

Wisconsin Agribusiness Classic - January 2018

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FEED LABEL REQUIREMENTS AND OTHER UPDATES

JANUARY 10, 2017 – WISCONSIN AGRIBUSINESS CLASSIC

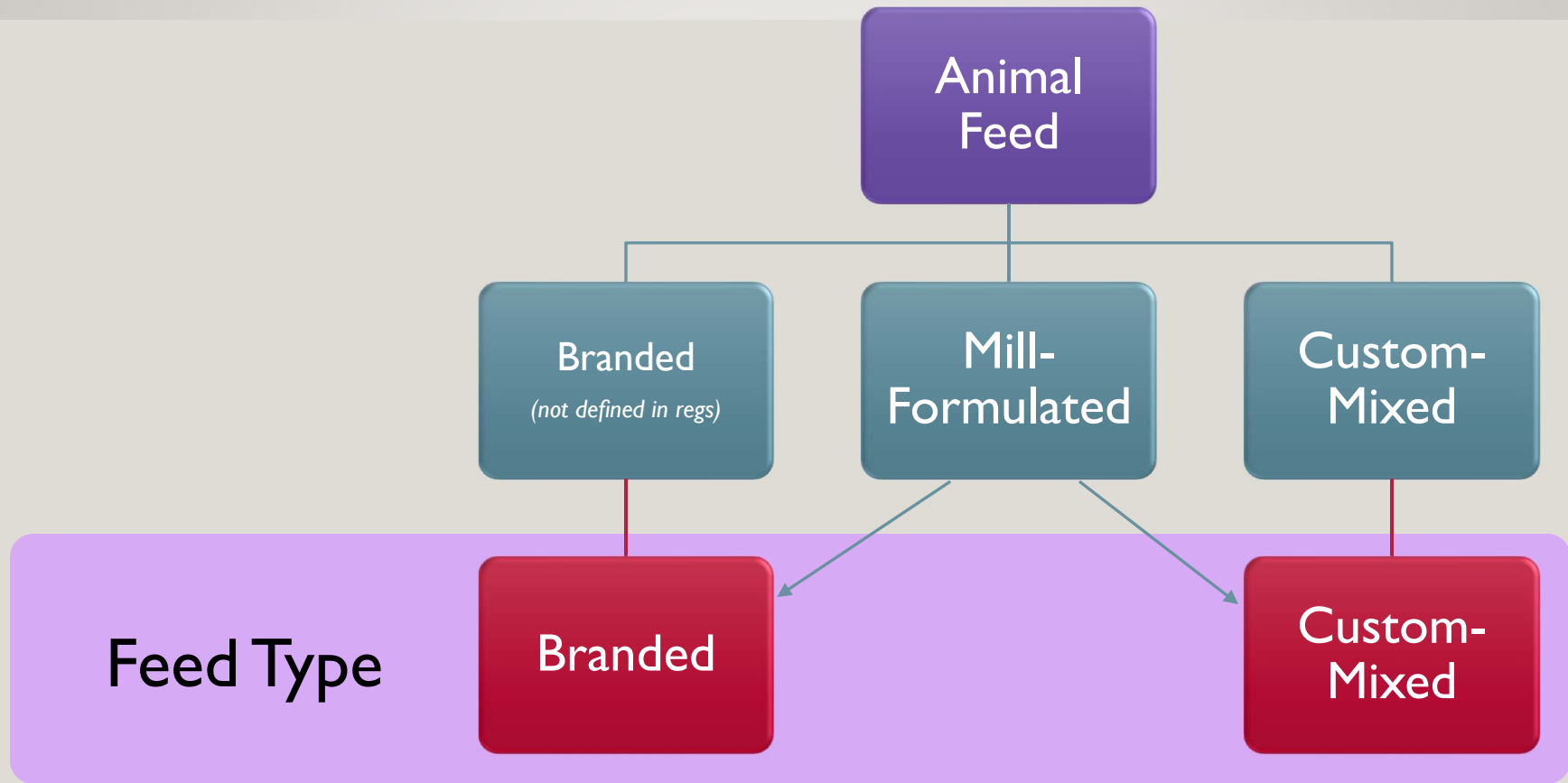
HEATHER BARTLEY, FEED SPECIALIST



2 AGENDA

- Non-medicated feed label requirements
 - Custom-mixes
 - Branded (or floor stock)
- Background on New Animal Drugs
- Medicated feed label requirements.
 - Branded (or floor stock)
 - Custom-mixes
- DATCP updates

3 FEED TYPE V. FEED LABEL



4 NON-MEDICATED “CUSTOM-MIX” LABEL REQUIREMENTS

1. Manufacturer name & address
2. Purchaser name & address
3. Date feed sold/delivered to purchaser
4. Name of the feed – include species/class to extent possible
5. Net quantity of the feed
6. Name & quantity of every ingredient in the feed
7. Use directions
8. Precautionary statements, if applicable

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NON-MEDICATED “CUSTOM-MIX” EXAMPLE

Sugar Magnolia Feeds®
100 W. Mill St.
City, State Zip

Name of customer:

Dairy Ridge Farm
W234S3159 Ridge Rd
City State Zip

Sold: May 13, 2015

4-20-15 Dairy Ridge Dairy Complete

Feed Products:

44% Soybean Meal
Brewers Dried Grain
Corn Distillers Grain
Whole Cotton Seed
Ground Limestone
Sugar Cane Molasses
ABC White Salt
University Dairy Premix

Net weight: 2 ton

1700 lb
800 lb
700 lb
300 lb
200 lb
150 lb
100 lb
50 lb




6 NON-MEDICATED “BRANDED” LABEL REQUIREMENTS

In this order:

1. Brand Name, if applicable
2. Product name
3. Purpose statement – intended use + species & class
4. Guaranteed analysis – species specific, see ATCP 42.14
5. Ingredient statement – no brand names, no quality statements
6. Use directions, if appropriate
7. Precautionary statements, if applicable
8. Manufacturer information
9. Net quantity – metric & Imperial (i.e. lbs.)

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NON-MEDICATED “BRANDED” EXAMPLE

Brand Name	YOUR NAME FEEDS
Product Name	Bucketful Dairy Concentrate
	
Purpose Statement	For lactating dairy cattle
Guaranteed Analysis	<p style="text-align: center;">Guaranteed Analysis</p> <p>Crude Protein, minimum38.0% (This includes not more than 3.5% equivalent crude protein from non-protein nitrogen)</p> <p>Crude Fat, minimum4.0% Crude Fiber, maximum4.0% Acid Detergent Fiber, max.5.6% Calcium, minimum0.8% Calcium, maximum1.3% Phosphorus, minimum0.65% Selenium, minimum0.3 ppm Vitamin A, minimum7000 IU/LB</p>
Ingredient Statement	<p style="text-align: center;">Ingredient Statement</p> <p>Grain Products, Plant Protein Products, Processed Grain By-Products, Urea, Calcium Carbonate, Animal Protein Products, Dicalcium Phosphate, Salt, Copper Sulfate, Manganous Oxide, Zinc Oxide Vitamin A Supplement, D-Activated Animal Sterol (source of Vitamin D3), Monocalcium Phosphate, Riboflavin Supplement, Choline Chloride, Biotin, Thiamine Mononitrate, Pyridoxine Hydrochloride, Ethoxyquin (a preservative), Niacin, Ferrous Sulfate, Cobalt Carbonate, Calcium Iodate, Vitamin E Supplement, Sodium Selenite.</p>
Use Directions	<p style="text-align: center;">FEEDING DIRECTIONS:</p> <p>Mix 400 lbs of Bucketful into 1600 lbs of shell corn, feed as sole grain ration, feed 14 lbs of this mixture to a 1200 lb. cow.</p>
Precautionary Statement (if required)	
Responsible Party's Name & Address	YOUR NAME FEEDS City, State, Zip
Quantity Statement	NET WT 50 LB (22.67 kg)

8 BACKGROUND: NEW ANIMAL DRUGS

- Any animal drug as we know it is a “new animal drug”
- Approved for use via “New Animal Drug Application” (NADA)
- Application packet includes environmental impacts, animal safety impacts, human safety impacts, user safety impacts, etc.
- Most importantly, includes *packaging and labeling*

9 WHY IS THE NADA IMPORTANT?

- A medicated feed is considered adulterated if it is not manufactured and labeled in accordance with the drug approval.
 - Reference:
 - Wis.Admin. Code §ATCP 42.52(2)(g)
 - 21 USC 360(b)(2)(A)(i)

10 NADA + YOU = EASIER STREET

- Use Blue Bird Labels
 - <https://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/>
- Other resources:
 - Feed Additive Compendium
 - CFR
 - Nutritionists
 - Sales Reps
 - Suppliers
 - Consultants
 - Etc.


II MEDICATED “BRANDED” FORMAT REQUIREMENTS

In this order:

1. Brand Name, if applicable
2. Product name
3. “Medicated”
4. Purpose statement – intended use + species & class
5. Drug indication
6. Active ingredient level
7. Guaranteed analysis – species specific, see ATCP 42.14
8. Ingredient statement – no brand names, no quality statements
9. Use directions & precautionary statements
10. Manufacturer information
11. Net quantity – metric & Imperial (i.e. lbs.)

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MEDICATED “BRANDED” FORMAT EXAMPLE

Brand Name	YOUR NAME FEEDS
Product Name	 Start-Her Starter Calf Feed Medicated
Purpose Statement & Medicated claim	Starter feed for dairy replacement heifers For control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i>
Drug Guarantee	Active drug ingredient Lasalocid30 grams /ton
Guaranteed Analysis	Guaranteed Analysis Crude Protein, minimum.....16% Crude Fat, minimum.....4% Crude Fiber, maximum.....4% Acid Detergent Fiber, max.5.6% Calcium, minimum.....0.8% Calcium, maximum1.3% Phosphorus, minimum.....0.65% Selenium, minimum0.2 ppm Vitamin A, minimum.....7000 IU/LB
Ingredient Statement	Ingredient Statement Grain Products, Plant Protein Products, Processed Grain By-Products, Urea, Calcium Lignin Sulfonate, Animal Fat, Vitamin A Supplement, D-Activated Animal Sterol (source of Vitamin D3), Vitamin E Supplement, Folic Acid, Ethoxyquin (a preservative), Ground Limestone, Dicalcium Phosphate, Salt, Copper Sulfate, Manganous Oxide, Zinc Oxide, Ferrous Sulfate, Cobalt Carbonate, Calcium Iodate, Sodium Selenite.
Use Directions	FEEDING DIRECTIONS: Each pound of Start-Her contains 15 mgs of lasalocid. Hand feed enough Start-Her to provide 1 mg per 2.2 pounds of body weight. (i.e. provide 4.5 lb. to a 150 lb. animal) Maximum rate of 350 mg per day.
Precautionary Statement (if required)	CAUTION: The safety of lasalocid in unapproved species has not been established. Do not allow horse or other equine access to feeds containing lasalocid, as ingestion may be fatal.
Responsible Party's Name & Address	YOUR NAME FEEDS City, State, Zip
Quantity Statement	NET WT 50 LB (22.67 kg)

13 MEDICATED “CUSTOM-MIX” LABEL REQUIREMENTS

1. Manufacturer name & address
2. Purchaser name & address
3. Date feed sold/delivered to purchaser
4. Name of the feed – include species/class to extent possible
5. “Medicated”
6. Name & quantity of every ingredient in the feed
7. Net quantity of the feed
8. Drug indication
9. Active ingredient level
10. Use directions & precautionary statements

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MEDICATED "CUSTOM-MIX" EXAMPLE

Sugar Magnolia Feeds®
100 W. Mill St.
City, State Zip

Name of customer:
Jim Smith Dairy
W234S3159 Ridge Rd
City State Zip

Sold: May 13, 2015

MEDICATED

JSMITHCALFNOV04

Feed Products:


44% Soybean Meal
Brewers Dried Grain
Corn Distillers Grain
Whole Cotton Seed
Ground Limestone
Sugar Cane Molasses
ABC White Salt
University Dairy Premix
Blue Bird 0.5% Deccox

Net weight: 2 ton

1700 lb
800 lb
700 lb
270 lb
200 lb
150 lb
100 lb
50 lb
30 lb



Directions for use: See attached medicated label.

CUSTOMER-FORMULA MEDICATED LABEL ATTACHMENT FOR INVOICE 2004 DATED 10/05/15							
JIM SMITH DAIRY CALF CATTLE FEED MEDICATED COMPLETE FEED CONTAINING DECCOX™(DECOQUINATE) FORMULA # JSMITHCALFNOV04							
STATEMENT OF PURPOSE							
For the prevention of coccidiosis in cattle (including ruminating and nonruminating calves and veal calves) caused by Eimeria bovis and Eimeria zuernii.							
ACTIVE DRUG INGREDIENT							
Decoquinat						34.09 grams/ton 17.05 milligrams/pound	
USE DIRECTIONS							
Feed at a rate of 22.7 mg decoquinat per 100 lb of bodyweight per day as indicated in the feeding chart below. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard.							
Cattle WT. (pounds)	decoquinat required (mg)	lbs. To feed per day		Cattle WT. (pounds)	decoquinat required (mg)	lbs. to feed per day	
100	22.7	1.33		600	136.2	7.99	
200	45.4	2.66		700	158.9	9.32	
300	68.1	4.00		800	181.6	10.65	
400	90.8	5.33		900	204.3	11.99	
500	113.5	6.66		1000	227	13.32	
PRECAUTIONARY STATEMENTS							
WARNING: Do not feed to cows producing milk for food.							
CAUTION: Do not use in feeds containing bentonite.							
MANUFACTURED BY: BLUE BIRD FED MILL, ANY CITY, M ANY STATE 55555 Net Weight on Bag and/or Invoice							
DECCOX™ is a trademark of Alpha Pharma Inc.						label revision 08/08/08	

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QUESTIONS?



16 CONTACT INFORMATION

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Protection

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Never hesitate to ask FDA/CVM: askcvm@fda.hhs.gov