

§ 179.41 Pulsed light for the treatment of food.

Pulsed light may be safely used for treatment of foods under the following conditions:

(a) The radiation sources consist of xenon flashlamps designed to emit broadband radiation consisting of wavelengths covering the range of 200 to 1,100 nanometers (nm), and operated so that the pulse duration is no longer than 2 milliseconds (msec);

(b) The treatment is used for surface microorganism control;

(c) Foods treated with pulsed light shall receive the minimum treatment reasonably required to accomplish the intended technical effect; and

(d) The total cumulative treatment shall not exceed 12.0 Joules/square centimeter (J/cm².)

Dated: July 30, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-20853 Filed 8-14-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Parts 522 and 556**Animal Drugs, Feeds, and Related Products; Florfenicol Solution**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Schering-Plough Animal Health. The NADA provides for use of florfenicol injectable solution for cattle for the treatment of bovine respiratory disease.

EFFECTIVE DATE: August 15, 1996.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1644.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health, Schering-Plough Corp., P.O. Box 529, Kenilworth, NJ 07033, has filed NADA 141-063 Nuflor® Injectable Solution (300 milligrams florfenicol per milliliter) for intramuscular treatment of cattle for bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*. The NADA is approved as of May 31, 1996, and the regulations are amended by adding new § 522.955 to reflect the approval. The regulations are also amended to provide

for a tolerance for florfenicol residues in cattle in new § 556.283. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval for use in food-producing animals qualifies for 5 years of marketing exclusivity beginning May 31, 1996, because the application is for a new animal drug, no active ingredient of which has been approved in any other application.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects**21 CFR Part 522**

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. New § 522.955 is added to read as follows:

§ 522.955 Florfenicol solution.

(a) *Specifications.* Each milliliter of sterile solution contains 300 milligrams of florfenicol.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.283 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 20 milligrams per kilogram body weight (3 milliliters per 100 pounds). A second dose should be given 48 hours later.

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*.

(iii) *Limitations.* For intramuscular use only. Do not inject more than 10 milliliters at each site. Injection should be given only in the neck musculature. Do not slaughter within 28 days of last treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. Not for use in veal calves, calves under 1 month of age, or calves being fed an all milk diet. Use may cause violative tissue residues to remain beyond the withdrawal time. Not for use in cattle of breeding age. The effect of florfenicol on bovine reproductive performance, pregnancy, and lactation have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. New § 556.283 is added to read as follows:

§ 556.283 Florfenicol.

The safe concentrations for total florfenicol-related residues in cattle are 2.0 parts per million (ppm) in muscle, 6.0 ppm in liver, and 12.0 ppm in kidney and fat. A tolerance of 3.7 ppm for the marker residue, florfenicol amine, has been established in cattle liver.

Dated: July 25, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96-20854 Filed 8-14-96; 8:45 am]

BILLING CODE 4160-01-F

PENSION BENEFIT GUARANTY CORPORATION**29 CFR Part 4044****Allocation of Assets in Single-Employer Plans; Interest Rate for Valuing Benefits**

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans prescribes interest assumptions for valuing benefits under terminating single-employer plans. This final rule amends the regulation to adopt interest assumptions for plans with valuation dates in September 1996.

EFFECTIVE DATE: September 1, 1996.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024 (202-326-4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION: The PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions for valuing plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974.

Among the actuarial assumptions prescribed in part 4044 are interest rates

and factors. These interest rates and factors are intended to reflect current conditions in the financial and annuity markets.

Two sets of interest rates and factors are prescribed, one set for the valuation of benefits to be paid as annuities and one set for the valuation of benefits to be paid as lump sums. This amendment adds to appendix B to part 4044 the annuity and lump sum interest rates and factors for valuing benefits in plans with valuation dates during September 1996.

For annuity benefits, the interest rates will be 6.30 percent for the first 20 years following the valuation date and 4.75 percent thereafter. For benefits to be paid as lump sums, the interest assumptions to be used by the PBGC will be 5.25 percent for the period during which benefits are in pay status, 4.50 percent during the seven-year period directly preceding the benefit's placement in pay status, and 4.00 percent during any other years preceding the benefit's placement in pay status. The annuity and lump sum interest assumptions are unchanged from those in effect for August 1996.

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest rates and factors promptly so that the rates and factors can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation of benefits in plans with valuation dates during September 1996, the PBGC finds that good cause exists for making the rates and factors set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4044

Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR part 4044 is hereby amended as follows:

PART 4044—[AMENDED]

1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

Appendix B to Part 4044—[Amended]

2. In appendix B, a new entry is added to Table I, and Rate Set 35 is added to Table II, as set forth below. The introductory text of each table is republished for the convenience of the reader and remains unchanged.

Appendix B to Part 4044—Interest Rates Used To Value Annuities and Lump Sums**TABLE I.—ANNUITY VALUATIONS**

[This table sets forth, for each indicated calendar month, the interest rates (denoted by i_1 , i_2 , . . . , and referred to generally as i_t) assumed to be in effect between specified anniversaries of a valuation date that occurs within that calendar month; those anniversaries are specified in the columns adjacent to the rates. The last listed rate is assumed to be in effect after the last listed anniversary date]

For valuation dates occurring in the month—	The values of i_t are:					
	i_t	for t =	i_t	for t =	i_t	for t =
* * *	*	*	*	*	*	*
September 19960630	1–20	.0475	>20	N/A	N/A

TABLE II.—LUMP SUM VALUATIONS

[In using this table: (1) For benefits for which the participant or beneficiary is entitled to be in pay status on the valuation date, the immediate annuity rate shall apply; (2) For benefits for which the deferral period is y years (where y is an integer and $0 < y \leq n_1$), interest rate i_1 shall apply from the valuation date for a period of y years, and thereafter the immediate annuity rate shall apply; (3) For benefits for which the deferral period is y years (where y is an integer and $n_1 < y \leq n_1 + n_2$), interest rate i_2 shall apply from the valuation date for a period of $y - n_1$ years, interest rate i_1 shall apply for the following n_1 years, and thereafter the immediate annuity rate shall apply; (4) For benefits for which the deferral period is y years (where y is an integer and $y > n_1 + n_2$), interest rate i_3 shall apply from the valuation date for a period of $y - n_1 - n_2$ years, interest rate i_2 shall apply for the following n_2 years, interest rate i_1 shall apply for the following n_1 years, and thereafter the immediate annuity rate shall apply]

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
35	09-1-96	10-1-96	5.25	4.50	4.00	4.00	7	8

Issued in Washington, DC, on this 12th day of August 1996.

Martin Slate,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 96-20845 Filed 8-14-96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 415

[BPD-827-CN]

RIN 0938-AG96

Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1996

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

ACTION: Correction of final rule with comment period.

SUMMARY: This document corrects technical errors that appeared in the final rule with comment period published in the Federal Register on December 8, 1995 (60 FR 63124) entitled "Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1996."

EFFECTIVE DATES: January 1, 1996, except part 415, which is effective July 1, 1996.

FOR FURTHER INFORMATION CONTACT: Shana Olshan, (410) 786-5714; William Morse, (410) 786-4520.

SUPPLEMENTARY INFORMATION:

Background

In the Federal Register Document [95-29754], dated December 8, 1995, on page 63172 there is a technical error in

the preamble and, on pages 63177 and 63187 there are technical errors in the regulations text in § 414.30 ("Conversion factor update") and § 415.178 ("Anesthesia services"), respectively. In § 414.30, due to a typographical error, we inadvertently identified a revision being made to paragraph (b)(3) as adding a new paragraph (c). We correct both the amendatory statement and the regulations text. In the final rule, we also inadvertently retained language reflected in the July 26, 1995 (60 FR 38430) proposed rule concerning documentation of a preoperative and postoperative visit by the teaching physician in connection with anesthesia services. To be consistent with our policy of not requiring the teaching surgeon to be present at the preoperative and postoperative visit, we intended to revise the language related to the teaching anesthesiologist.

Correction of Errors

Preamble

Beginning on page 63171, in column 3, the first sentence of the last paragraph is corrected to read: "The information collection requirements in § 415.178 ("Anesthesia services"), paragraph (b), concern documentation of the teaching physician's presence or participation in the administration of the anesthesia. To be consistent with our policy concerning teaching surgeons, we will not require documentation of presence at the preoperative and postoperative visit."

Regulations Text

1. On page 63177, in column 1, item 4 is corrected to read as follows:

"4. In § 414.30, the introductory text to the section and the introductory text to paragraph (b) are republished and paragraphs (b)(2) and (3) are revised to read as follows:

§ 414.30 Conversion factor update.

Unless Congress acts in accordance with section 1848(d)(3) of the Act—

* * * * *

(b) *Downward adjustment.* The downward adjustment may not exceed the following:

* * * * *

(2) For CY 1994, 2.5 percentage points.

(3) For CYs 1995 and thereafter, 5 percentage points."

§ 415.178 [Corrected]

2. On page 63187, in column 1, paragraph (b) of § 415.178 ("Anesthesia services") is corrected to read as follows: "(b) *Documentation.* Documentation must indicate the physician's presence or participation in the administration of the anesthesia."

(Section 1848 of the Social Security Act (42 U.S.C. 1395w-4))

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 8, 1996.

Neil J. Stillman,

Deputy Assistant Secretary for Information Resources Management

[FR Doc. 96-20764 Filed 8-14-96; 8:45 am]

BILLING CODE 4120-01-M

42 CFR Parts 417, 473 and 498

[BPD-704-CN]

Medicare and Medicaid Programs: Provider Appeals; Technical Amendments; Corrections

AGENCY: Health Care Financing Administration, HHS.

ACTION: Correction notice.

SUMMARY: Federal Register document 96-13521 beginning on page 32347 of the issue of June 24, 1996, updated HCFA regulations that pertain to provider appeals from determinations