#181

Blue Bird Medicated Feed Labels

Guidance for Industry

This version of the guidance replaces the version that was made available on September 29, 2015. This version incorporates relevant policy previously located in the withdrawn CPG Sec. 665.200 Checklist Labeling for Custom Mixed Medicated Feeds.

Submit comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number [Insert docket number].

For further information regarding this document, contact AskCVM@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville MD 20855, and may be viewed on the Internet at either https://www.fda.gov/AnimalVeterinary/default.htm or https://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
July 2019

Table of Contents

Contains Nonbinding Recommendations

Blue Bird Medicated Feed Labels

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

A new animal drug application (NADA) for a Type A medicated article is required to include, among other things, representative labeling proposed to be used for Type B and Type C medicated feeds containing the new animal drug (21 CFR 514.1 (b)(3)(v)(*b*)). The Center for Veterinary Medicine (the Center or CVM) uses the term Blue Bird labels to refer to such representative labeling (November 19, 1999; 64 FR 63195 at 63197). Blue Bird labels are created by Type A medicated article sponsors and function as a guide to manufacturers of medicated feeds in the preparation of final printed feed labels.[1] The purpose of this guidance is to provide NADA sponsors of Type A medicated articles with the Center's current thinking on the recommended content and format of Blue Bird labels.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Type A medicated articles are intended solely for use in the manufacture of another Type A medicated article or in the manufacture of Type B or Type C medicated feed (21 CFR 558.3(b)(2)). Type B medicated feed is intended solely for the manufacture of other medicated feeds (Type B or Type C) and therefore it cannot be fed as is without being further diluted to Type C medicated feed. Type B medicated feed contains a substantial quantity of nutrients including vitamins and/or other nutritional ingredients in an amount not less than 25% of the weight. Type B medicated feed is manufactured by diluting a Type A medicated article or another Type B medicated feed (21 CFR 558.3(b)(3)). Type C medicated feed is intended as the complete feed for the animal or may be fed 'top dressed' (added on top of usual ration) or offered 'free choice' in conjunction with other animal feed. It is manufactured by diluting a Type A medicated article, a Type B medicated feed, or another Type C medicated feed (21 CFR 558.3(b)(4)).

[1] Final printed feed labels are also known as product or brand labels.

The sponsor of a Type A medicated article must submit, as part of its NADA, two labeling components. One is the specimens of labeling to be used for such new animal drug which must include adequate directions for the manufacture and use of finished feeds for all conditions for which the new animal drug is intended, recommended, or suggested in any of the labeling, including advertising, sponsored by the applicant (21 CFR 514.1 (b)(3)(v)(a)). The other labeling component required for such drugs is the representative labeling proposed to be used for the Type B and Type C medicated feeds containing the new animal drug (21 CFR 514.1 (b)(3)(v)(b)). This guidance provides recommendations on the content and format of the representative Blue Bird labeling proposed to be used for Type B and Type C medicated feeds only. It does not address the labeling of Type A medicated articles.

III. BLUE BIRD LABEL FORMAT AND CONTENT RECOMMENDATIONS[2]

The Act and its implementing regulations require animal food containing new animal drugs to be labeled in conformance with an approved application. As stated previously, during the new animal drug approval process, the drug sponsor submits representative labeling for Type B and Type C medicated feeds as part of the drug approval process. These labels are referred to as Blue Bird labels. Blue Bird labels serve as a guide to manufacturers of medicated animal feeds when preparing final printed medicated feed labeling. If the final Type B or C labeling does not conform with the new animal drug approval, including the approved representative labeling, the medicated feed is deemed unsafe under section 512(a)(2) of the Act, adulterated under section 501(a)(6), and/or misbranded under section 502(f)(1) of the Act.

Medicated feeds are required to be labeled with adequate directions for use enabling their use in a safe and effective manner. Therefore, clear medicated feed labeling is essential to ensure the medicated feed is properly used. As a result, Blue Bird labels generally include information on a single drug or drug combination use in a single animal species or production class within a species. The final printed labels for Type B or Type C medicated feeds are expected to follow the format of the respective Blue Bird label. Therefore, the final medicated feed labeling typically would include only a single drug or drug combination use in a single animal species of production class within a species.

A label typically should not include more than one approved use in more than one animal species or production category, or more than one withdrawal period, because such labeling could confuse the user. However, a final printed label may contain multiple drug or drug combination uses in multiple species or production classes when the Blue Bird label does so. Misleading labeling and incorrect use of a medicated feed could result in the medicated feed being deemed unsafe, adulterated, and/or misbranded.

A. TYPE "B " BLUE BIRD MEDICATED FEED LABEL:

1. Name of the Medicated Feed

[2] In an effort to modernize and consolidate policy related to medicated feed labeling, this section incorporates relevant policy previously located in the withdrawn CPG Sec. 665.200 Checklist Labeling for Custom Mixed Medicated Feeds.

We recommend that the name of a medicated feed on the Blue Bird label include the intended species and production class and the Type B medicated feed designation. Blue Bird feed names for the same drug or combination should allow the Blue Bird label to be distinguishable from other Blue Bird labels for the same drug or combination. Any information that is not part of the Blue Bird feed's name (e.g., weight statement) should not appear in the name.

2. Indication(s) for Use

This section should include the specific approved intended use of the medicated feed. The language in this section should match exactly the approved language found in the approved application.

3. Active Drug Ingredient(s)

We recommend that only established drug name(s) (21 CFR 514.1(a)(4)(i)) appear in this section. The drug name may be asterisked with trade or brand names included at the bottom of the label.

Maximum drug concentrations in Type B medicated feed are specified in 21 CFR 558.4. The drug concentration should be listed to the right of the drug name either as a single drug concentration or a range *(e.g.,* 1,000 to 20,000 g/ton). Where drug concentrations are listed in a range, the drug level should reference a footnote indicating that the final printed feed label should only include a single drug concentration.

For example: "*The final printed feed label should list only a single drug concentration.*"

Drug concentration is usually expressed in grams per ton (g/ton) of feed. Alternatively, if the drug level exceeds 2,000 g/ton, it may be stated in grams per pound (g/lb) of feed. If a drug combination is used in the feed, the same units of measurement should be used for all drugs in the combination.

4. Guaranteed Analysis

We recommend that this section of a Blue Bird label include nutritional guarantees that are tailored for a species/production class the feed is intended for, as listed in the current year's Association of American Feed Control Officials (AAFCO) Official Publication[3]. Additional guarantees, such as pH and dry matter content, should be included when necessitated by NADA approval, e.g., for liquid medicated feeds.

5. Ingredients

Instead of including the names of actual feed ingredients on the Blue Bird label, we

[3] Copies may be obtained through http://www.aafco.org.

recommend the inclusion of a statement indicating that the ingredient names on a final label will be AAFCO-defined names.

Examples of two acceptable statements for this section are:

> *"Each ingredient as named in accordance with the names and definitions adopted by the Association of American Feed Control Officials" or "Ingredients as defined by AAFCO."*

6. Mixing Directions

The mixing directions should instruct the user on how to prepare either another Type B or a Type C medicated feed using a Type B medicated feed.

Mixing directions may be for a single concentration or for a range of drug concentrations.

(i) An example statement for a single drug concentration:

> *"Mix ___ pounds of this Type B medicated feed with ___ pounds of non-medicated feed to manufacture one ton of Type C medicated feed containing ___ grams of ___ per one ton."*

For example, if the concentration of drug "X" in a Type B medicated feed is 1000 grams per ton and the desired drug concentration in a final Type C medicated feed is 50 grams per ton, then the mixing directions statement could read:

> *"Mix 100 pounds of this Type B medicated feed with 1,900 pounds of non-medicated feed to manufacture one ton of Type C medicated feed containing 50 grams of "X" per one ton."*

(ii) An example statement for a drug range in which w and x correspond to the amount of the low (w) and high (x) range of the drug listed on the Type B medicated feed label that would result in a concentration of 50 grams of the drug per ton on feed when diluted with non-medicated feed in the amount signified by y when the low drug concentration is used and z when the high drug concentration is used.

> *"Mix _w to x_ pounds of this Type B medicated feed with _y to z_ pounds of non- medicated feed to manufacture one ton of Type C medicated feed containing ____ grams of ____ per one ton."*

For example, if the concentration of drug "X" in a Type B medicated feed is 0.05 to 2.5 grams per pound and the desired drug concentration in a final Type C medicated feed is 50 grams per ton, then the mixing directions statement could read:

> *"Mix 1000 to 20 pounds of this Type B medicated feed with 1000 to 1980 pounds of non-medicated feed to manufacture one ton of Type C medicated feed containing 50 grams of "X" per one ton."*

Since Type B medicated feeds are intended solely for the manufacture of other medicated feeds (21 CFR 558.3(b)(3)), the inclusion of feeding instructions for the resulting Type C medicated feed on the label of a Type B medicated feed may be misleading and cause the Type B product to be misbranded. However, if the proposed labeling for the Type B feed includes feeding instructions for the Type C feed and, upon reviewing such labels, CVM finds that the information presented is presented in a manner that is not misleading regarding the proper use of Type B medicated feed, then the labeling would not misbrand the Type B product.

The agitation/recirculation directions, sometimes called "Mixing Directions," which are required under the regulations for liquid Type B medicated feeds (21 CFR 558.5), to be included on the labels for certain liquid medicated feeds, should be clearly distinguished from the mixing/feed preparation instructions of this section.

7. Caution

Any applicable caution statements including those related to animal safety, drug stability, or misuse of the feed containing the drug, that were deemed necessary for approval of the NADA should be listed in this section.

Example: *"Not for use in pregnant swine."*

In addition, if the product is a Veterinary Feed Directive (VFD) drug, the following caution statement is required by regulation and should appear in this section (21 CFR 558.6(a)(6)):

> ***"CAUTION:** Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian."*

8. Warning

Any applicable warning statements including those related to human food safety or human user safety that were deemed necessary for approval of the NADA should be listed in this section.

Example: *"Withdraw 5 days before slaughter."*

9. Manufacturer Information

A generic statement may appear in this section of the Blue Bird label to indicate where the actual identifying information for the manufacturer is to be inserted in the final feed labeling.

Example: *Blue Bird Feed Mill, Robin, Indiana 12345*

10. Weight Statement

A template statement may appear in this section of the Blue Bird label with the actual weight in U.S. standard (avoirdupois) and metric units to be inserted in the final labeling.

Example: *Net Weight____lb (__ kg)*
Bag or Bulk

11. Other Label Information

The label should include the following information as applicable:

(i) Lot, Batch or Control Number

(ii) Expiration Date - Medicated feeds that contain certain drugs or certain drugs at certain levels are required (21 CFR 514.1(b)(5)(x)) to establish an expiration date. When applicable, the expiration date should be included on the Blue Bird label.

(iii) Any other information that may be specifically required for NADA approval.

B. TYPE "C" BLUE BIRD MEDICATE D FE E D LABE L:

1. Name of the Medicated Feed

The same principles that apply to the Type B Blue Bird medicated feed label apply here except the name includes the Type C designation.

2. Indication(s) for Use

Same recommendation as for the Type B Blue Bird medicated feed label.

3. Active Drug Ingredient(s)

Only established drug name(s) should appear in this section. The drug name may be asterisked with trade or brand names included at the bottom of the label.

The amount of the drug approved for use in the feed should be listed to the right of the drug name. If a drug combination is used in the feed, the same units of measurement should be used for all drugs in the combination. Drug levels are usually expressed in grams per ton of feed. Alternatively, if the drug level exceeds 2,000 g/ton, it may be stated in grams per pound (g/lb) of feed.

Where drug concentrations are approved in a range (e.g., 10 to 30 grams per ton), the drug level could be expressed as a range and should reference a footnote indicating that the final printed feed label should only include a single drug concentration. For example:

"The final printed feed label should list only a single drug concentration."

Where the amount of the drug that animals need to consume daily, and not the drug concentration in feed, is specified in the approval, the label may bear the appropriate concentration in which the drug should be present in Type C medicated feed to deliver the approved amount of the drug.

4. Guaranteed Analysis

Same recommendation as for the Type B Blue Bird medicated feed label.

5. Ingredients

Same recommendation as for the Type B Blue Bird medicated feed label. When a formula for a free-choice medicated feed is made public, the ingredients should be listed exactly as approved.

6. Feeding Directions

The feeding directions should instruct the user on how to feed this Type C medicated feed. Individual drug approvals may state specifically how the feed is to be fed. An example of typical feeding directions is *"Feed continuously as the sole ration."*

7. Caution

Same recommendation as for the Type B Blue Bird medicated feed label.

8. Warning

Same recommendation as for the Type B Blue Bird medicated feed label.

9. Manufacture r Information

Same recommendation as for the Type B Blue Bird medicated feed label.

10. Weight Statement

Same recommendation as for the Type B Blue Bird medicated feed label.

11. Other Label Information

Same recommendation as for the Type B Blue Bird medicated feed label.

C. EXAMPLES OF TYPE B AND TYPE C BLUE BIRD LABELS :

Examples of Blue Bird Labels for Type B and Type C Medicated Feed can be found starting on pages 11 and 12, respectively.

Contains Nonbinding Recommendations

Drug X/Drug Y Growing Swine Ration
(drug X and drug Y Type B Medicated Feed)

For the reduction in severity of swine mycoplasma pneumonia caused by *Mycoplasma hyopneumoniae*; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

Active Drug Ingredients

Drug X.....19,200 g/ton
Drug Y…….40,000 g/ton

Guaranteed Analysis

Crude Protein (min)……._____%
Lysine (min)……..……._____%
Crude Fat (min)……...……_____%
Crude Fiber (max)……..._____%
Calcium (min)……._____%
Calcium (max)……._____%
Phosphorus (min)……._____%
Salt (min)[1] ...……..._____%
Salt (max)[1] ...……...……..._____%
Sodium (min)[2] ...……._____%
Sodium (max)[2] ……_____%
Selenium (min)……._____ppm
Zinc (min)……... _____ppm

[1] If added.
[2] Shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Ingredients as defined by AAFCO.

Mixing Directions

Mix 10 pounds of this Type B medicated feed with 1990 lb non-medicated feed ingredients to manufacture one ton of complete Type C medicated swine feed containing 96 grams of Drug X and 200 grams of Drug Y.

CAUTION: Not to be fed to swine that weigh more than 250 pounds.

WARNING: Withdraw 6 days before slaughter.

Manufactured by
Blue Bird Feed Mill
Robin, IN 00000

Net Weight___lb (_____kg)
Bag or Bulk
Lot number (if applicable)_____

Contains Nonbinding Recommendations

Drug X/Drug Y Growing Swine Ration
(drug X and drug Y Type C Medicated Feed)

For the reduction in severity of swine mycoplasma pneumonia caused by *Mycoplasma hyopneumoniae*; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

Active Drug Ingredients

Drug X……...96 g/ton
Drug Y……..……..……...200 g/ton

Guaranteed Analysis

Crude Protein (min)……._____%
Lysine (min)……._____%
Crude Fat (min)…….._____%
Crude Fiber (max)……..._____%
Calcium (min)……...…… _____%
Calcium (max)…… _____%
Phosphorus (min)……._____%
Salt (min)[1] ……..._____%
Salt (max)[1] ……...……..._____%
Sodium (min)[2] ……._____%
Sodium (max)[2] ……._____%
Selenium (min)……..._____%
Zinc (min)……..._____%

[1] If added.
[2] Shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Ingredients as defined by AAFCO.

Feeding Directions

Feed as sole ration for 21 days.

CAUTION: Not to be fed to swine that weigh more than 250 pounds.

WARNING: Withdraw 6 days before slaughter.

Manufactured by
Blue Bird Feed Mill
Robin, IN 00000

Net Weight ____lb (_____kg)
Bag or Bulk
Lot number (if applicable)_____