 1987. That legislation precludes end-stage renal disease (ESRD) facilities from reusing dialysis bloodlines after July 1, 1988 unless the Secretary has established a protocol for their reuse and the facility follows the protocol. These provisions constitute both a Medicare condition of coverage for ESRD facilities and a condition for payment for dialysis treatment involving reused bloodlines for those facilities which elect to reuse them.

EFFECTIVE DATE: June 1, 1990.

FOR FURTHER INFORMATION CONTACT: John Powell, (301) 966-9671.

SUPPLEMENTARY INFORMATION:

I. Background

A. Summary of Rulemaking Activities

Under section 9335(k) of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Public Law 99-509, which established a new section 1881(f)(7) of the Social Security Act (the Act), dialysis facilities are prohibited from reusing certain items while performing

hemodialysis on or after January 1, 1988, unless the Secretary has established protocols for their reuse and the facilities follow the protocols. Reuse involves the cleaning, disinfecting, and preparation of disposable hemodialysis items for subsequent use for the same patient. The statute applies to dialyzer filters, bloodlines and other dialysis supplies. The failure of a dialysis facility to comply with this requirement constitutes grounds for denial of payment for the affected services or termination of the facility from the Medicare program. On October 3, 1987, we published final rules containing standards for reuse of hemodialyzer filters and several other dialysis supplies (52 FR 36926).

On December 22, 1987 the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100-203, was enacted. Section 4036(c) of OBRA '87 changed the date applicable to the reuse of bloodlines to July 1, 1988. On July 27, 1988 we published a proposed rule to address establishing the necessary protocols for the reuse of bloodlines.

B. Experience with New and Reused Bloodlines

Arterial and venous bloodlines are used to transfer a patient's blood through the filtering devices of a hemodialysis machine and to return it to the patient. Because bloodlines are essential to the operation of the hemodialysis machine, they are considered medical devices and thus are subject to the Food and Drug Administration (FDA) regulations, under the authority of the Medical Device Amendments of 1976. As discussed below, manufacturers of accepted bloodlines have labeled them "for single use only". Despite that labeling, it has been the practice of many dialysis facilities to reuse bloodlines.

The Public Health Services (PHS) has reviewed a considerable amount of available evidence concerning dialysis performed with new and reused bloodlines. The evidence available to PHS came from several major studies, each of which concluded that there was no detrimental clinical consequence associated with reusing bloodlines. A study conducted by National Medical Care (NMC), an organization that operates a number of dialysis facilities, that involved approximately 12,000 patients annually, indicated that since 1985, their arterial bloodline reuse program has not resulted in any statistical difference in patient complication rates between their facilities reusing arterial bloodlines and those not reusing them. A second study was conducted by a physician, Dr.

David Ogden, a nephrologist associated with the University of Arizona and a renal director of a dialysis center. This study showed that out of 170,000 reuses of bloodlines under his direction there were no substantial problems with reuse. In addition, a study conducted by the Centers for Disease Control, "National Surveillance of Dialysis—Associated Hepatitis and Other Diseases in the United States," during 1986 showed that 14 percent of centers then approved by HCFA reported reusing arterial bloodlines. This study also showed that there was no association between the reuse of bloodlines and any increased risk of hepatitis B virus (HBV) infection in either patients or staff members and no association between the reuse of bloodlines and the occurrence of pyrogenic reaction or septicemia in patients. Further, an earlier report by the National Center for Health Services Research Office of Health Technology Assessment examined the relative safety of hemodialyzer reuse and concluded that the practice (which essentially parallels that for bloodlines reuse) is indeed safe, provided that reprocessing is performed properly.

Currently, however, there is not a consensus within the dialysis community concerning a single use protocol for dialysis bloodlines (the AAMI protocol for reuse of bloodlines has not been formally accepted by the organization membership). Also, to the extent protocols might vary to account for particular characteristics of individual bloodlines, the Secretary is unable to establish a protocol applicable to all bloodlines. Therefore, the Secretary is establishing a regulation to permit Medicare reimbursement for bloodlines reused in accordance with FDA acceptance as described below.

In December 1986, the Director of FDA's Center for Devices and Radiological Health sent a letter to all domestic and foreign manufacturers of dialyzers and bloodlines. The letter urged manufacturers to reassess their labeling practice and to consider providing product-specific information and precautionary statements relevant to reprocessing and reuse. This action was taken in the belief that the majority of manufacturers to whom the letter was directed are aware that their devices are being reused.

On January 28, 1987, FDA received a request from a bloodline manufacturer, National Medical Care Inc., to have its arterial bloodline, Erika model number 9608, considered for relabeling. No other requests have been received. That manufacturer has applied to the FDA,