SUBJECT: **Type A Medicated Articles**	**IMPLEMENTATION DATE** October 1, 1991
	COMPLETION DATE Continuing

DATA REPORTING

PRODUCT CODES	**PRODUCT/ASSIGNMENT CODES**
Industry code: 67	71005 (GMP) 71005A (Non-GMP)

FIELD REPORTING REQUIREMENTS

As soon as the District becomes aware of any significant adverse inspectional, analytical, or other information which could or should affect the Agency's new product approval decisions with respect to a firm, the District should immediately notify Center for Veterinary Medicine (CVM), Division of Compliance HFV-230, by e-mail (linda.benjamin@fda.hhs.gov) or FAX, ((240) 276 -9201), and they, in turn, will notify appropriate CVM Units.

1. Reporting:

Send inspection reports (including FDA-483 and labeling) to the Medicated Feeds Team, HFV-226. For all inspections that result in the issuance of a Warning Letter, forward an electronic copy of the signed and dated Warning Letter (not redacted) via e-mail to the Compliance Program Manager. Notify the Compliance Program Manager of those firms identified as Out-of-Business (OOB) or Not Official Establishment Inventory (NOEI). Also notify HFD-095 for cancellation of their Drug Registration.

2. FACTS Reporting:

a. Charge time for CGMP inspections to 71005.

b. Charge time for NON-CGMP investigations or inspections to PAC 71005A.

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PART I – BACKGROUND

1. GENERAL

On March 3, 1986 the Food and Drug Administration published a rule restructuring the Agency's Medicated Feeds Program. An important aspect of the revised program is the clear distinction between a new animal drug and an animal feed bearing or containing a new animal drug (i.e., a medicated feed).

2. DEFINITIONS

Type A: A Type A medicated article is a product that consists of one or more new animal drugs intended solely for use in manufacturing of another Type A article or in the manufacturing of a medicated feed; the medicated feed can be either a Type B medicated feed or a Type C medicated feed. A Type A medicated article is the subject of an approved New Animal Drug Application (NADA) under section 512(c) of the Food, Drug, and Cosmetic Act (FD&C Act) and is of a standardized potency.

Type B: A Type B medicated feed is a feed that contains a new animal drug plus a substantial quantity of nutrients (not less than 25% weight) and is intended solely for use in the manufacturing of other medicated feeds; the medicated feed can be another Type B medicated feed or a Type C medicated feed. A Type B medicated feed is produced by diluting a Type A medicated article, another Type B medicated feed, or is produced from an unstandardized drug component (bulk or "drum-run", which is a dried crude fermentation product).

If the Type B medicated feed is produced from a drug component, it is the subject of an approved New Animal Drug Application under section 512(c) of the FD&C Act. If the Type B Medicated Feed is produced from a Category II, Type A Medicated Article, a registered and licensed feed mill must manufacture the feed (21 CFR 558.3 and 21 CFR 207.20).

A Type B medicated feed conforms to the definition of animal feed in Section 201(x) of the Act (i.e., intended as a substantial source of nutrients for the animal). Before being fed to animals, it has to be substantially diluted with one or more nutrients to produce a Type C medicated feed.

The maximum permitted concentration of a drug in a Type B medicated feed is 100 times the highest continuous use level for Category II drugs. The "highest continuous use level" is the highest dosage at which a drug is approved for continuous use (14 days or more) or, if not approved for continuous use, the highest level used for disease prevention or control.

The maximum B levels are not cast in concrete; they will change based on approved changes in the new animal drug application. For example, a drug's category could change based on new data, or a higher continuous use level may be approved.

Type C: A Type C medicated feed is a feed that consists of a new animal drug that is intended to be offered as a complete feed for the animal, or may be fed top dressed or offered free-choice in conjunction with other animal feed to supplement the animal's total daily ration. A Type C medicated feed is produced by substantially diluting a Type A medicated article, a Type B or another Type C medicated feed or is produced from substantially diluting a drug component with other ingredients to a level of use specified in an approved New Animal Drug Application under section 512(c) of the FD&C Act.

If the Type C medicated feed is produced from a drug component, it is the subject of an approved New Animal Drug Application (NADA) under section 512(c) of the FD&C Act. If the Type C medicated feed is produced from a Category II, Type A medicated article, a registered and licensed feed mill must manufacture the feed.

3. REQUIREMENTS

a. DRUG REGISTRATION
Establishments manufacturing Type A medicated articles or Type B or C medicated feeds from unstandardized drug components are required to register annually as drug establishments and are subject to biennial inspection under section 510 of the FD&C Act.

b. NEW ANIMAL DRUG APPLICATION
An approved FDA-356V, New Animal Drug Application (NADA) is required for the manufacture of a Type A medicated article containing a new animal drug unless exempted under 21 CFR 558.15.

PART II - IMPLEMENTATION

The compliance program is to assure that a Type A medicated article(s) meets the requirements of the FFD&C Act as to safety, identity and strength and meets the quality and purity characteristic that it purports or is represented to possess.

1. OBJECTIVES

a. To inspect establishments producing Type A medicated articles for compliance with 21 CFR Part 226 (Type A Medicated Article CGMPs).

b. To take regulatory action against adulterated and misbranded Type A medicated articles and violative firms.

c. To deny approval to firms in violation of CGMPs of pending NADAs for Type A medicated articles or withdraw approval of existing NADAs.

d. To determine from inspections at manufacturers, repackers and relabelers the distributors of Type A medicated articles and investigate whether they, their consignees or the final users have proper authority to handle these products

2. PROGRAM MANAGEMENT/PLANNING INSTRUCTIONS

a. NON-CGMP INSPECTION
An investigation or inspection not directed to CGMP coverage under 21 CFR Part 226, Current Good Manufacturing Practice Regulations for Type A Medicated Articles, e.g., checking that NADA approved Type A medicated articles are distributed to authorized consignees.

b. INSPECTION PRIORITIES
In FY08, CVM began using risk-based criteria for inspection of Type A facilities. At the beginning of each fiscal year, an assignment will issue from the Center as to which facilities are to be inspected. From the list of facilities provided in the inspection, use the following priorities:

i. Give CGMP and NADA inspectional coverage to firms manufacturing, repacking or relabeling Type A medicated articles containing high risk drugs (Category II) Refer to ATTACHMENT A for (Category II) New Animal Drugs For Use in Animal Feeds.

ii. Give CGMP and NADA inspectional coverage to firms manufacturing, repacking or relabeling Type A medicated articles containing Category I drugs (ATTACHMENT A).

iii. During CGMP inspections have the investigator look for Non-CGMP violations. Should the investigator uncover illegal distribution of bulk new animal drug substances:

a) For imported substances, contact Kansas City Investigations Branch (HFR-SW350) for follow-up. Also See Import Alert # 68-09: "NEW BULK ANIMAL DRUG SUBSTANCES.".

b) For domestic substances, contact the home District for follow-up under the Animal Drug Manufacturing Inspections program, CP 7371.001.

c. PROGRAM INTERACTIONS

It should be noted that the Feed Manufacturing compliance program (7371.004) and the subject program are interrelated, since many establishments will be producing both products. Medicated feeds inspections are conducted under a Federal/State program and subject to 21 CFR Part 225, while Type A medicated articles are inspected strictly under a Federal program and subject to 21 CFR Part 226. This program is also related to the NADA Pre-Approval Inspections (7368.001) program, since FDA-356V's are required for Type A medicated articles.

PART III - INSPECTIONAL

INSPECTIONAL

a. CGMP INSPECTIONS

An establishment inspection should cover at least one Type A medicated article requiring a FDA-356V (NADA) approval. The basic approach is to determine whether the firm is complying with NADA commitments and CGMPs. Districts should determine if the firm has information available which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. All variances whether significant or minor should be reported. The products containing the drugs in ATTACHMENT A are subject to inspectional coverage.

Note: Do not inspect medicated block producers under this program. They are to be inspected under PART 225 CGMPs. The same applies to liquid feed supplements.

Since the declared potency of the finished Type A medicated articles is the basis for all further manufacturing of medicated feeds, potency (CGMP aspects that affect potency) may be considered the primary aspect of process control and inspectional attention. Similarly, the control of packaging and labeling is critical.

Inspection will be directed to determine the firm's compliance with 21 CFR Part 226, CGMPs for Type A medicated articles. Such compliance requires the manufacturer to set up component, process, laboratory controls, and an active program of quality assurance relating to those controls. Inspections will concentrate on those systems including, but not limited to, the following:

Note: Collect copies of labels for each finished drug Type A medicated article product.

(1) (226.30) Determine if scales and weighing equipment used for weighing components are accurate.

(2) (226.30, 226.40) If common mixing and handling equipment is used for different Type A medicated articles, determine the apparent effectiveness of the firm's procedures for clean-out and prevention of cross-contamination and report these in your EIR.' Determine if the mixing and handling equipment is constructed to facilitate clean-out.

(3) (226.20) Ensure that pesticides not intended for animal feed use and toxic materials are not stored, handled, or manufactured in common equipment or work areas.

(4) (226.42) Evaluate the firm's practices regarding labeling of components;

intermediate, and finished Type A medicated article containers or bins in order to prevent mix-ups.

(5) (226.42) Determine the firm's procedure for receipt, testing, and control of drug components. Report if specifications and testing methods are on file and also on the firm's practices regarding testing of drug components.

(6) (226.102) Review master formula records for adequacy of manufacturing instructions and evidence of review and endorsement as required by 226.102. Review a representative number of master formula records to determine if calculations regarding final drug levels are correct.

(7) (226.102) Examine a representative number of batch records in order to ensure conformance with master formula requirements. Determine whether or not batch records have been reviewed by responsible personnel and a determination of theoretical vs. actual batch yield made.

(8) (226.58) Report the firm's methods for stability determination and that assignment of expiration dates for Type A medicated articles indicated.

(9) (226.80) Report lot or batch numbering systems and the ability of the systems to identify batch production history using the lot or batch number which would appear on finished Type A medicated article containers.

(10) (226.58) Determine if the firm is completing finished Type A medicated article assays in accordance with 226.58(c).

b. NON-CGMP INSPECTIONS

When conducting CGMP inspections obtain non-CGMP information such as the source of the raw materials (bulk drugs, etc.). We have evidence that bulk drugs are being distributed to firms not holding approved NADAs which are needed to receive them. Also determine whether the firm is distributing finished products only to authorized consignees.

During each inspection the investigator should determine the following information on the distribution of all Type A articles: Dates and quantities of specific product(s) shipped; name, address and telephone number of company receiving the Type A article; and name of the responsible individual receiving the Type A article.

A sampling of the companies (distributors) receiving Type A articles should be investigated to determine that they are distributing products only to sites that have proper Agency authorization to handle such products.

If there are questions about whether or not an approved Medicated Feed Mill License exists, phone CVM's Medicated Feeds Team, HFV-226, at 240-453-6853.

c. SAMPLING

(1) Sampling Operations

Collect official samples to document plant violations. If there are no interstate shipments obtain a 301(k) sample of the finished product showing interstate movement of the drug component(s)

(2) Sample Collection

Refer to 10M sample schedule, chart 16.

(3) Sample Preparation and Shipment

Submit samples (domestic and import) of antibiotics to DEN-DO laboratory accompanied by labeling. Notify DEN-DO by telephone ((303) 236-3060) prior to shipment. Submit all other samples to the District's servicing laboratory.

d. IMPORT ACTIVITIES

Give surveillance coverage to imports of Type A medicated articles.

PART IV - ANALYTICAL

1. **Analyzing Laboratories (FDA Field Labs)**

   Domestic and Import Samples

   a. District servicing laboratories.

   b. Antibiotics - Denver Laboratory

2. **Analysis to be Conducted**

   Microbiological and chemical analyses for potency using AOAC and NADA methods.

3. **Methodology**

   a. Sample Preparation

   (1) Type A Medicated Articles (1 lb. subs.)

   (a) Bagged Material - Reduce each sub of the sample into equal portions by procedures found in AOAC, current edition, 965.16. This provides duplicate subs, one for FDA analysis the other for Section 702(b) (reserve) sample. Store the latter in air-tight containers (glass) under seal.

   Sub/Composite Portions - Prepare a representative portion of each sub for analysis by procedures found in AOAC, current edition, 950.02. Prepare a composite by thoroughly mixing together 50 gm from each of the subs.

   (b) Bulk Material - Reduce composite sample to two approximately equal size subs by procedures found in AOAC, current edition, 965.16. Pack one sub in air-tight glass container, identify and seal. This is a 702(b) sample. Prepare second sub for analysis by procedures found in AOAC, current edition, 950.02.

   (2) Type A Medicated Articles (6 oz. subs)

   Sample portions: Remove a two-ounce portion from each sub for drug analysis. Follow procedures found in AOAC current edition., 965.16. Place reserve sample in a sealed air-tight glass container and identify. Store for Section 702(b) requirements. If subs for FDA analysis are not in fine enough condition, grind according to procedures found in AOAC current edition, 950.02.

   b. Sample Examination

   Conduct all examinations on the composite portion. If the product is subject to an NADA and is found violative by a method other than the NADA, the check analysis should be by methods specified in the approved NADA.

4. **Method Inquiries**

   Call Division of Field Science (HFC-142), 301-796-5992 or refer to the Food Additives Analytical Manual. For NADA analytical methods call Dennis McCurdy, (HFV-226), 240-453-6852.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

A compliance strategy should be developed on a case-by-case basis before recommending regulatory action or administrative sanctions. In certain cases it may be necessary to combine an administrative sanction with a contemplated regulatory action.

District management should encourage responsible individuals to take the initiative in voluntarily correcting violations.

For assistance in the developing compliance strategy, the District may contact the Division of Compliance (HFV-230).

In addition to 501(a)(2)(B) for CGMP violations, 501(a)(5) for failure to have an approved NADA on file and 501(c) for potency and purity that differ from the approval application, the Type A medicated article may be in violation of Section 502(f)(1) in that it does not bear adequate directions for use and of Section 502(f)(2) in that it lacks required warnings as are necessary for protection of the users, e.g., precautions for handlers.

1. Administrative Sanctions

   Recommend denying approval of pending or future NADAs or withdrawing approval of existing NADAs based on inspectional evidence of Type A medicated article CGMP violations. Inspectional findings should identify significant CGMP deviations supported by convincing documentation that substantiates the contention about the firm's inability to meet CGMP requirements, or NADA commitments, if applicable.

   If the firm has failed to register or has cancelled registration because it no longer manufactures Type A medicated articles, advise HFV-230 so action can be taken to withdraw approval of NADAs held by the firm. In these instances the firm may be requested to provide a written request for withdrawal of application approvals.

2. Regulatory Actions

   a. Warning Letter

      The Warning Letter is generally the first action of choice. One exception is the case where there is a reasonable likelihood of an immediate hazard to human and/or animal health resulting from a violative product in which case seizure may be warranted. Other exceptions include those cases involving gross and flagrant violations.

      Whenever the CGMP deviations affect the approval of other pending NADAs, the Warning Letter should clearly state "because of Current Good Manufacturing Practices Regulation (CGMPR) deviations we have notified the Center for Veterinary Medicine not to approve any New Animal Drug Applications that you may submit for approval consideration until you have corrected the violations."

   b. Seizure, Injunction, Prosecution

These actions may be recommended on a case-by-case basis, ordinarily following appropriate and specific prior warning.

3. Imports

Refer to Import Alert, 68-09, Bulk New Animal Drug Substances, which allows the Agency to detain without physical examination, animal bulk drug substances found to be different than those referenced in NADAs or INADs for the production of Type A Medicated Articles. Where such instances are encountered, collect evidence of the article in question, including labeling, and notify DIOP of the findings. Also, where GMP violations indicate import source materials of a substandard quality please forward a copy of the FDA-483 to DIOP, along with supporting documentation.

4. Exports

A Type A medicated article containing a new animal drug requiring approval may not be legally exported unless it is subject to an approved NADA and complies with all the requirements of Section 801(d) of the Act. Violations are subject to regulatory action.

A Type A medicated article may be exported if it is for investigational use (INAD) and conforms to the exemption under Section 512(j) and 21 CFR Part 511, or if it falls within the exemption granted by 21 CFR 558.15.

PART VI - REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. REFERENCES
   a. Investigations Operations Manual.

   b. 21 CFR Part 226, Current Good Manufacturing Practice Regulations for Type A Medicated Articles; 21 CFR Part 225, Current Good Manufacturing Practice Regulations for Medicated Feeds.

   c. 21 CFR Part 558, New Animal Drugs for Use in Animal Feed. This reference identifies NADA approved drug articles. It also provides sponsor Nos. for manufacturers listed in Section 510.600(c).

   d. 21 CFR Part 510.7, Consignees of New Animal Drugs for Use in the Manufacture of Animal Feed.

   e. Regulatory Procedures Manual, Chapter 5

2. ATTACHMENT A
List of Category I and II drugs

3. PROGRAM CONTACTS

   a. Program (Project) Manager
   Leader, Medicated Feeds Team
   Division of Animal Feeds (HFV-226), CVM
   Tel. No.: 240-453-6858

   b. Program Monitor
   (HFV-226)
   Division of Animal Feeds, CVM
   Tel. No.: 240-453-6853

   c. Regulatory Inquiries
   Division of Compliance (HFV-232), CVM
   Tel. No.: 240-276-9201
   Fax No. 240-276-1498

   d. Investigations Branch (HFC-132)
   Division of Domestic Field Investigations, ORA
   Jim Dunnie
   Tel. No.: 301-796-5438

e. Information regarding illegal bulk animal drug substances:
Compliance Branch (HFR-SW340)
Kansas City District
Tel. No.: 913-752-2101

f. DEN-DO lab address and phone for shipping samples:
Food and Drug Administration
6th and Kipling St.
Building 20
Denver Federal Center
Denver, CO 80225-0087
Tel. No.: 303-236-3060

PART VII - CENTER RESPONSIBILITIES

The Medicated Feeds Team, (HFV-226) will monitor program accomplishments and make appropriate changes to ensure resource utilization in accordance with the program objectives. The team will evaluate and report on the program accomplishments.

Category I			
Drug	**Assay limits percent[1] Type A**	**Type B maximum (200x)**	**Assay limits percent[1] Type B/C[2]**
Aklomide	90–110	22.75 g/lb (5.0%)	85–120.
Amprolium with Ethopabate	94–114	22.75 g/lb (5.0%)	80–120.
Bacitracin methylene disalicylate	85–115	25.0 g/lb (5.5%)	70–130.
Bacitracin zinc	84–115	5.0 g/lb (1.1%)	70–130.
Bambermycins	90–110	800 g/ton (0.09%)	80–120/70–130.
Buquinolate	90–110	9.8 g/lb (2.2%)	80–120.
Chlortetracycline	85–115	40.0 g/lb (8.8%)	80–115/70–130.
Coumaphos	95–115	6.0 g/lb (1.3%)	80–120.
Decoquinate	90–105	2.72 g/lb (0.6%)	80–120.
Dichlorvos	100–115	33.0 g/lb (7.3%)	90–120/80–130.
Diclazuril	90–110	182 g/t (0.02%)	85–115/70–120.
Efrotomycin	94–113	1.45 g/lb (0.32%)	80–120.
Erythromycin (thiocyanate salt)	85–115	9.25 g/lb (2.04%)	<20g/ton 70–115/150–50; >20g/ton 75–125.
Iodinated casein	85–115	20.0 g/lb (4.4%)	75–125.
Laidlomycin propionate potassium	90–110	1 g/lb (0.22%)	90–115/85–115.
Lasalocid	95–115	40.0 g/lb (8.8%)	Type B (cattle and sheep): 80–120; Type C (all): 75–125.
Lincomycin	90–115	20.0 g/lb (4.4%)	80–130.
Melengestrol acetate	90–110	10.0 g/ton (0.0011%)	70–120.
Monensin	85–115	40.0 g/lb (8.8%)	Chickens, turkeys, and quail: 75–125; Cattle: 5–10 g/ton 80–120; Cattle: 10–30 g/ton 85–115; Goats: 20 g/ton 85–115; Liq. feed: 80–120.

Category I			
Drug	**Assay limits percent[1] Type A**	**Type B maximum (200x)**	**Assay limits percent[1] Type B/C[2]**
Narasin	90–110	7.2 g/lb (1.6%)	85–115/75–125.
Nequinate	95–112	1.83 g/lb (0.4%)	80–120.
Niclosamide	85–120	225g/lb (49.5%)	80–120.
Nystatin	85–125	5.0 g/lb (1.1%)	75–125.
Oleandomycin	85–120	1.125 g/lb (0.25%)	<11.25 g/ton 70–130; >11.25 g/ton 75–125.
Oxytetracycline	90–120	20.0 g/lb (4.4%)	75–125/65–135.
Penicillin	80–120	10.0 g/lb (2.2%)	65–135.
Poloxalene	90–110	54.48 g/lb (12.0%)	Liq. feed: 85–115.
Ractopamine	85–105	2.46 g/lb (0.54%)	80–110/75–125.
Salinomycin	95–115	6.0 g/lb (1.3%)	80–120.
Semduramicin (as semduramicin sodium)	90–110	2.27 g/lb (0.50%)	80–110
Semduramicin (as semduramicin sodium biomass)	90–110	2.27 g/lb (0.50%)	80–120
Tiamulin	113.4 g/lb, 100–108	3.5 g/lb (0.8%)	90–115.
	5 and 10 g/1b, 90–115		70–130.
Tylosin	80–120	10.0 g/lb (2.2%)	75–125.
Virginiamycin	85–115	10.0 g/lb (2.2%)	70–130.
Zoalene	92–104	11.35 g/lb (2.5%)	85–115.

1/ Percent of labeled amount.

2 /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 Type C medicated feed.

Category II			
Drug	**Assay limits percent[1] Type A**	**Type B maximum (100x)**	**Assay limits percent[1] Type B/C[2]**
Amprolium	94–114	11.35 g/lb (2.5%)	80–120.
Apramycin	88–112	7.5 g/lb (1.65%)	80–120.
Arsanilate sodium	90–110	4.5 g/lb (1.0%)	85–115/75–125.
Arsanilic acid	90–110	4.5 g/lb (1.0%)	85–115/75–125.
Carbadox	90–110	2.5 g/lb (0.55%)	75–125.
Carbarsone	93–102	17.0 g/lb (3.74%)	85–115.
Clopidol	94–106	11.4 g/lb (2.5%)	90–115/80–120.
Famphur	100–110	5.5 g/lb (1.21%)	90–115/80–120.
Fenbendazole	93–113	8.87 g/lb (1.96%)	75–125
Florfenicol	90–110	Swine feed: 9.1 g/lb (2.0%)	Swine feed: 85–115
		Catfish feed: n/a	Catfish feed: 80–110
		Salmonid feed: n/a	Salmonid feed: 80–110
Halofuginone hydrobromide	90–115	272.0 g/ton (.03%)	75–125.
Hygromycin B	90–110	1,200 g/ton (0.13%)	75–125.
Ivermectin	95–105	1,180 g/ton (0.13%)	80–110.
Levamisole	85–120	113.5 g/lb (25%)	85–125.
Maduramicin ammonium	90–110	545 g/ton (.06%)	80–120.
Morantel tartrate	90–110	66.0 g/lb (14.52%)	85–115.
Neomycin	80–120	7.0 g/lb (1.54%)	70–125.
Oxytetracycline	80–120	10.0 g/lb (2.2%)	65–135.
Neomycin sulfate	80–120	100 g/lb (22.0%)	70–125.
Nicarbazin (granular)	90–110	5.675 g/lb (1.25%)	85–115/75–125
Narasin	90–110	5.675 g/lb (1.25%)	85–115/75–125
Nicarbazin (powder)	98–106	5.675 g/lb (1.25%)	85–115/80–120
Nitarsone	90–110	8.5 g/lb (1.87%)	85–120.
Nitromide	90–110	11.35 g/lb (2.5%)	80–120.
Sulfanitran	85–115	13.6 g/lb (3.0%)	75–125.

Category II			
Drug	**Assay limits percent[1] Type A**	**Type B maximum (100x)**	**Assay limits percent[1] Type B/C[2]**
Nitromide	90–110	11.35 g/lb (2.5%)	85–115.
Sulfanitran	85–115	5.65 g/lb (1.24%)	75–125.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
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	90–110	5.675 g/lb (1.25%)	85–115/75–125.
Ormetoprim (5/3)	90–110	3.405 g/lb (0.75%)	85–115.
Sulfadimethoxine	90–110	85.1 g/lb (18.75%)	85–115/75–125.
Ormetoprim (5/1)	90–110	17.0 g/lb (3.75%)	85–115.
Sulfaethoxypyridazine	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.

Category II			
Drug	**Assay limits percent[1] Type A**	**Type B maximum (100x)**	**Assay limits percent[1] Type B/C[2]**
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.
Zilpaterol	90–110	680 g/t (0.075%)	80–110/75–115

1/ Percent of labeled amount.

2/ 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.