

CATEGORY II—Continued

Drug	Assay limits percent <sup>1</sup> Type A	Type B maximum (100x)	Assay limits percent <sup>1</sup> Type B/C <sup>2</sup>
Novobiocin .....	85-115	17.5 g/lb (3.85%) .....	80-120.
Pyrantel tartrate .....	90-110	36 g/lb (7.9%) .....	75-125.
Robenidine .....	95-115	1.5 g/lb (0.33%) .....	80-120.
Ronnel .....	85-115	27.2 g/lb (6.0%) .....	80-120.
Roxarsone .....	90-110	2.275 g/lb (0.5%) .....	85-120.
Roxarsone .....	90-110	2.275 g/lb (0.5%) .....	85-120.
Aklomide .....	90-110	11.35 g/lb (2.5%) .....	85-120.
Roxarsone .....	90-110	2.275 g/lb (0.5%) .....	85-120.
Clopidol .....	94-106	11.35 g/lb (2.5%) .....	80-120.
Bacitracin methylene disalicylate .....	85-115	5.0 g/lb (1.1%) .....	70-130.
Roxarsone .....	90-110	2.275 g/lb (0.5%) .....	85-120.
Monensin .....	90-110	5.5 g/lb (1.2%) .....	75-125.
Sulfadimethoxine .....	95-115	5.675 g/lb (1.25%) .....	85-115/75-125.
Ormetoprim (5/3) .....	95-115	3.405 g/lb (0.75%) .....	85-115.
Sulfadimethoxine .....	95-115	85.1 g/lb (18.75%) .....	85-115/75-125.
Ormetoprim (5/1) .....	95-115	17.0 g/lb (3.75%) .....	85-115.
Sulfaethoxyypyridazine .....	95-105	50.0 g/lb (11.0%) .....	85-115.
Sulfamerazine .....	85-115	18.6 g/lb (4.0%) .....	85-115.
Sulfamethazine .....	85-115	10.0 g/lb (2.2%) .....	80-120.
Chlortetracycline .....	85-115	10.0 g/lb (2.2%) .....	85-125/70-130.
Penicillin .....	85-115	5.0 g/lb (1.1%) .....	85-125/70-130.
Sulfamethazine .....	85-115	10.0 g/lb (2.2%) .....	80-120.
Chlortetracycline .....	85-115	10.0 g/lb (2.2%) .....	85-125/70-130.
Sulfamethazine .....	85-115	10.0 g/lb (2.2%) .....	80-120.
Tylosin .....	80-120	10.0 g/lb (2.2%) .....	75-125.
Sulfanitran .....	85-115	13.6 g/lb (3.0%) .....	75-125.
Aklomide .....	90-110	11.2 g/lb (2.5%) .....	85-120.
Sulfanitran .....	85-115	13.6 g/lb (3.0%) .....	75-125.
Aklomide .....	90-110	11.2 g/lb (2.5%) .....	85-120.
Roxarsone .....	90-110	2.715 g/lb (0.60%) .....	85-120.
Sulfanitran .....	85-115	13.6 g/lb (3.0%) .....	75-125.
Aklomide .....	90-110	11.2 g/lb (2.5%) .....	85-120.
Roxarsone .....	90-110	2.27 g/lb (0.5%) .....	85-120.
Sulfaquinoxaline .....	98-106	11.2 g/lb (2.5%) .....	85-115.
Sulfathiazole .....	85-115	10.0 g/lb (2.2%) .....	80-120.
Chlortetracycline .....	85-125	10.0g/lb (2.2%) .....	70-130.
Penicillin .....	80-120	5.0 g/lb (1.1%) .....	70-130.
Thiabendazole .....	94-106	45.4 g/lb (10.0%) .....	>7% 85-115; <7% 90-110.
Tilmicosin .....	90-110	18.2 g/lb (4.0%) .....	85-115.

<sup>1</sup> Percent of labeled amount.  
<sup>2</sup> Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

(e) When drugs from both categories are in combination, the Category II requirements will apply to the combination drug product.

[51 FR 7392, Mar. 3, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.4, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.5 New animal drug requirements for liquid Type B feeds.**

(a) Information available to the Commissioner of Food and Drugs shows that certain drugs are unstable when added to some liquid Type B medicated feeds. The demonstrated instability of

these drugs gives rise to the question of the stability of other drugs when added to liquid Type B medicated feeds, except where specific approval has been granted for such use. Therefore, the labeling of a drug to provide for its use in a liquid Type B medicated feed causes the drug to be a new animal drug for such use for which an approved new animal drug application is required pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act.

(b) The addition of a drug to a liquid Type B medicated feed causes such Type B feed to become an animal feed bearing or containing a new animal

drug for which an approved application is required pursuant to section 512(m) of the act.

(c) Each drug product, intended for oral administration to animals, which contains any of the drugs listed in paragraph (d) of this section and which bears labeling for its use in animal feed and/or drinking water shall also include in such labeling the following statement: "FOR USE IN \_\_\_\_\_ ONLY. NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS," the blank being filled in with the words "DRY FEEDS," "DRINKING WATER," "DRY FEEDS AND DRINKING WATER" as applicable, unless:

(1) Such drug product is the subject of an approved new animal drug application providing for its use in liquid Type B medicated feeds, or;

(2) The labeling provisions of this paragraph have been waived on the basis of approval of a petition which includes a copy of the product label; a description of the formulation; and information which establishes that the physical, chemical, or other properties of the particular drug product are such that it cannot reasonably be expected to be diverted for use in liquid Type B medicated feeds. Such petitions shall be submitted to the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(d) The labeling provisions of paragraph (c) of this section apply to all forms of bacitracin, oxytetracycline, and chlortetracycline.

(e) For any drug which is the subject of an approved new animal drug application, the labeling provisions of paragraph (c) of this section may be implemented without prior approval as provided for in §514.8(d) and (e) of this chapter.

[40 FR 13959, Mar. 27, 1975, as amended at 52 FR 2684, Jan. 26, 1987; 57 FR 6475, Feb. 25, 1992]

**§ 558.15 Antibiotic, nitrofurans, and sulfonamide drugs in the feed of animals.**

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses in animal feed of antibiotic and

sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975, or the nitrofurans drugs by no later than September 5, 1975, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products except the nitrofurans drugs not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, or by December 4, 1973, in the case of nitrofurans drugs, if marketing is to continue during the interim. New animal drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

(b) Any person interested in developing data which will support retaining approval for such uses of such antibiotic, nitrofurans, and sulfonamide drugs pursuant to section 512(l) of the Federal Food, Drug, and Cosmetic Act shall submit to the Commissioner the following:

(1) By July 19, 1973, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides; for all other antibiotics by October 17, 1973; and for the nitrofurans drugs by March 4, 1974. The Food and Drug Administration encourages sponsors to consult with the Center for Veterinary Medicine on protocol design and plans for future studies.

(2) By April 20, 1974, data from completed studies on the tetracyclines, streptomycin, dihydrostreptomycin, the sulfonamides, and penicillin assessing the effect of the subtherapeutic use of the drug in feed on the salmonella