

**#181**

## Guidance for Industry

### Blue Bird Medicated Feed Labels

Comments and suggestions regarding this guidance should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the Docket No. FDA-2008-D-0165. Comments may also be submitted electronically on the Internet at <http://www.regulations.gov>. All comments should be identified with the exact title of the document. Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

For questions regarding this guidance contact Dragan Momcilovic, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-453-6856, E-mail: [Dragan.Momcilovic@fda.hhs.gov](mailto:Dragan.Momcilovic@fda.hhs.gov).

Additional copies of this guidance may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at <http://www.fda.gov/cvm>.

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Veterinary Medicine  
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# **GUIDANCE FOR INDUSTRY**

## **BLUE BIRD MEDICATED FEED LABELS<sup>1</sup>**

This guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

### **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) 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 animal feeds in the preparation of final printed feed labels.<sup>2</sup> 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.

FDA's guidance documents, including this guidance, 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)).

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<sup>1</sup> This guidance has been prepared by the Office of Surveillance and Compliance in the Center for Veterinary Medicine.

<sup>2</sup> 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**

#### **A. Type “B” Blue Bird Medicated Feed Label:**

##### **1. Name of the medicated feed**

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., 1000 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 AAFCO Official Publication<sup>3</sup>. 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**

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<sup>3</sup> Copies may be obtained from the Assistant Secretary-Treasurer, P.O. Box 478, Oxford, IN 47971

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

“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(f)):

**“CAUTION:** *Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian’s professional practice.”*

## 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 Medicated Feed Label:**

## **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. Manufacturer 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:**

**Drug X/Drug Y  
Growing Swine Ration  
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)<sup>1</sup>.....%  
Salt (max)<sup>1</sup>.....%  
Sodium (min)<sup>2</sup>.....%  
Sodium (max)<sup>2</sup>.....%  
Selenium (min).....ppm  
Zinc (min).....ppm

<sup>1</sup>If added.

<sup>2</sup>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

### Drug X/Drug Y Growing Swine Ration 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)<sup>1</sup>.....%  
Salt (max)<sup>1</sup>.....%  
Sodium (min)<sup>2</sup>.....%  
Sodium (max)<sup>2</sup>.....%  
Selenium (min).....ppm  
Zinc (min).....ppm

<sup>1</sup>If added.

<sup>2</sup>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