

AAFCO Pet Food Regulations Label Review Checklist

Hilton Nashville Downtown
August 1, 2008



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Label Review Checklist

- OP = Page 174; Labeling Guide = Tab Page 99
- Each Point and Question to be presented with examples.
- Presenters will be from state and federal regulatory agencies and from industry

Label Review Checklist

- Rewrite of AAFCO Pet Food Regulations in 1999, published in 2000 Official Publication (OP)
- Checklist serves both regulators & industry
- How the checklist works
 - Yes** = compliance
 - No** = not in compliance

Label Review Checklist

- Point I – Animal Species
- Point II – Quantity Statement
- Point III – Product Claims
- Point IV - Product Comparison Claims

- Point V – Product Name
- Point VI – Guaranteed Analysis
- Point VII - Ingredient Statement

Label Review Checklist

- Point VIII – Nutritional Adequacy
- Point IX – Feeding Directions
- Point X – Calorie Content

- Point XI - Descriptive Terms
- Point XII – Manufacturer/Distributor
- Point XIII – Attachments
- Point XIV – Additional Comments

I. Animal Species - Regulation PF2(a)(2)

Do the words "Dog Food", "Cat Food",
"Canine Formula", "Feline Diet", or similar
designation appear conspicuously on the
principal display panel?

Yes _____ No _____

Point I

I. Animal Species - Regulation PF2(a)(2)

Do the words "Dog Food", "Cat Food",
"Canine Formula", "Feline Diet", or similar
designation appear conspicuously on the
principal display panel?

Yes _____ No _____

Point I

NO!

Noel's
High Performance



Point I

NO!

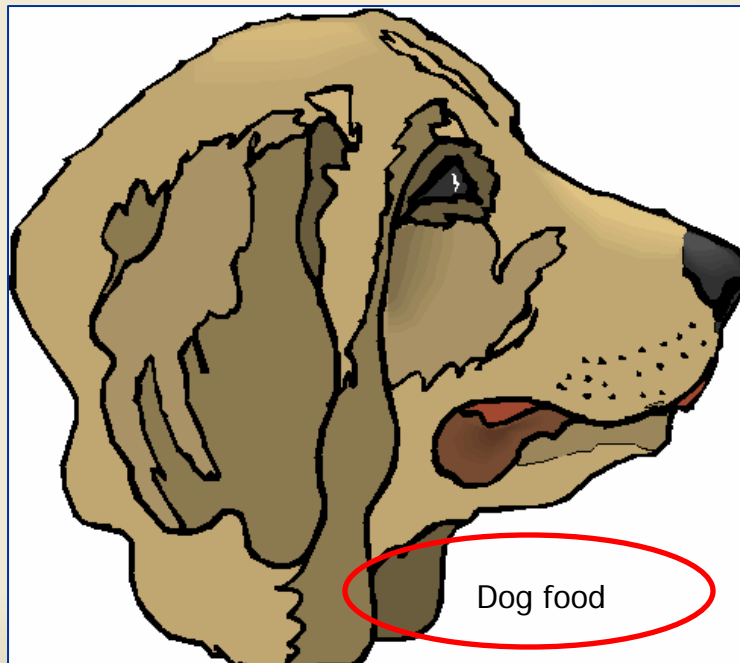
Noel's
High Performance
Food



Point I

NO!

Noel's High Performance



Point I

YES!

Noel's
High Performance
Dog Food



Point I

I. Animal Species -

The words "Dog Food", "Cat Food", "Canine Formula", "Feline Diet", or similar designation appear conspicuously on the principal display panel.

aka: Purpose statement or statement of intended use

Point I - Summary

II. Quantity Statement – Regulation PF2(a)(3)

21 CFR 501.105

Is there a quantity statement in lower third portion of principal display panel?

Yes _____ No _____

If yes:

1. Is the quantity statement in either net weight or net volume (avoirdupois) or by count?

Yes _____ No _____

2. If volume is listed, is there a weight equivalent listed elsewhere on label? PF4(c)(4) and PF4(d)(4)

Yes _____ No _____

Point II

Noel's
High Performance
Dog Food

NO!



Point II

Noel's
High Performance
Dog Food

Net Wt. 5 lbs. (2.26 kg)

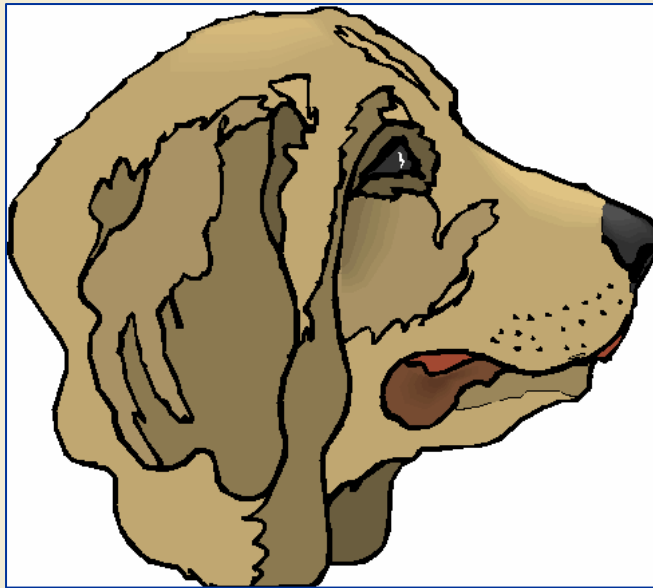


NO!

Point II

Noel's
High Performance
Dog Food

NO!

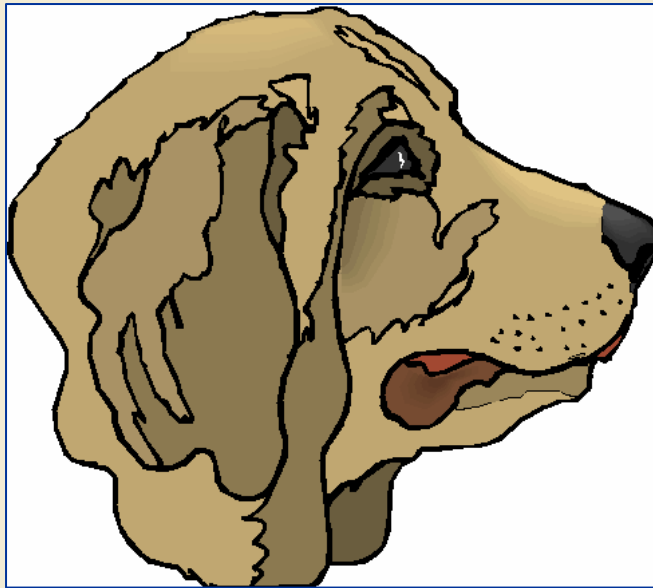


Point II

Net Wt. 5 lbs. (2.26 kg)

Noel's
High Performance
Dog Food

YES!



Net Wt. 5 lbs. (2.26 kg)

Point II

II. Quantity Statement – Regulation PF2(a)(3) 21 CFR 501.105

Is there a quantity statement in lower third portion
of principal display panel?

Yes _____ No _____

If yes:

1. Is the quantity statement in either net weight
or net volume (avoirdupois) or by count?

Yes _____ No _____

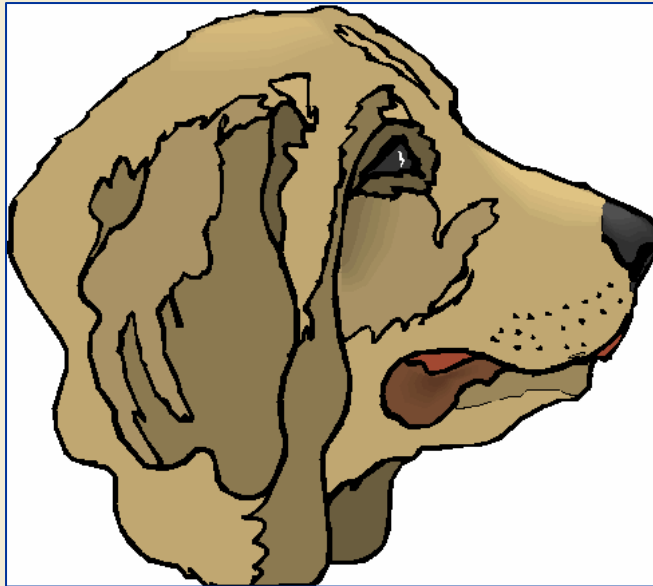
2. If volume is listed, is there a weight equivalent listed
elsewhere on label? PF4(c)(4) and PF4(d)(4)

Yes _____ No _____

Point II-1

Noel's
High Performance
Dog Food

NO!



5 pounds

Point II-1

Noel's
High Performance
Dog Food

YES!



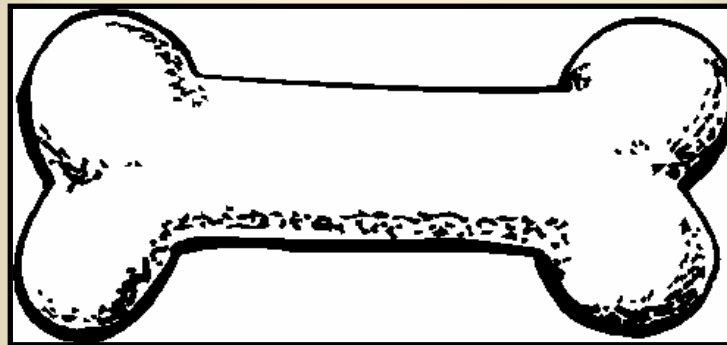
Net wt 5 lb (2.26 kg)

Point II-1

20

Noel's
Dog Biscuits

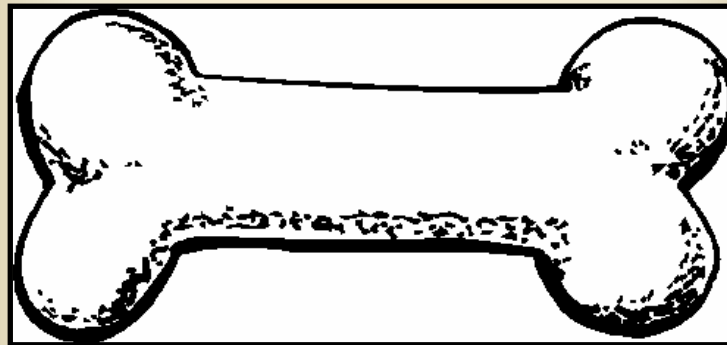
NO!



Point II-1

Noel's
Dog Biscuits

YES!



20 Large Biscuits

Point II-1

II. Quantity Statement – Regulation PF2(a)(3) 21 CFR 501.105

Is there a quantity statement in lower third portion
of principal display panel?

Yes _____ No _____

If yes:

1. Is the quantity statement in either net weight
or net volume (avoirdupois) or by count?

Yes _____ No _____

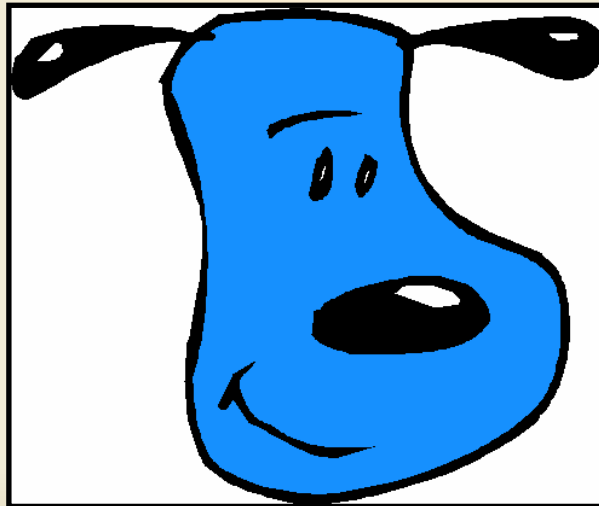
2. If volume is listed, is there a weight equivalent listed
elsewhere on label? PF4(c)(4) and PF4(d)(4)

Yes _____ No _____

Point II-2

NO!

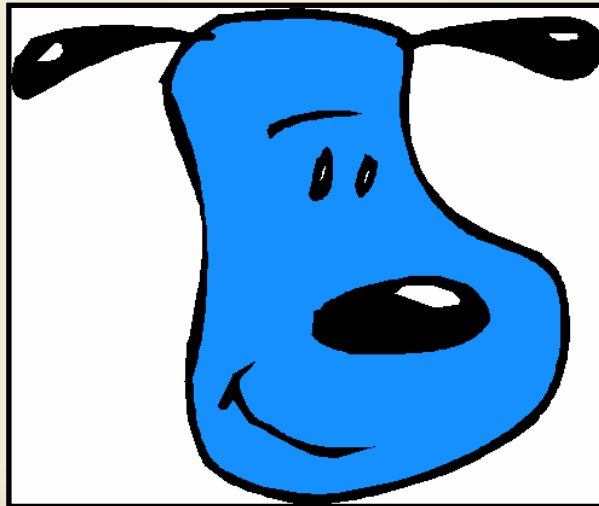
NOEL'S
Liquid Vitamins
for Dogs



Net weight 16 oz (454 g)

Point II-2

NOEL'S
Liquid Vitamins
for Dogs



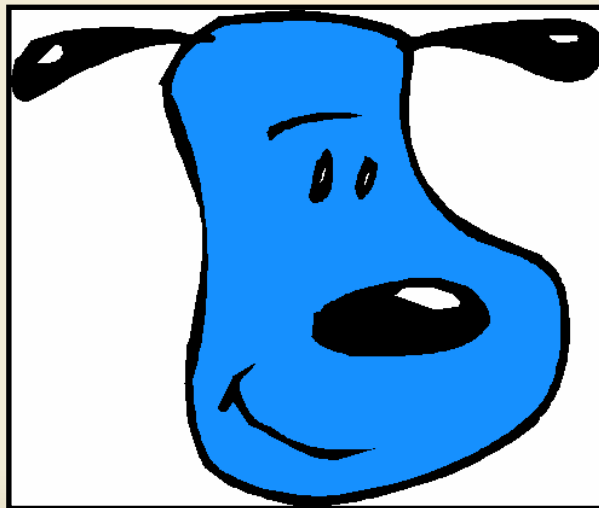
Net Vol. 8 oz. (235 ml)

NO!



Point II-2

NOEL'S
Liquid Vitamins
for Dogs



Net Vol 8 fl oz (235 ml)

1 fl oz = 28 g



YES!

II. Quantity Statement –

Quantity statement is in lower 30% of principal display panel

1. Quantity statement is in either net weight or net volume in avoirdupois with metric following or by count with sufficient description.
2. If volume is listed, there is a weight equivalent listed elsewhere on label that is consistent with net quantity or feeding directions.

Point II - Summary

III. Product Claims - PF2(c)(d)(e)(f)(g)(h)

If product claims or graphic representations are made:

1. Does adequate substantiation exist for each claim?
Yes _____ No _____
2. Are the claims truthful and not misleading?
Yes _____ No _____
3. If health claims are made, does adequate substantiation exist and have they been reviewed by the Center for Veterinary Medicine?
Yes _____ No _____

Point III

Noel's
High Performance
Dog Food

NO!



Makes your dog feel energized

Net wt 5 lb (2.26 kg)

Point III-1

Claims that are not allowed

- Stops itching
- Stops shedding
- No more tartar
- Controls odors
- Prevents hip dysplasia
- Prevents cancer

III. Product Claims - PF2(c)(d)(e)(f)(g)(h)

If product claims or graphic representations are made:

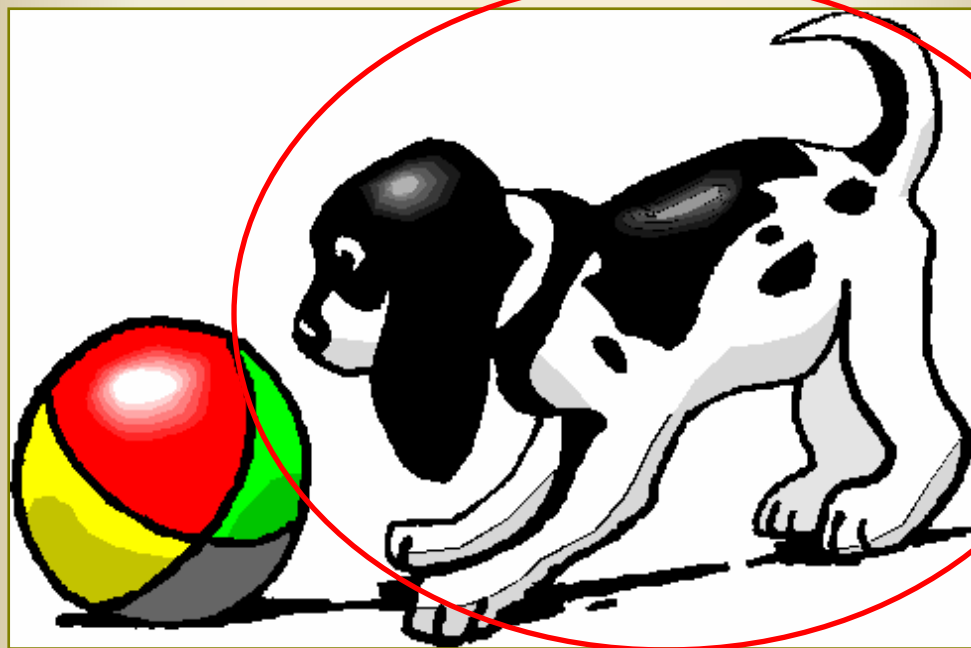
1. Does adequate substantiation exist for each claim?
Yes _____ No _____
2. Are the claims truthful and not misleading?
Yes _____ No _____
3. If health claims are made, does adequate substantiation exist and have they been reviewed by the Center for Veterinary Medicine?
Yes _____ No _____

Point III-2

Noel's High Performance
Adult Dog Food

NO!

Picture of
playful
puppy

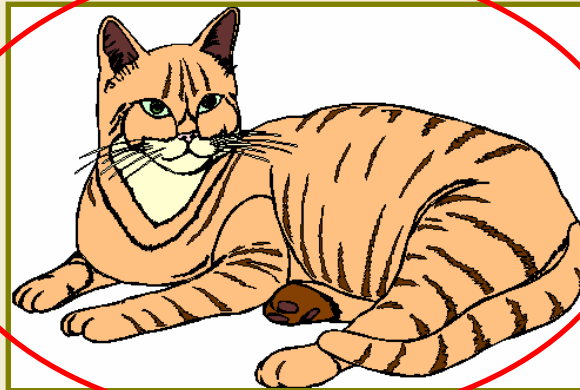


Net Wt. 5 lbs. (2.26 kg.)

Point III-2

Noel's High Performance
Dog Food

NO!



Net wt 16 oz (454 g)

Point III-2

III. Product Claims - PF2(c)(d)(e)(f)(g)(h)

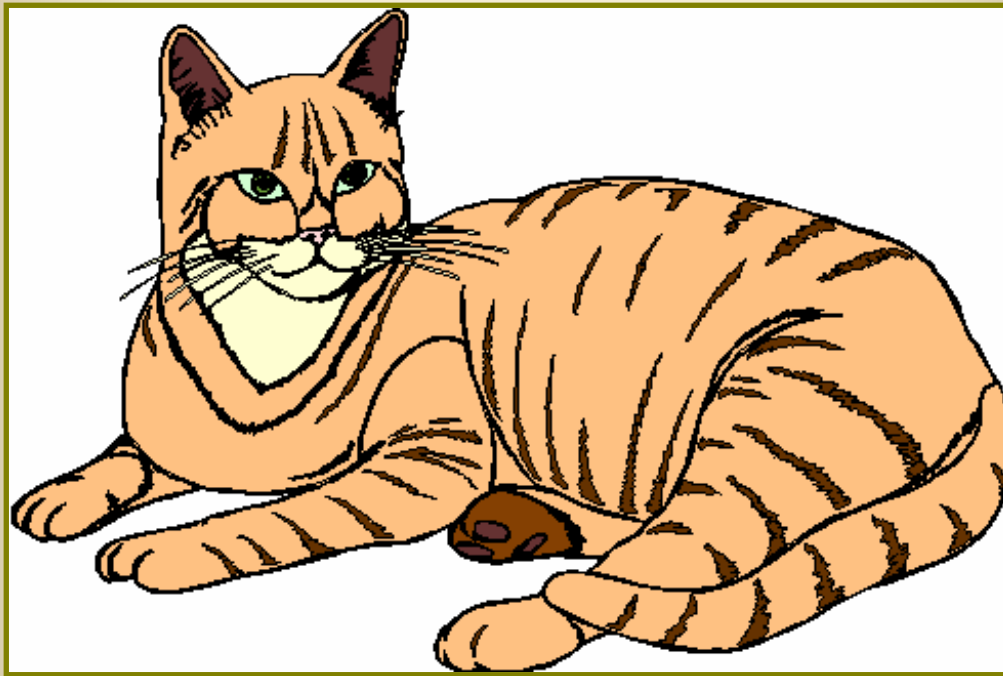
If product claims or graphic representations are made:

1. Does adequate substantiation exist for each claim?
Yes _____ No _____
2. Are the claims truthful and not misleading?
Yes _____ No _____
3. If health claims are made, does adequate substantiation exist and have they been reviewed by the Center for Veterinary Medicine?
Yes _____ No _____

Point III-3

Noel's Urinary Health
Cat Food

MAYBE!



Net wt 16 oz (454 g)

Point III-3

III. Product Claims –

The product claims or graphic representations are made:

1. Adequate substantiation exists for each claim either on label or in company files
2. The claims are truthful and not misleading
3. Health claims are made and have adequate substantiation exist and have been reviewed by the Center for Veterinary Medicine. Regulator reviewing the label can ask company and/or FDA for verification.

Point III- Summary

Tartar Control Claims

- Claims to cleanse, freshen or whiten teeth based on abrasive or mechanical action, not objectionable.
- Claims for plaque or tartar reduction or control of breath odor, of low regulatory priority, if based only on abrasive action.
- Drug claims of preventing or treating dental disease not allowed, unless subject to NADA.
- Ingredients not GRAS for intended purpose of affecting teeth may be considered unapproved feed ingredients or unapproved drugs.
- Claims based on any action other than mechanical require an approved NADA.

Point III

Natural Claims

- AAFCO defined feed term – derived from plant, animal or mined, unprocessed or subject to physical, heat, rendering, purification, extraction, hydrolysis, enzymolysis or fermentation, but not subjected to chemically synthetic process.
- Ingredients can be taken a part but not put together.
- 'All natural' only if every ingredient is natural.
- Vitamins, minerals & Taurine might not be natural.
Then use the disclaimer: 'with added vitamins & minerals' in the same style, color and ½ the size of the 'Natural.'
- Can link term 'Natural' to a specific ingredient, such as natural cheese flavor. Must be careful not to imply that the whole product is natural.

Point III

Organic

- AAFCO defined feed term – (process) A formula feed or a specific ingredient within a formula that has been produced & handled in compliance with USDA National Organic Program (7 CFR Part 205).
- Current NOP does not specifically address pet food.
- NOSB's Pet Food Task Force considered issues and drafted proposed language related specifically for pet foods and pet food labeling, includes specialty pet foods, but not horses, llamas, wild birds, or zoo animals.
- These are under consideration. Until they are adopted companies must follow current regulations.

Point III

IV. Product Comparison Claims - Regulation PF2(h)

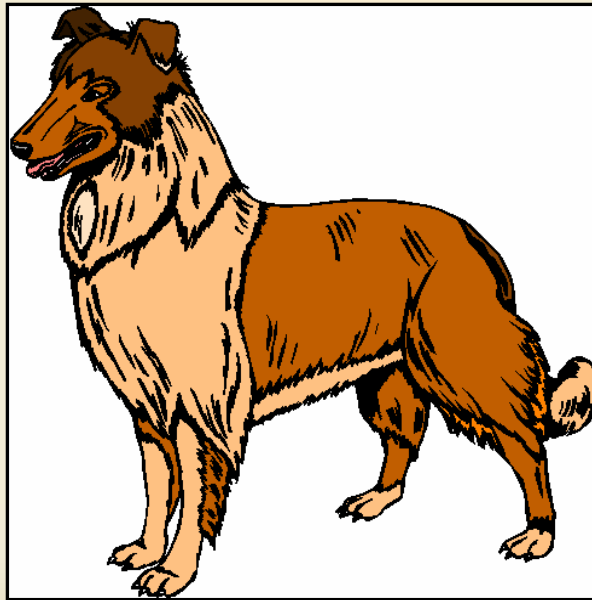
1. If the label includes any claims of comparison to another product, is the name of the product of comparison included on the label?
Yes _____ No _____
2. If "yes", is documentation, data, etc., available to support the claim?
Yes _____ No _____
3. Is the claim limited to one (1) year production?
Yes _____ No _____

Point IV

Noel's High Performance
Dog Food

20% More Protein

NO!



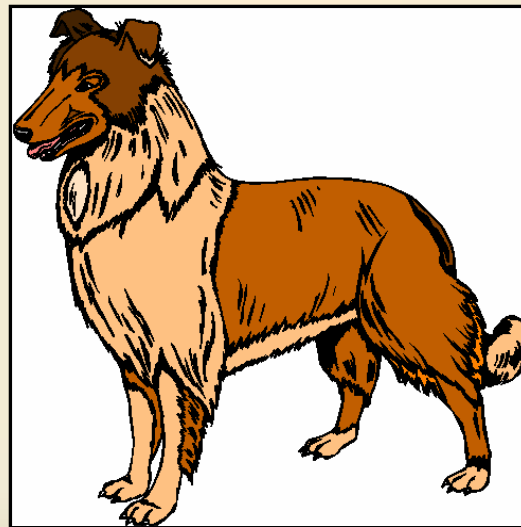
Net wt 16 oz (454 g)

Point IV-1

Noel's High Performance
Dog Food

YES!

20% more protein than Noel's Meaty
Nuggets Dog Food



Net wt 16 oz (454 g)

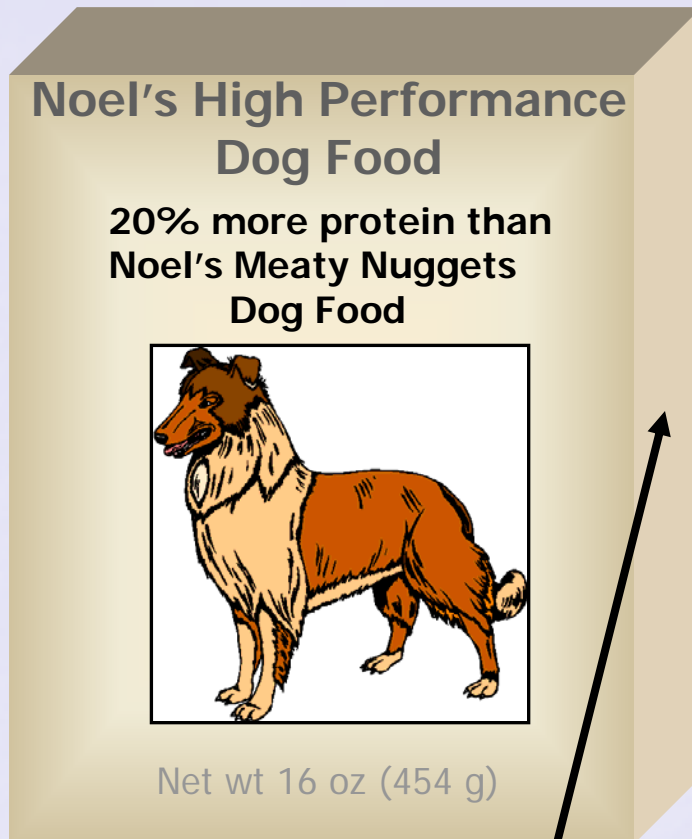
Point IV-2

IV. Product Comparison Claims - Regulation PF2(h)

1. If the label includes any claims of comparison to another product, is the name of the product of comparison included on the label?
Yes _____ No _____
2. If "yes", is documentation, data, etc., available to support the claim?
Yes _____ No _____
3. Is the claim limited to one (1) year production?
Yes _____ No _____

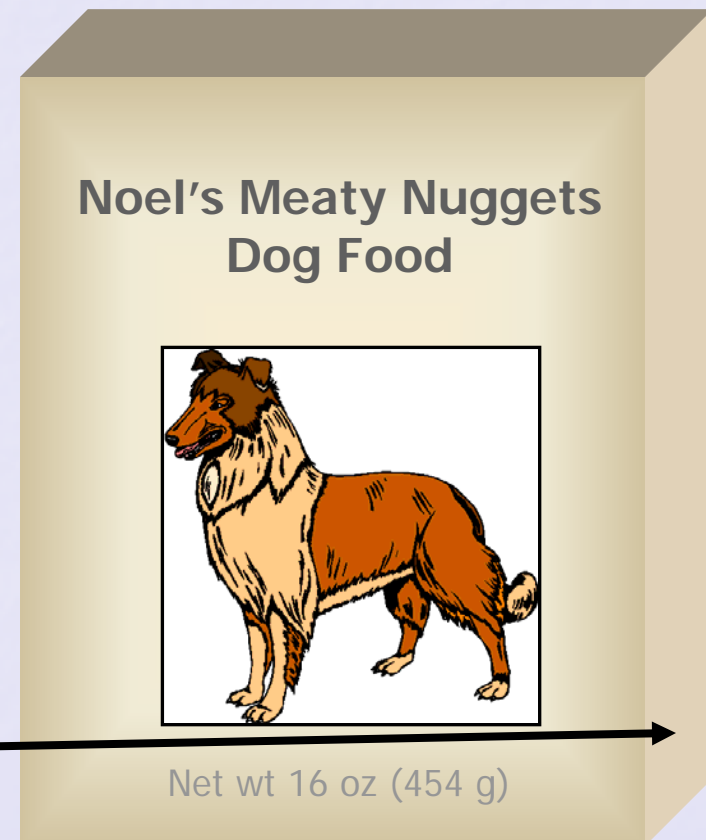
Point IV

YES!



Crude protein, min 24%

Crude protein, min 20%



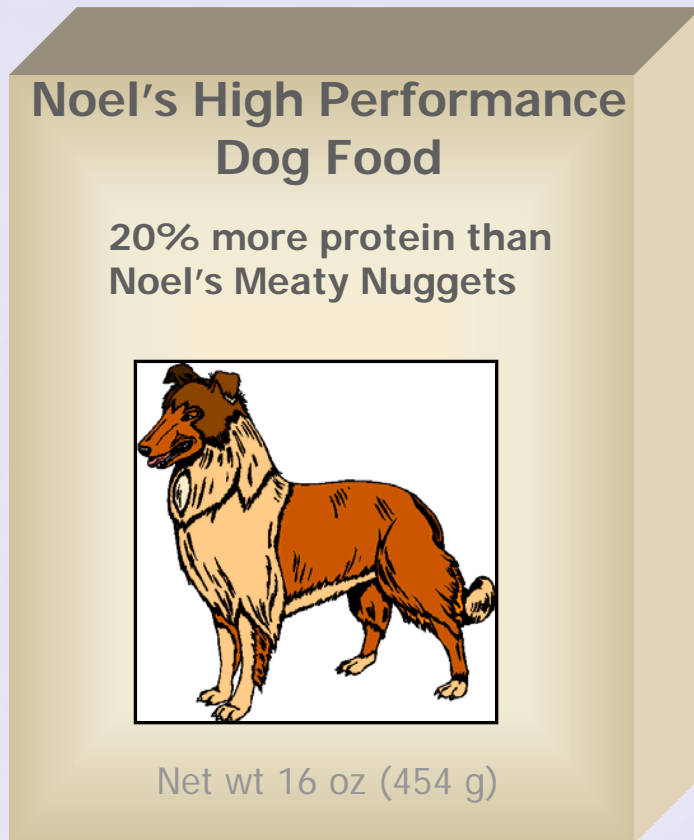
Point IV-2

IV. Product Comparison Claims - Regulation PF2(h)

1. If the label includes any claims of comparison to another product, is the name of the product of comparison included on the label?
Yes _____ No _____
2. If "yes", is documentation, data, etc., available to support the claim?
Yes _____ No _____
3. Is the claim limited to one (1) year production?
Yes _____ No _____

Point IV

Maybe



2007 Registration

2008 Registration



Point IV-3

IV. Product Comparison Claims -

1. The label includes claims of comparison to another product, the name of the product of comparison is included on the label.
2. Documentation, data, etc., is available to support the claim.
3. The claim limited to one (1) year production or resubstantiated with new data on file.

Point IV - Summary

V. Product Name - Regulation PF3

The following AAFCO Official Pet Food Regulations refer to ingredient(s) that form part of the product name:

A. **"95% Rule"** - Regulation PF3(b)(1)

If an ingredient (or combination of ingredients) with no descriptive term(s) is part of the product name (Example: My Favorite Beef Dog Food):

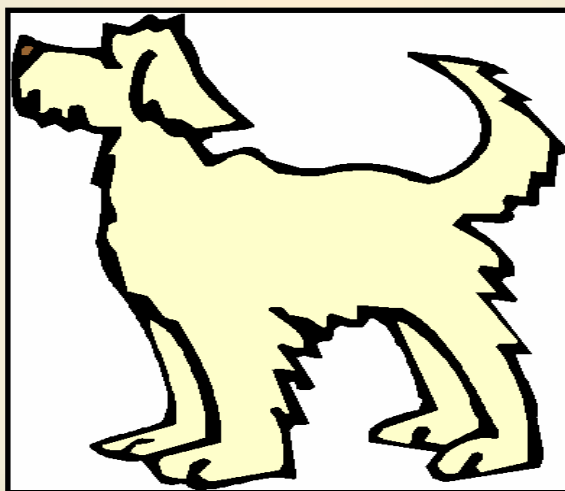
1. Is/Are the named ingredient(s) derived from animals, poultry, or fish?
Yes ____ No ____
2. Is the formulation comprised of at least 95% of the named ingredient(s), exclusive of water sufficient for processing?
Yes ____ No ____

Point V

95%

NO!

Noel's
Wheat
Dog Food



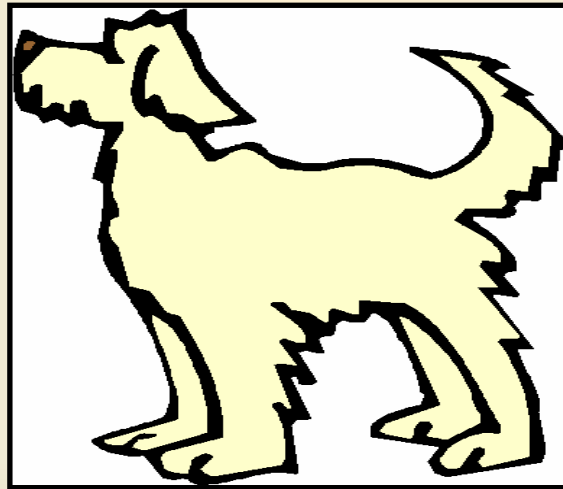
Net Wt. 5 lb. (2.26 Kg.)

Point V-1

95%

YES!

Noel's
Beef
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

Point V-A1

V. Product Name - Regulation PF3

The following AAFCO Official Pet Food Regulations refer to ingredient(s) that form part of the product name:

A. **"95% Rule"** - Regulation PF3(b)(1)

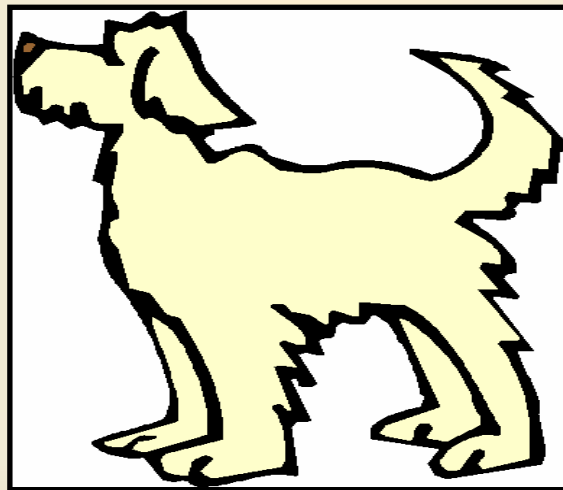
If an ingredient (or combination of ingredients) with no descriptive term(s) is part of the product name (Example: My Favorite Beef Dog Food):

1. Is/Are the named ingredient(s) derived from animals, poultry, or fish?
Yes ____ No ____
2. Is the formulation comprised of at least 95% of the named ingredient(s), exclusive of water sufficient for processing?
Yes ____ No ____

95%

NO!

Noel's
Beef, Lamb & Veal
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

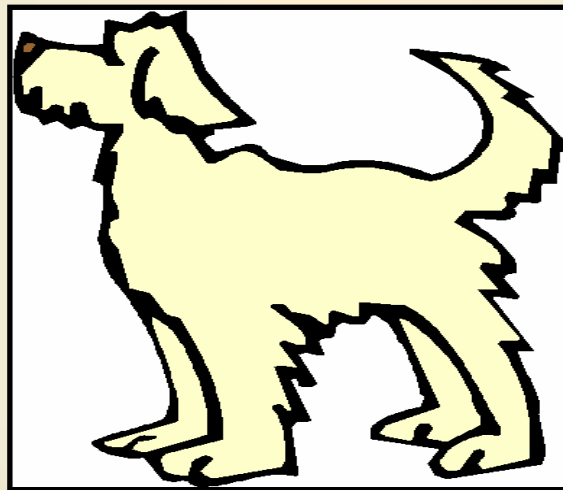
Ingredients:
Chicken meal,
beef, wheat,
corn, rice,
lamb, vitamins,
veal

Point V-A2

95%

YES!

Noel's
Beef, Lamb & Veal
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

Ingredients:
Beef, lamb, veal,
vitamins, minerals

Point V-A2

V. Product Name - Regulation PF3 (continued)

A 3. Is the same name listed in the ingredient statement?

Yes _____ No _____

A 4. If multiple ingredients are listed, are they in the same

order in both product name and ingredient statement and is each ingredient at least 3% of formula?

Yes _____ No _____

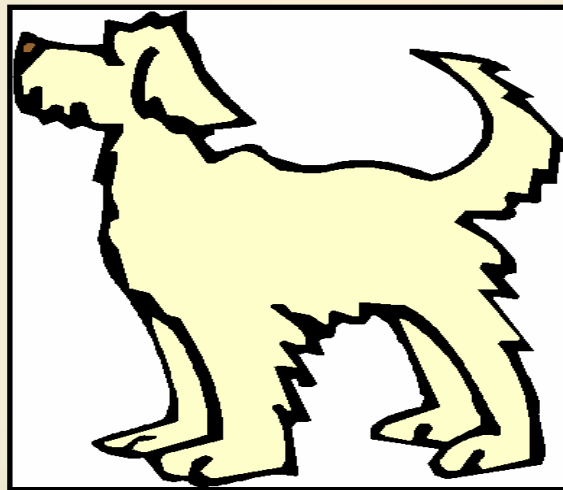
A 5. Are all ingredients that are included in the product name printed in the same size, style and color print?

Yes _____ No _____

Point V-3

95%

Noel's
Beef, Lamb & Veal
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

NO!



Ingredients:
Chicken meal,
beef meal, wheat,
corn, rice,
lamb, vitamins,
veal flavor

Point V-A3

V. Product Name - Regulation PF3 (continued)

A 3. Is the same name listed in the ingredient statement?

Yes _____ No _____

A 4. If multiple ingredients are listed, are they in the same order in both product name and ingredient statement and is each ingredient at least 3% of formula?

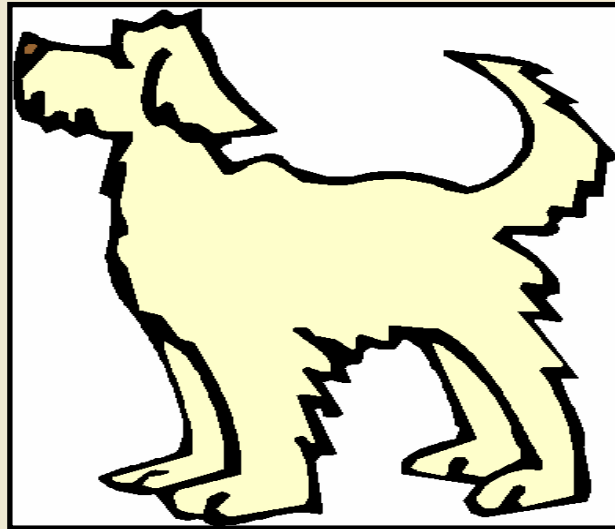
Yes _____ No _____

A 5. Are all ingredients that are included in the product name printed in the same size, style and color print?

Yes _____ No _____

95%

Noel's
Beef, Lamb & Veal
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

NO!



Ingredients:
Chicken meal,
beef, wheat,
veal, rice,
vitamins, lamb

Point V-A4

V. Product Name - Regulation PF3 (continued)

A 3. Is the same name listed in the ingredient statement?

Yes _____ No _____

A 4. If multiple ingredients are listed, are they in the same

order in both product name and ingredient statement and is each ingredient at least 3% of formula?

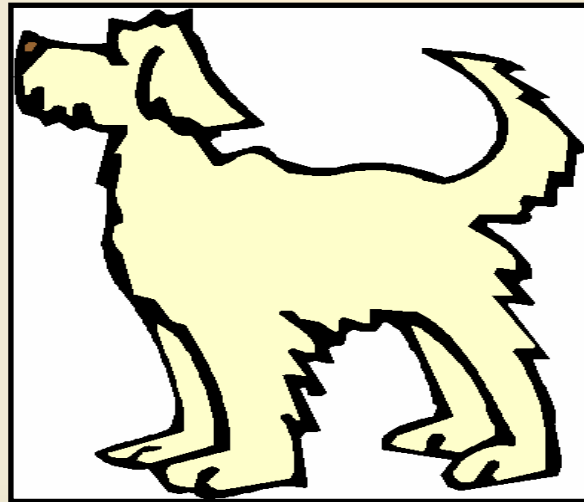
Yes _____ No _____

A 5. Are all ingredients that are included in the product name printed in the same size, style and color print?

Yes _____ No _____

95%

Noel's
BEEF, Lamb & Veal
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

NO!

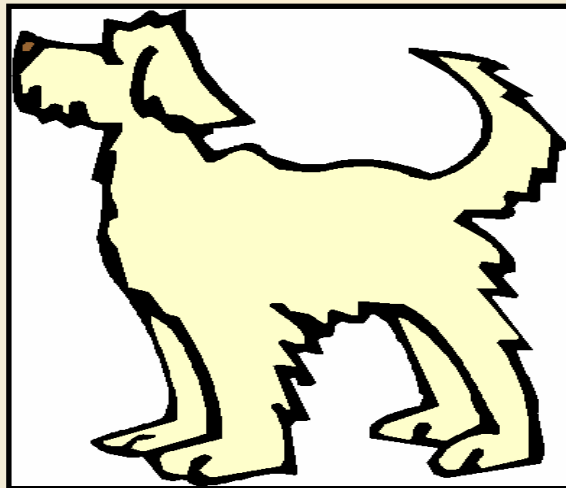


Ingredients:
Chicken meal,
beef, wheat,
veal, rice,
lamb, vitamins

Point V-A5

95%

Noel's
Beef, Lamb & Veal
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

YES!

Ingredients:
Beef, lamb,
veal, wheat

Point V-A

V. Product Name - Regulation PF3 (continued)

B. **"25% Rule"** - Regulation PF3(b)(2)

If an ingredient is part of the product name and is listed with a primary descriptor term such as dinner, entree, formula, etc. (Example: My Favorite Salmon Entree Cat Food):

B1. Is the ingredient at least 25% of the formulation, exclusive of water sufficient for processing?

Yes _____ No _____

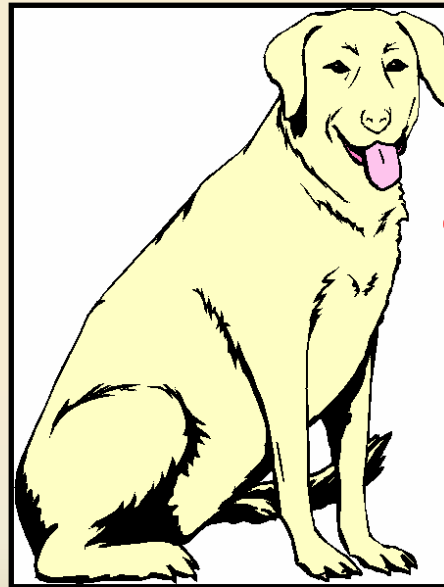
B2. If more than one ingredient is named, is each ingredient at least 3% of the formulation, with named ingredients totaling at least 25% of the formulation? (Example: My Favorite Beef, Chicken and Lamb Dinner Dog Food)

Yes _____ No _____

25%

NO!

Noel's
Turkey Formula
Dog Food



Ingredients:
Chicken byproduct meal,
rice, wheat, corn,
turkey, vitamins,
beef, minerals



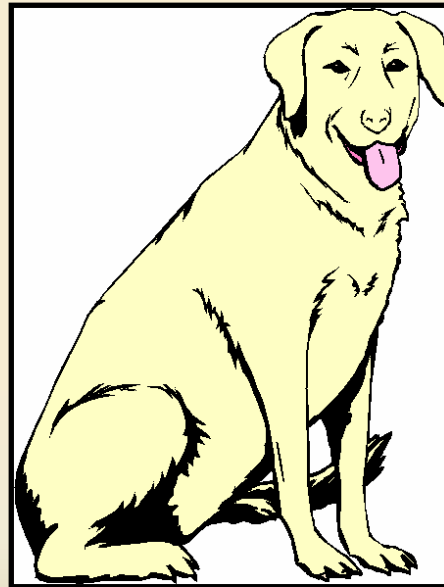
Net Wt. 5 lb. (2.26 Kg.)

Point V-B1

25%

YES!

Noel's
Turkey Formula
Dog Food



Ingredients:
Turkey, chicken
byproduct meal,
Rice, wheat, corn
vitamins



Net Wt. 5 lb. (2.26 Kg.)

V. Product Name - Regulation PF3 (continued)

B. **"25% Rule"** - Regulation PF3(b)(2)

If an ingredient is part of the product name and is listed with a primary descriptor term such as dinner, entree, formula, etc. (Example: My Favorite Salmon Entree Cat Food):

B 1. Is the ingredient at least 25% of the formulation, exclusive of water sufficient for processing?

Yes _____ No _____

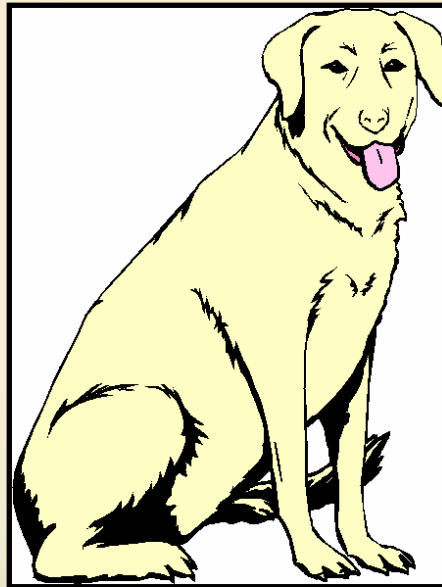
B 2. If more than one ingredient is named, is each ingredient at least 3% of the formulation, with named ingredients totaling at least 25% of the formulation? (Example: My Favorite Beef, Chicken and Lamb Dinner Dog Food)

Yes _____ No _____

25%

Noel's
Turkey, Fish and Beef Formula
Dog Food

NO!



Ingredients:
Chicken byproduct meal,
Rice, wheat, turkey,
Corn, fish, vitamins,
beef, minerals

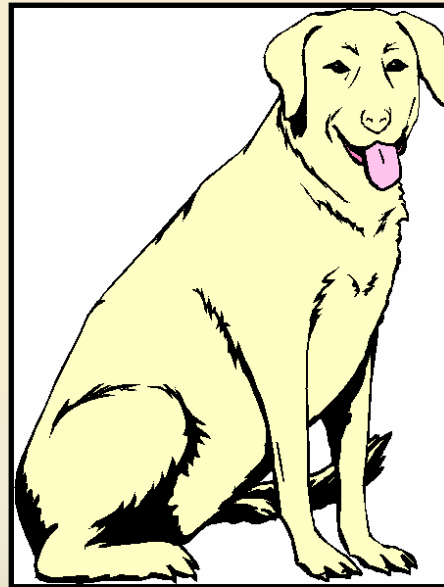
Net Wt. 5 lb. (2.26 Kg.)

Point V-B2

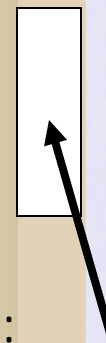
25%

YES!

Noel's
Turkey, Fish and Beef Formula
Dog Food



Ingredients:
Turkey, fish, rice
wheat, beef, corn,
Chicken meal, vitamins,
minerals



Net Wt. 5 lb. (2.26 Kg.)

Point V-B2

B. "25% Rule" - Regulation PF3(b)(2)
(continued)

B 3. Are the names listed in ingredient statement?
Yes _____ No _____

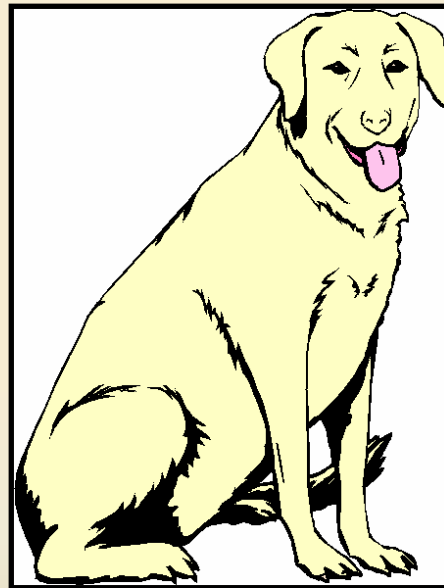
B 4. Are they in the same order in both the product
name and ingredient list?
Yes _____ No _____

B 5. Are all ingredients and primary descriptor that
are included in the product name printed in
same size, style and color print?
Yes _____ No _____

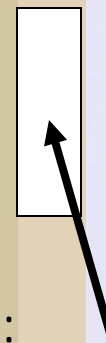
25%

NO!

Noel's
Turkey Formula
Dog Food



Ingredients:
Turkey meal,
rice, wheat, corn,
chicken, vitamins,
beef, minerals



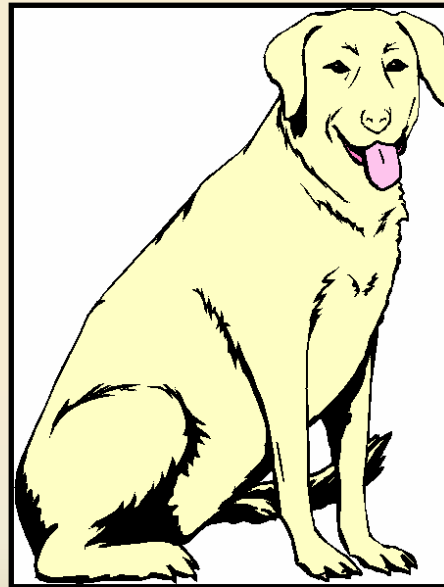
Net Wt. 5 lb. (2.26 Kg.)

Point V-B3

25%

YES!

Noel's
Turkey Formula
Dog Food



Ingredients:
Turkey, rice,
wheat, corn,
chicken, vitamins,
beef, minerals



Net Wt. 5 lb. (2.26 Kg.)

Point V-B3

B. "25% Rule" - Regulation PF3(b)(2)
(continued)

B 3. Are the names listed in ingredient statement?
Yes _____ No _____

B 4. Are they in the same order in both the product
name and ingredient list?
Yes _____ No _____

B 5. Are all ingredients and primary descriptor that
are included in the product name printed in
same size, style and color print?
Yes _____ No _____

25%

NO!

Noel's
Turkey, Fish and Beef Formula
Dog Food



Ingredients:
Chicken byproduct meal,
beef, rice, wheat,
corn, fish, vitamins,
turkey, minerals

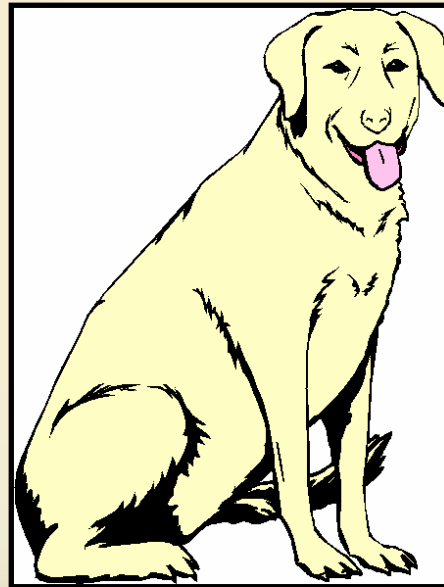
Net Wt. 5 lb. (2.26 Kg.)

Point V-B4

25%

YES!

Noel's
Turkey, Fish and Beef Formula
Dog Food



Ingredients:
Turkey, fish, rice
wheat, beef, corn,
chicken meal, vitamins,
minerals



Net Wt. 5 lb. (2.26 Kg.)

Point V-B4

B. "25% Rule" - Regulation PF3(b)(2)
(continued)

B 3. Are the names listed in ingredient statement?
Yes _____ No _____

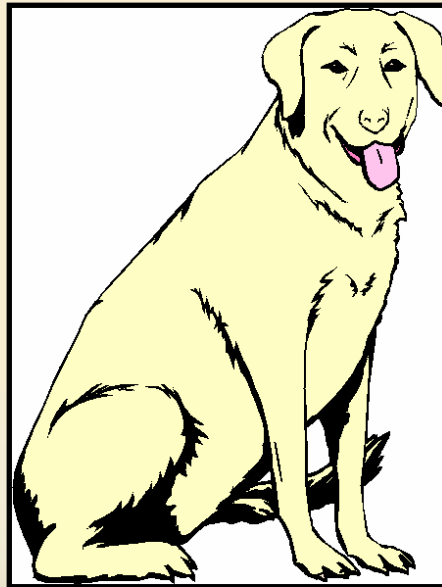
B 4. Are they in the same order in both the product
name and ingredient list?
Yes _____ No _____

B 5. Are all ingredients and primary descriptor that
are included in the product name printed in
same size, style and color print?
Yes _____ No _____

25%

NO!

Noel's
Turkey, Fish and **BEEF** Formula
Dog Food



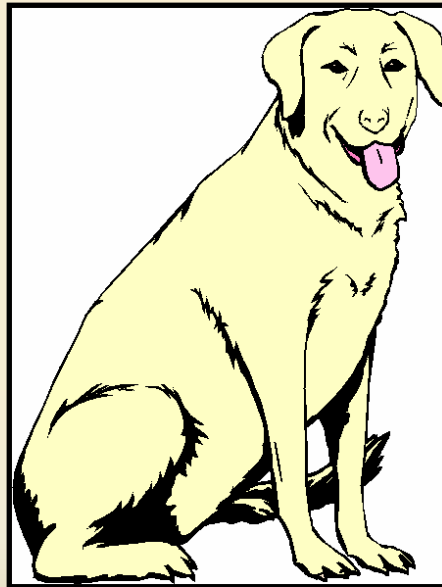
Net Wt. 5 lb. (2.26 Kg.)

Point V-B5

25%

YES!

Noel's
Turkey, Fish and Beef Formula
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

Point V-B5

C. “With Rule” - Regulation PF3(c)

If there is an ingredient name in the product name that includes a descriptor term such as “with” (Example: My Favorite Dog Food With Beef):

C 1. Does each ingredient named constitute at least 3% of the formulation, exclusive of water sufficient for processing?

Yes _____ No _____

C 2. Are they in the same order in both the product name and ingredient list?

Yes _____ No _____

C 3. Is the word “with” in the same size, style, color and case print as the ingredients that are included in the product name?

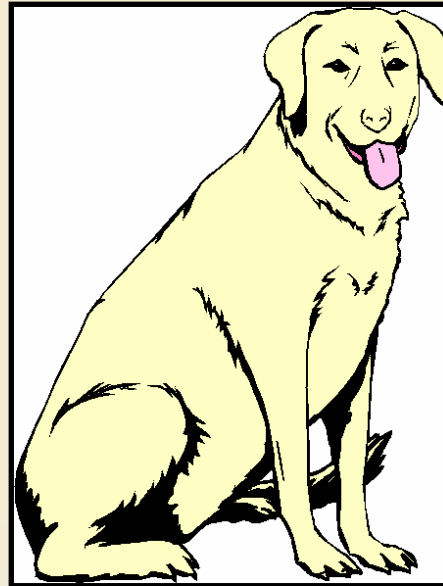
Yes _____ No _____

Point V-C1

With

NO!

Noel's
With Turkey, Fish and Beef
Dog Food



Ingredients:
Chicken byproduct meal,
beef, rice, wheat,
corn, vitamins, fish,
turkey, minerals



Net Wt. 5 lb. (2.26 Kg.)

Point V-C1

C. “With Rule” - Regulation PF3(c)

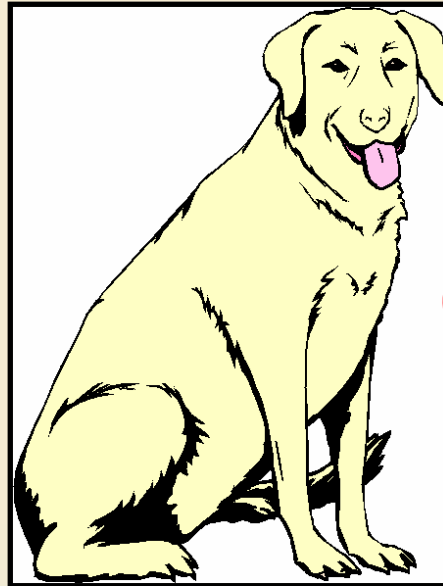
If there is an ingredient name in the product name that includes a descriptor term such as “with” (Example: My Favorite Dog Food With Beef):

- C 1. Does each ingredient named constitute at least 3% of the formulation, exclusive of water sufficient for processing?
Yes _____ No _____
- C 2. Are they in the same order in both the product name and ingredient list?
Yes _____ No _____
- C 3. Is the word “with” in the same size, style, color and case print as the ingredients that are included in the product name?
Yes _____ No _____

With

NO!

Noel's
With Turkey, Fish and Beef
Dog Food



Ingredients:
Chicken byproduct meal,
beef, rice, wheat,
corn, fish, vitamins,
turkey, minerals



Net Wt. 5 lb. (2.26 Kg.)

Point V-C2

C. “With Rule” - Regulation PF3(c)

If there is an ingredient name in the product name that includes a descriptor term such as “with” (Example: My Favorite Dog Food With Beef):

- C 1. Does each ingredient named constitute at least 3% of the formulation, exclusive of water sufficient for processing?
Yes _____ No _____
- C 2. Are they in the same order in both the product name and ingredient list?
Yes _____ No _____
- C 3. Is the word “with” in the same size, style, color and case print as the ingredients that are included in the product name?
Yes _____ No _____

Point V-C3

With

NO!

Noel's
Favorite Dog Food
with Beef, Chicken and Rice



Net Wt. 5 lb. (2.26 Kg.)

Point V-C3

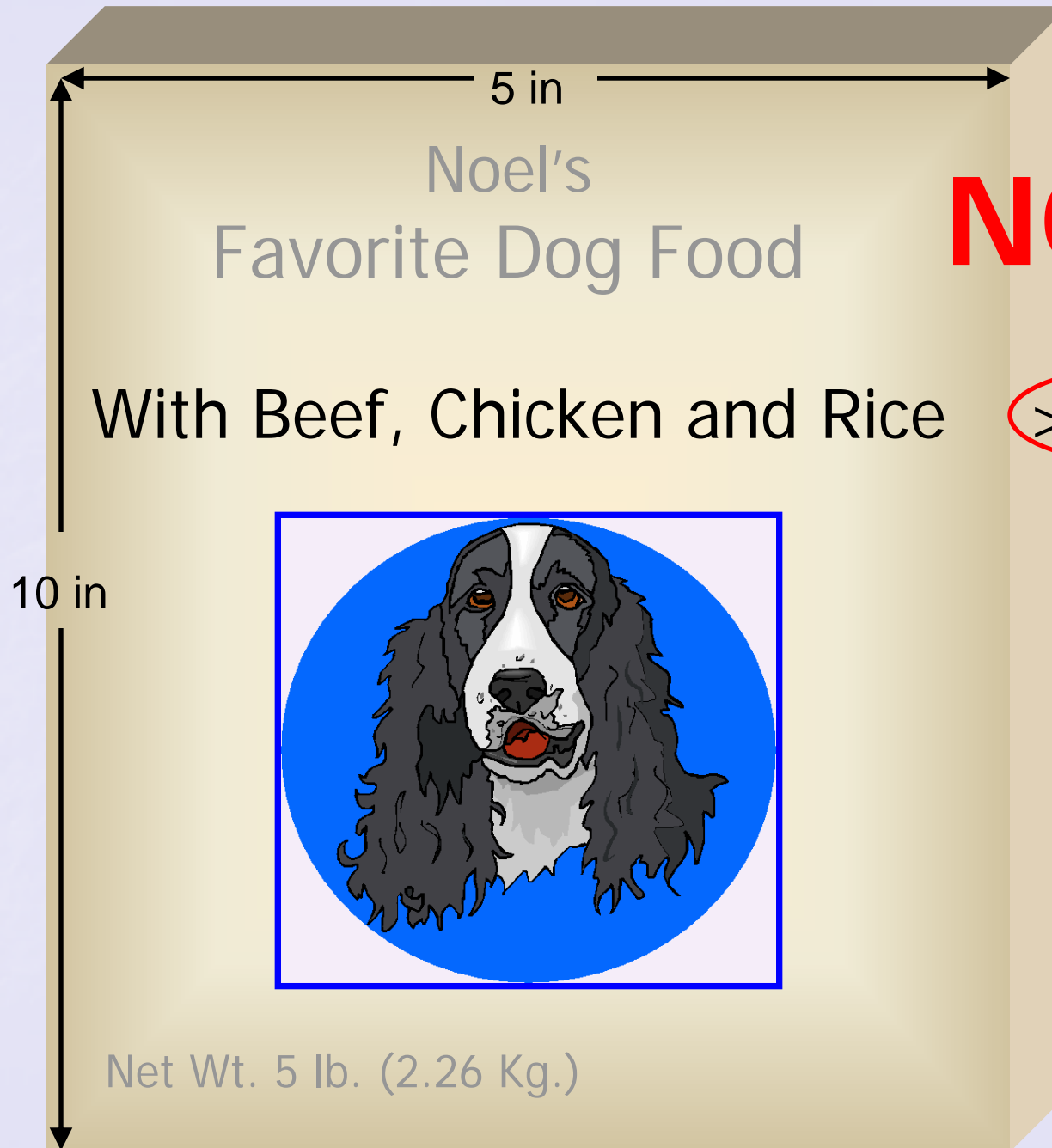
C. "With Rule" - Regulation PF3(c)

C 4. Does the product name meet the print size specification listed below? Yes _____ No _____

<u>Panel Size</u>	<u>Maximum "with"</u> <u>Type Size</u>
<5 sq. in.	1/8"
5-25 sq. in.	1/4"
25-100 sq. in.	3/8"
100-400 sq. in.	1/2"
400 sq. in. +	1"

With

PDP =
50 sq in



NO!

> 3/8 in

Point V-C4

With

PDP =
50 sq in



YES!

< 3/8 in

Point V-C4

D. “Flavors” - Regulation PF3(d)

If there is an ingredient named as a flavor (Example: My Favorite Chicken Flavor(ed) Dog Food):

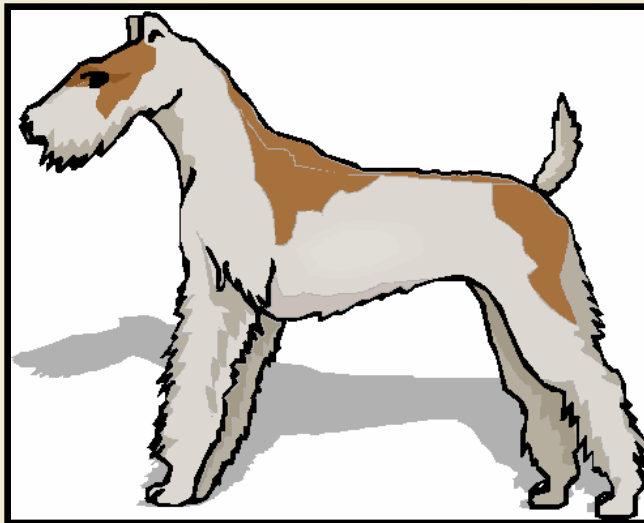
D 1. Is this flavor source listed in the ingredient statement and if name is different is the flavor source identified?
Yes _____ No _____

D 2. Is the word “flavor(ed)” the same size type and as conspicuous as the name of the flavor designation in the product name?
PF3(d)(2)
Yes _____ No _____

Point V-D1

Flavor

Noel's
Rabbit Flavor
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

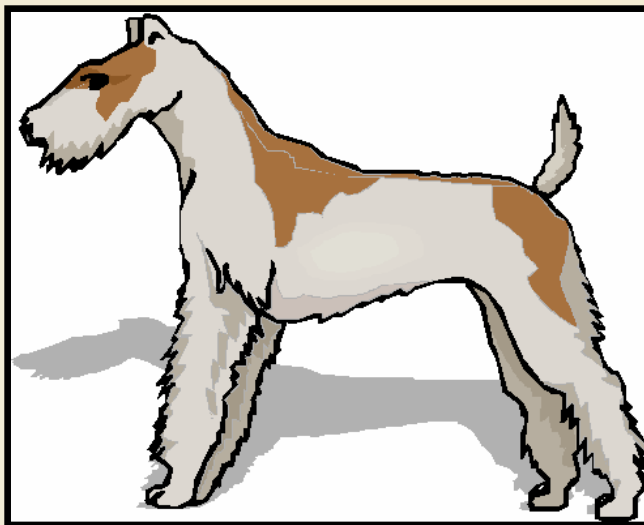
NO!

Ingredients:
wheat, corn,
rice, vitamins,
flavor

Point V-D1

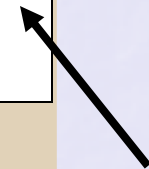
Flavor

Noel's
Rabbit Flavor
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

YES!



Ingredients:
wheat, corn,
rice, rabbit,
vitamins,

Point V-D1

D. “Flavors” - Regulation PF3(d)

If there is an ingredient named as a flavor (Example: My Favorite Chicken Flavor(ed) Dog Food):

D 1. Is this flavor source listed in the ingredient statement and if name is different is the flavor source identified?
Yes _____ No _____

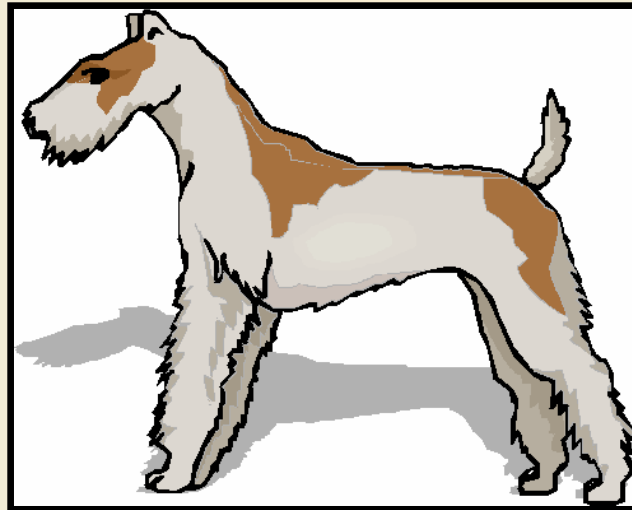
D 2. Is the word “flavor(ed)” the same size type and as conspicuous as the name of the flavor designation in the product name?
PF3(d)(2)
Yes _____ No _____

Point V-D2

Flavor

Noel's
Beef
Flavor
Dog Food

NO!



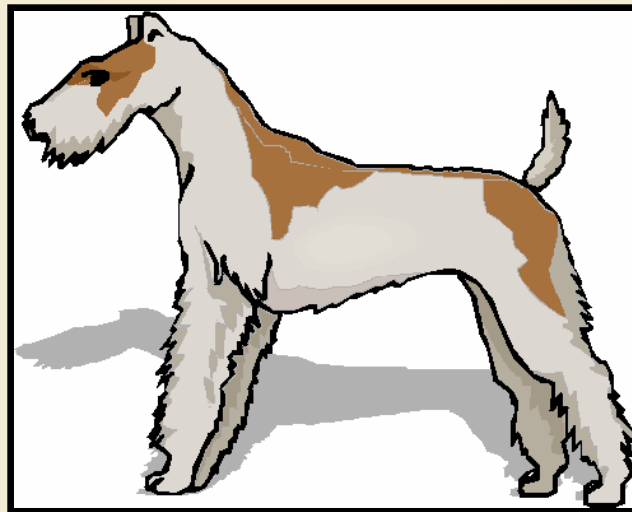
Net Wt. 5 lb. (2.26 Kg.)

Point V-D2

Flavor

Noel's
Beef Flavor
Dog Food

YES!



Net Wt. 5 lb. (2.26 Kg.)

Point V-D2

V. Product Name - Regulation PF3

A. **"95% Rule"** -

Product name has an ingredient (or combination of ingredients) with **no descriptive term(s)** as part of the product name and the formulation comprised of at least **95% of the named ingredient(s)**, exclusive of water sufficient for processing.

B. **"25% Rule"** -

Product name has a qualifier and named ingredient is at least 25% of product by weight.

C **"With" Rule** -

Named ingredient is at least 3% of product and entire descriptor complies with maximum size requirement.

D. **"Flavor" Rule** -

Source of flavor is identifiable and descriptor complies with style and color requirements.

VI. Guaranteed Analysis - Regulation PF4

1. Are all required nutrients guaranteed?

Yes _____ No _____

If yes:

2. Are they in the proper order as found in PF4(a)?

Yes _____ No _____

3a. Are there nutrients mentioned elsewhere on the label that would require a guarantee?

Yes _____ No _____

3b. Is that guarantee present in the guaranteed analysis?

Yes _____ No _____

Point VI-1

NO!

Guaranteed analysis:

Protein 22%

Fiber 5%

Moisture 10%

Point VI-1

VI. Guaranteed Analysis - Regulation PF4

1. Are all required nutrients guaranteed?

Yes _____ No _____

If yes:

2. Are they in the proper order as found in PF4(a)?

Yes _____ No _____

3a. Are there nutrients mentioned elsewhere on the label that would require a guarantee?

Yes _____ No _____

3b. Is that guarantee present in the guaranteed analysis?

Yes _____ No _____

Point VI-2

NO!

Guaranteed analysis:

Protein 22%

Fiber 5%

Moisture 10%

Fat 4%

Point VI-2

YES!

Guaranteed analysis:

Crude Protein, min 22%

Crude Fat, min 4%

Crude Fiber, max 5%

Moisture, max 10%

Point VI-2

VI. Guaranteed Analysis - Regulation PF4

1. Are all required nutrients guaranteed?

Yes _____ No _____

If yes:

2. Are they in the proper order as found in PF4(a)?

Yes _____ No _____

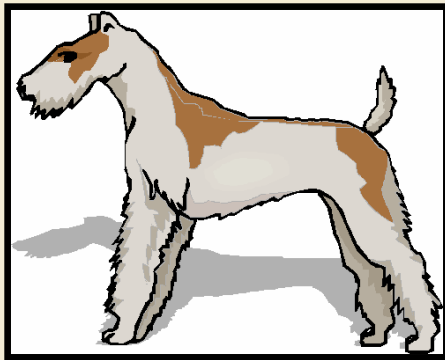
3a. Are there nutrients mentioned elsewhere on the label that would require a guarantee?

Yes _____ No _____

3b. Is that guarantee present in the guaranteed analysis?

Yes _____ No _____

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

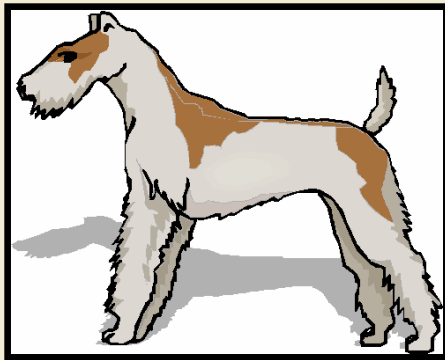
Net wt 10 lb (4.54 kg)

NO!

Guaranteed analysis:
Crude Protein, min 22%
Crude Fat, min 4%
Crude Fiber, max 5%
Moisture, max 10%

Point VI-3

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

Net wt 10 lb (4.54 kg)

Guaranteed analysis:
Crude Protein, min 22%
Crude Fat, min 4%
Crude Fiber, max 5%
Moisture, max 10%
Calcium, min 1%
Phosphorus, min 0.8%

YES!

Point VI-3

VI. Guaranteed Analysis - Regulation PF4 (continued)

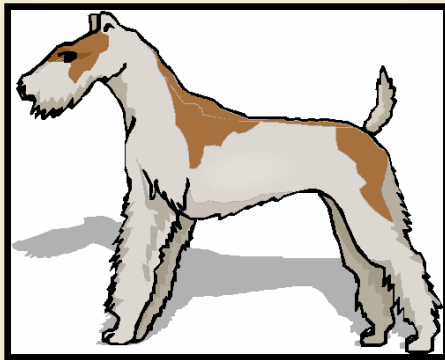
4. If a guarantee is made for a nutrient not listed as essential, is it asterisked to a disclaimer statement? PF4(a)(3)

Yes _____ No _____

5. Are the correct units used? (Must follow those used in AAFCO Nutrient Profiles.)

Yes _____ No _____

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus
Has Omega-3 fatty acids

Net wt 10 lb (4.54 kg)

NO!

Guaranteed analysis:

Crude Protein, min 22%

Crude Fat, min 4%

Crude Fiber, max 5%

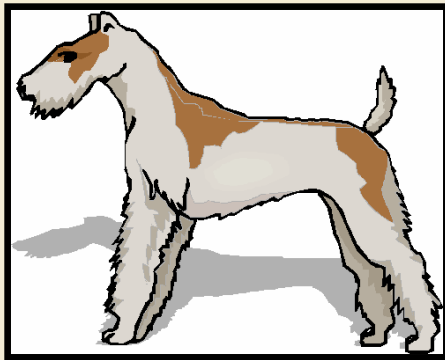
Moisture, max 10%

Calcium, min 1%

Phosphorus, min 0.8%

Omega-3 fatty acids, min 0.3%

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus
Has Omega-3 fatty acids

Net wt 10 lb (4.54 kg)

YES!

Guaranteed analysis:

Crude Protein, min 22%

Crude Fat, min 4%

Crude Fiber, max 5%

Moisture, max 10%

Calcium, min 1%

Phosphorus, min 0.8%

Omega-3 fatty acids, min 0.3%*

*not recognized as an essential
nutrient by the AAFCO Dog Food
Nutrient Profiles.

VI. Guaranteed Analysis - Regulation PF4 (continued)

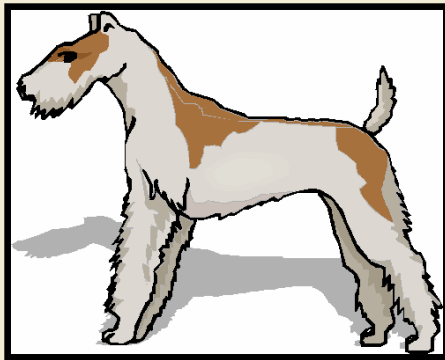
4. If a guarantee is made for a nutrient not listed as essential, is it asterisked to a disclaimer statement? PF4(a)(3)

Yes _____ No _____

5. Are the correct units used? (Must follow those used in AAFCO Nutrient Profiles.)

Yes _____ No _____

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

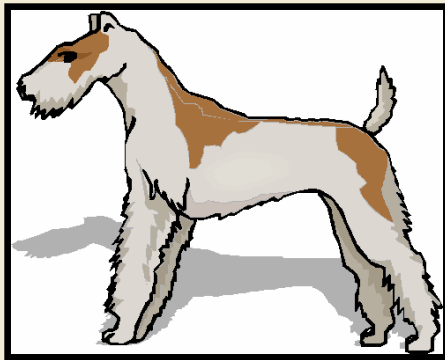
Net wt 10 lb (4.54 kg)

NO!

Guaranteed analysis:
Crude Protein, min 22%
Crude Fat, min 4%
Crude Fiber, max 5%
Moisture, max 10%
Calcium, min 1000 mg/kg
Phosphorus, min 800 mg/kg

Point VI-5

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

Net wt 10 lb (4.54 kg)

YES!

Guaranteed analysis:
Crude Protein, min 22%
Crude Fat, min 4%
Crude Fiber, max 5%
Moisture, max 10%
Calcium, min 1%
Phosphorus, min 0.8%

Point VI-5

VI. Guaranteed Analysis -

All required nutrients are guaranteed, in the proper order and with the proper units.

If nutrients are mentioned elsewhere on the label that would require a guarantee, then that guarantee is in the proper order and units as shown in the AAFCO Dog and Cat Food Nutrient Profiles.

If a guarantee is for a nutrient that is not listed in the AAFCO Dog and Cat Food Nutrient Profiles, then the guarantee is followed by an asterisk referencing the disclaimer.

Point VI- Summary

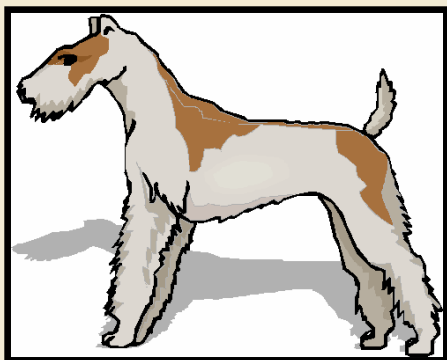
VII. Ingredient Statement – Regulation PF5

1. Are all ingredients listed in the same size, type and in a single, uninterrupted ingredient statement? Yes _____ No _____

If yes:

2. Are ingredients listed in order of descending predominance by weight? PF5(a)(2)
Yes _____ No _____
3. Are defined ingredients listed by their AAFCO names? PF5(a)(3) Yes _____ No _____

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

Net wt 10 lb (4.54 kg)

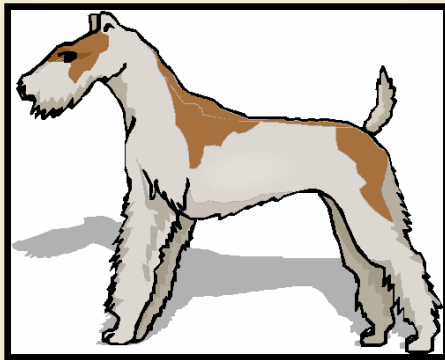
NO!

Ingredients: **BEEF**,
wheat, rice, corn,
liver.

Vitamins & minerals

Point VII-1

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

Net wt 10 lb (4.54 kg)

YES!

Ingredients: Beef,
wheat, rice, corn,
liver, vitamins,
minerals

Point VII-1

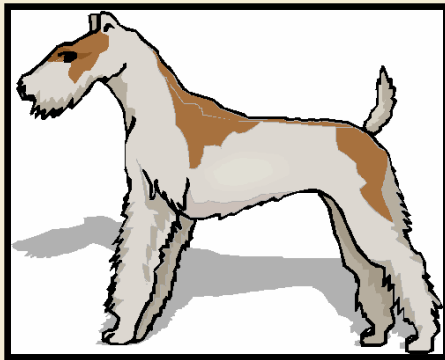
VII. Ingredient Statement – Regulation PF5

1. Are all ingredients listed in the same size, type and in a single, uninterrupted ingredient statement? Yes _____ No _____

If yes:

2. Are ingredients listed in order of descending predominance by weight? PF5(a)(2)
Yes _____ No _____
3. Are defined ingredients listed by their AAFCO names? PF5(a)(3) Yes _____ No _____

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

Net wt 10 lb (4.54 kg)

Maybe!

Ingredients: Beef,
wheat, rice, corn,
liver, vitamins,
minerals

Point VII-2

VII. Ingredient Statement – Regulation PF5

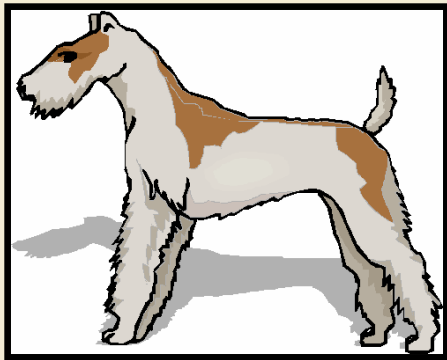
1. Are all ingredients listed in the same size, type and in a single, uninterrupted ingredient statement? Yes _____ No _____

If yes:

2. Are ingredients listed in order of descending predominance by weight? PF5(a)(2)
Yes _____ No _____

3. Are defined ingredients listed by their AAFCO names? PF5(a)(3) Yes _____ No _____

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

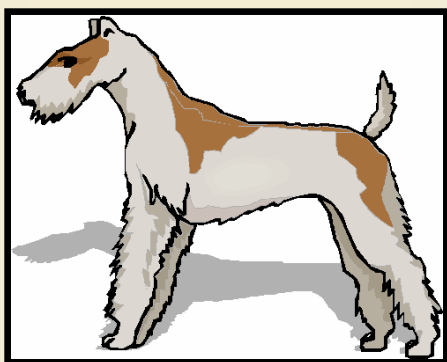
Net wt 10 lb (4.54 kg)

NO!

Ingredients: Beef,
wheat, helianthus,
rice, corn,
liver, vitamins,
minerals

Point VII-3

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

Net wt 10 lb (4.54 kg)

YES!

Ingredients: Beef,
wheat, sunflower meal,
rice, corn, liver,
vitamins, minerals

Point VII-3

VII. Ingredient Statement – (continued)

4. If ingredient has no established AAFCO name or definition, are common or usual names used?

PF5(a)(4)

Yes _____ No _____

5. Brand or trade names have not been used?

PF5(c)

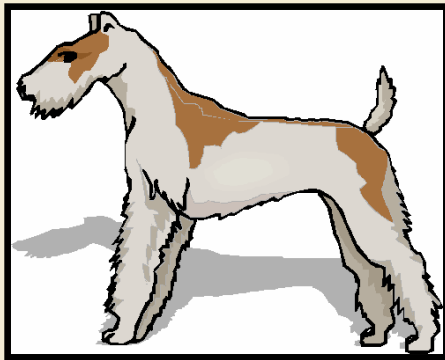
Yes _____ No _____

6. There are no references to ingredient quality or grade? PF5(d)(3)

Yes _____ No _____

Point VII-4

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

Net wt 10 lb (4.54 kg)

YES!

Ingredients: Beef,
wheat, rice, corn,
liver, salt, vitamins,
minerals

Point VII-4

VII. Ingredient Statement – (continued)

4. If ingredient has no established AAFCO name or definition, are common or usual names used?

PF5(a)(4)

Yes _____ No _____

5. Brand or trade names have not been used?

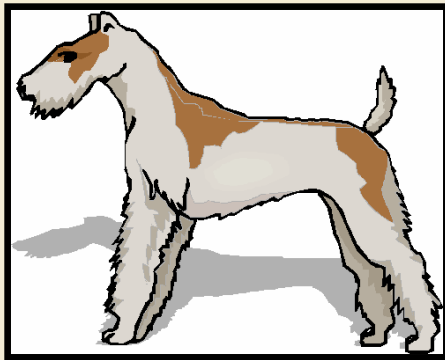
PF5(c)

Yes _____ No _____

6. There are no references to ingredient quality or grade? PF5(d)(3)

Yes _____ No _____

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

Net wt 10 lb (4.54 kg)

NO!

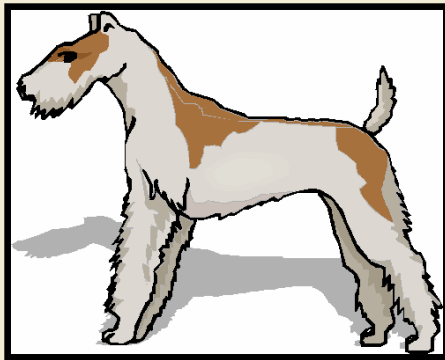
Ingredients: Beef,
RightGro[®], rice,
corn, liver, vitamins,
minerals

Point VII-5

VII. Ingredient Statement – (continued)

4. If ingredient has no established AAFCO name or definition, are common or usual names used?
PF5(a)(4)
Yes _____ No _____
5. Brand or trade names have not been used?
PF5(c)
Yes _____ No _____
6. There are no references to ingredient quality or grade? PF5(d)(3)
Yes _____ No _____

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

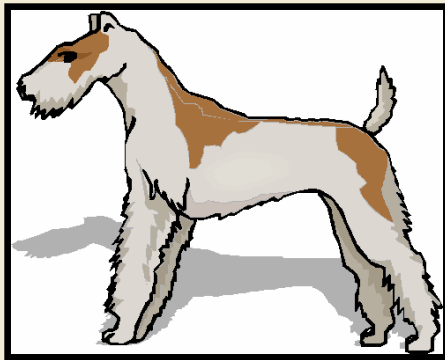
Net wt 10 lb (4.54 kg)

NO!

Ingredients: Beef,
Grade 2 wheat, rice,
corn, liver, vitamins,
minerals

Point VII-6

Noel's
Beef Formula
Dog Food



Beef is 1st ingredient
Balanced Calcium & Phosphorus

Net wt 10 lb (4.54 kg)

YES!

Ingredients: Beef,
wheat, rice, corn,
liver, vitamins,
minerals

Point VII

Ingredients – Listing of vitamins & minerals

YES!

Ingredients: Chicken, Chicken Meal, Brown Rice, Chicken Fat (preserved with mixed tocopherols), Sunflower Oil, Flaxseed, Vitamin E supplement, Potassium Chloride, Choline Chloride, Calcium Carbonate, Zinc Proteinate, Iron Proteinate, Niacin, d-Calcium Pantothenate, Copper Proteinate, Manganese Proteinate, Menadione Sodium Bisulfite Complex (source of vitamin K activity), Thiamine Mononitrate, Pyridoxine Hydrochloride, Riboflavin, Vitamin D3 supplement, Vitamin B12 supplement, Taurine, DL-Methionine, Folic Acid, Biotin

Point VII

Ingredients – Listing of vitamins & minerals

YES!

Ingredients: Chicken, Chicken Meal, Brown Rice, Chicken Fat (preserved with mixed tocopherols), Sunflower Oil, Flaxseed, Vitamins (Vitamin E supplement, Niacin, d-Calcium Pantothenate, Menadione Sodium Bisulfite Complex (source of vitamin K activity), Thiamine Mononitrate, Pyridoxine Hydrochloride, Riboflavin, Vitamin D3 supplement, Vitamin B12 supplement, Folic Acid, Biotin), Potassium Chloride, Choline Chloride, Calcium Carbonate, Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Taurine, DL-Methionine

Only when vitamins or minerals are added as a premix.

Only the vitamins or minerals that are actually in the premix.

Point VII

VII. Ingredient Statement –

All ingredients are listed in the same size, type and in a single, uninterrupted ingredient statement. They are listed in order of descending predominance by weight.

If they are defined by AAFCO, they are listed by that name.

Or if not, then by their common or usual name.

No brand names, trademark name or indications of quality or grade are shown.

VIII. Nutritional Adequacy

If the product is complete and balanced:

1. Does the label contain the proper nutritional adequacy statement and the proper wording?

PF7(c)(1)(A)(B)(C) or PF7(c)(3)

Yes _____ No _____

2. If the product is labeled for “use by or under the supervision of a veterinarian” does it also contain a nutritional adequacy statement?

PF7(d) Yes _____ No _____

3. Are affidavits available upon request to support nutritional claims?

Yes _____ No _____

Point VIII-CB1

VIII. Nutritional Adequacy – Regulation PF7(c)(1)(A)

Substantiation by formulation

- A. “(Name of product) is formulated to meet the nutritional levels established by the AAFCO Dog (or Cat) Food Nutrient Profiles for _____.” (Blank is to be completed by using the stage or stages of the pet’s life, such as, gestation/lactation, growth, maintenance or the words “All Life Stages”); or

Point VIII

VIII. Nutritional Adequacy – Regulation PF7(c)(1)(B)

Substantiation by animal feeding protocol

- B. “Animal feeding tests using AAFCO procedures substantiate that (Name of product) provides complete and balanced nutrition for _____.”
(Blank is to be completed by using the stage or stages of the pet’s life tested, such as, gestation/lactation, growth, maintenance or the words “All Life Stages”); or

Point VIII

VIII. Nutritional Adequacy – Regulation PF7(c)(1)(C)

Substantiation by nutritional similarity – “family”

- C. “(Name of Product) provides complete and balanced nutrition for _____
(Blank is to be completed by using the stage or stages of the pet’s life, such as, gestation/lactation, growth, maintenance or the words “All Life Stages”) and is comparable in nutritional adequacy to a product which has been substantiated using AAFCO feeding tests.”

Point VIII

VIII. Nutritional Adequacy – Regulation PF7(c)(3)

- (3) The statement: “This product is intended for intermittent or supplemental feeding only”, if a product does not meet the requirements of Regulation PF7(a) or (b) or any other special nutritional or dietary need and so is suitable only for limited or intermittent or supplementary feeding.

Point VIII

VIII. Nutritional Adequacy

If the product is complete and balanced:

1. Does the label contain the proper nutritional adequacy statement and the proper wording?

PF7(c)(1)(A)(B)(C) or PF7(c)(3)

Yes _____ No _____

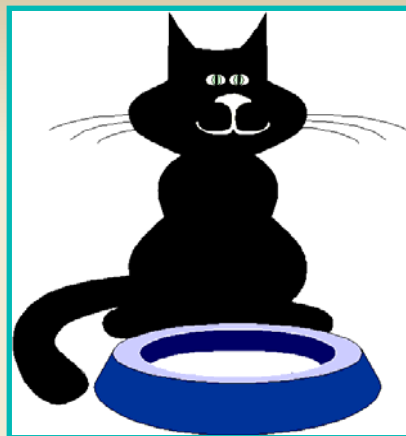
2. If the product is labeled for “use by or under the supervision of a veterinarian” does it also contain a nutritional adequacy statement?

PF7(d) Yes _____ No _____

3. Are affidavits available upon request to support nutritional claims?

Yes _____ No _____

Point VIII-CB1



Noel's Super Premium
Cat Adult Food

Net Wt. 5 lbs. (2.26 Kg.)

NO!

Noel's is formulated
to meet the nutritional
levels established by
the AAFCO cat food
profiles for maintenance.



Noel's Super Premium
Cat Adult Food

Net Wt. 5 lbs. (2.26 Kg.)

YES!

Noel's Super Premium
Cat Adult Food is
formulated to meet the
nutritional levels
established by the
AAFCO Cat Food
Nutrient Profiles for
maintenance.

Point VIII_CB1

VIII. Nutritional Adequacy

If the product is complete and balanced:

1. Does the label contain the proper nutritional adequacy statement and the proper wording?
PF7(c)(1)(A)(B)(C) or PF7(c)(3)
Yes _____ No _____
2. If the product is labeled for “use by or under the supervision of a veterinarian” does it also contain a nutritional adequacy statement?
PF7(d) Yes _____ No _____
3. Are affidavits available upon request to support nutritional claims?
Yes _____ No _____

Point VIII-CB2



Noel's Super Premium
Cat Adult Food

Net Wt. 5 lbs. (2.26 Kg.)

NO!

Use only as directed
By your veterinarian.



Noel's Super Premium Cat Adult Food

Net Wt. 5 lbs. (2.26 Kg.)

YES!

Use only as directed
By your veterinarian.

Noel's Super Premium
Cat Adult Food is
formulated to meet the
nutritional levels
established by the
AAFCO Cat Food
Nutrient Profiles for
maintenance.

Point VIII-CB2

VIII. Nutritional Adequacy

If the product is complete and balanced:

1. Does the label contain the proper nutritional adequacy statement and the proper wording?
PF7(c)(1)(A)(B)(C) or PF7(c)(3)
Yes _____ No _____
2. If the product is labeled for “use by or under the supervision of a veterinarian” does it also contain a nutritional adequacy statement?
PF7(d) Yes _____ No _____
3. Are affidavits available upon request to support nutritional claims?
Yes _____ No _____

Point VIII-



Noel's Super Premium
Cat Adult Food

Net Wt. 5 lbs. (2.26 Kg.)

Ask for Affidavit!

Noel's Super Premium Cat Adult Food is formulated to meet the nutritional levels established by the AAFCO Cat Food Nutrient Profiles for maintenance.

Point VIII-CB2

Noel's
Super Premium
Cat Biscuit



Complete and balanced

Net Wt. 5 lbs. (2.26 Kg.)

No!



Point VIII

Noel's
Super Premium
Cat Biscuit



Treats for Cats

Complete and balanced

Net Wt. 5 lbs. (2.26 Kg.)

Yes!

Noel's Super Premium Cat Biscuit is formulated to meet the nutritional levels established by the AAFCO Cat Food Nutrient Profiles for all life stages.

Point VIII

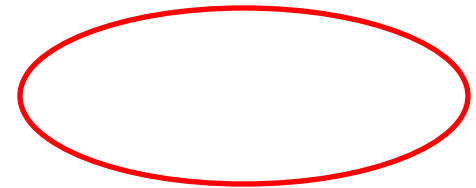
Noel's
Super Premium
Cat Biscuit



Treats for Cats

Net Wt. 5 lbs. (2.26 Kg.)

Yes!



Point VIII

VIII. Nutritional Adequacy –

There is an unqualified complete and balanced claim, with a nutritional adequacy statement for all life stages.

There is a qualified claim for only a certain life stage, and the claim and required qualification are on same panel using same size, style and color print.

If the product is a snack or treat, the words “snack” or “treat” appear conspicuously on the PDP.

The nutritional adequacy statement is written exactly as it appears in PF7.

If the product states to use only as directed by a veterinarian, it still has a nutritional adequacy statement.

Point VIII- Summary

IX. Feeding Directions – Regulation PF8

1. If product is labeled as complete and balanced does the label have feeding directions?
Yes _____ No _____
2. Do they follow PF8(a)? (Weight or unit of product per weight of dog or cat and frequency must be stated. Yes _____ No _____)
3. Are the feeding directions consistent with all of the intended uses of the product?
Yes _____ No _____

NOTE: If product is labeled as a snack or treat, and is not complete and balanced, feeding directions are voluntary.

Point IX-1

Noel's
Super Premium
Cat Food



Complete Nutrition

Net Wt. 5 lbs. (2.26 Kg.)

NO!



Point IX-1

Noel's
Super Premium
Cat Treat



Net Wt. 5 lbs. (2.26 Kg.)

YES!



Point IX-1

IX. Feeding Directions – Regulation PF8

1. If product is labeled as complete and balanced does the label have feeding directions?
Yes _____ No _____
2. Do they follow PF8(a)? (Weight or unit of product per weight of dog or cat and frequency must be stated. Yes _____ No _____)
3. Are the feeding directions consistent with all of the intended uses of the product?
Yes _____ No _____

NOTE: If product is labeled as a snack or treat, and is not complete and balanced, feeding directions are voluntary.

Noel's
Super Premium
Cat Food



Complete Nutrition

Net Wt. 5 lbs. (2.26 Kg.)

NO!

Feed your cat daily.

Point IX-2

Noel's
Super Premium
Adult Cat Food



Complete Nutrition
For Adult cats

Net Wt. 5 lbs. (2.26 Kg.)

YES!

Feeding Directions: Feed your
6-10 pound cat $\frac{3}{4}$ - 1 cup
of food per day. May split into
two feedings.

Point IX-2

IX. Feeding Directions – Regulation PF8

1. If product is labeled as complete and balanced does the label have feeding directions?
Yes _____ No _____
2. Do they follow PF8(a)? (Weight or unit of product per weight of dog or cat and frequency must be stated. Yes _____ No _____)
3. Are the feeding directions consistent with all of the intended uses of the product?
Yes _____ No _____

NOTE: If product is labeled as a snack or treat, and is not complete and balanced, feeding directions are voluntary.

Noel's
Super Premium
Cat Food



Complete Nutrition

Net Wt. 5 lbs. (2.26 Kg.)

NO!

Feeding Directions: Feed your
6-10 pound adult cat $\frac{3}{4}$ - 1
cup of food per day. May
split into two feedings.

Point IX-3

Noel's
Super Premium
Cat Food



Complete Nutrition

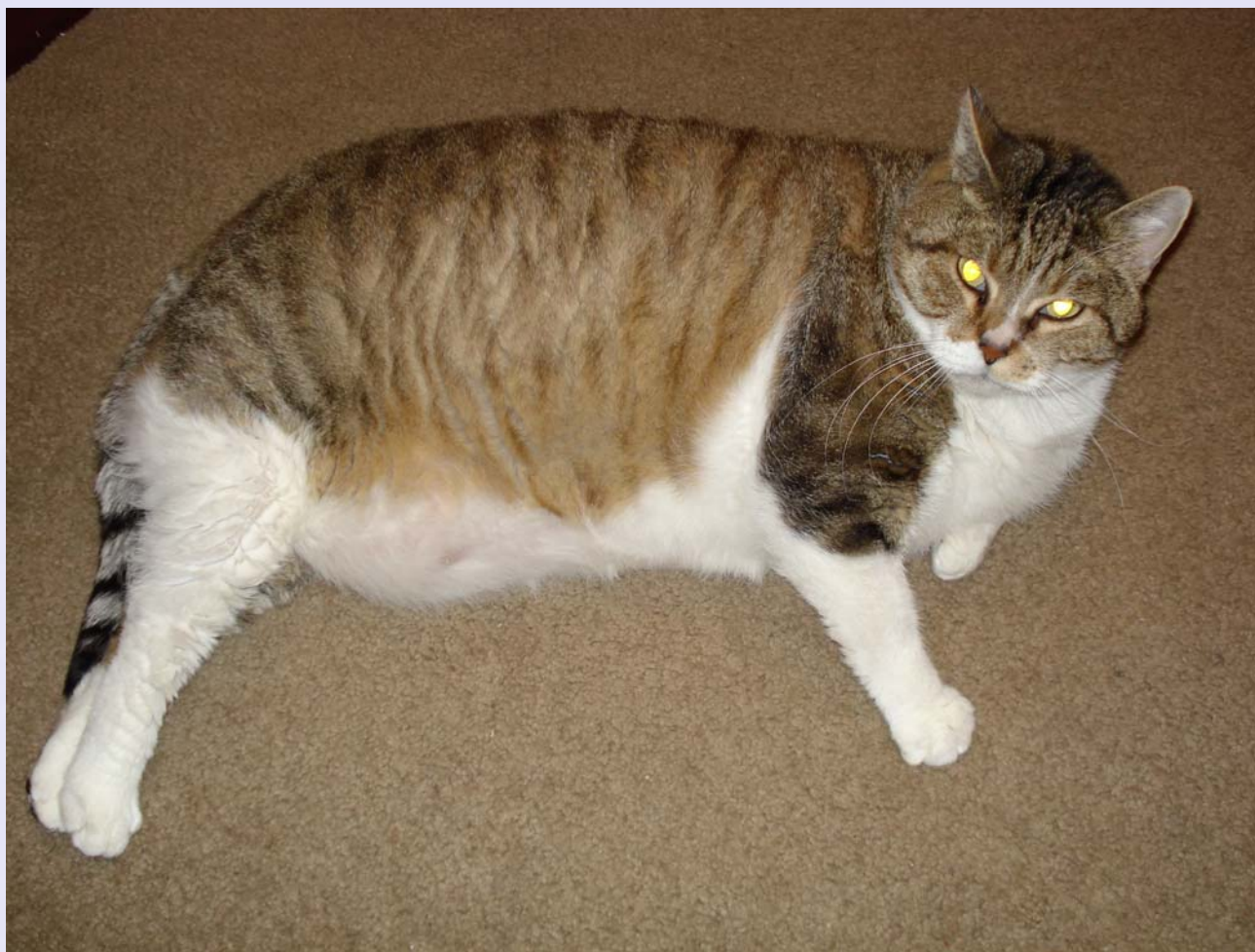
Net Wt. 5 lbs. (2.26 Kg.)

YES!

Feeding Directions: Feed your 6-10 pound adult cat $\frac{3}{4}$ - 1 cup of food per day. May split into two feedings. Adjust according to age and activity.

Feed weaned kittens $\frac{1}{2}$ - 1 cup per day. Feed pregnant or lactating queens 3 - 4 times their regular adult amounts per day.

Point IX-3





IX. Feeding Directions –

A complete and balanced product has feeding directions and they are given with weight or unit of product per weight of dog or cat and frequency.

The feeding directions are consistent with all of the intended uses (life stages) of the product.

If the product is a treat, it is clearly labeled as such and feeding directions are optional.

X. Calorie Content - Regulation PF9

A. If label contains a calorie content statement:

1. Is it separate and distinct from the guaranteed analysis? PF9(a)(1)
Yes _____ No _____
2. Does it appear under the heading "Calorie Content"? Yes _____ No _____
3. Is it in terms of ME and in kcal/kg units? PF9(a)(2) Yes _____ No _____

Point X-1

Noel's
Favorite Dog Food
With Beef, Chicken and Rice



Net Wt. 5 lb. (2.26 Kg.)

NO!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 15%

Crude fiber, max 5%

Moisture, max 10%

Calories 3450 kcal

Point X-1

X. Calorie Content - Regulation PF9

A. If label contains a calorie content statement:

1. Is it separate and distinct from the guaranteed analysis? PF9(a)(1)
Yes _____ No _____
2. Does it appear under the heading "Calorie Content"? Yes _____ No _____
3. Is it in terms of ME and in kcal/kg units? PF9(a)(2) Yes _____ No _____

Point X-2

Noel's
Favorite Dog Food
With Beef, Chicken and Rice



Net Wt. 5 lb. (2.26 Kg.)

NO!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 15%

Crude fiber, max 5%

Moisture, max 10%

Calories 3450 kcal

Point X-1

X. Calorie Content - Regulation PF9

A. If label contains a calorie content statement:

1. Is it separate and distinct from the guaranteed analysis? PF9(a)(1)
Yes _____ No _____
2. Does it appear under the heading "Calorie Content"? Yes _____ No _____
3. Is it in terms of ME and in kcal/kg units?
PF9(a)(2) Yes _____ No _____

Point X-1

Noel's
Favorite Dog Food
With Beef, Chicken and Rice



Net Wt. 5 lb. (2.26 Kg.)

NO!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 15%

Crude fiber, max 5%

Moisture, max 10%

Calorie content:
3450 kcal

Point X-1

Noel's
Favorite Dog Food
With Beef, Chicken and Rice



Net Wt. 5 lb. (2.26 Kg.)

YES!
(almost)

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 15%

Crude fiber, max 5%

Moisture, max 10%

Calorie content:
3450 kcal/kg,
300 kcal/cup

Point X-1

X. Calorie Content - Regulation PF9

4. Has it been determined by calculation or animal testing procedure?
Yes _____ No _____
5. If calculated, does the word "calculated" appear in parenthesis after the calorie statement? Yes _____ No _____
6. Do calorie contents determined by animal testing procedures compare to calculated values by 15% or less? Yes _____ No _____
7. Are affidavits available upon request to support calorie content statement?
Yes _____ No _____

Noel's
Favorite Dog Food
With Beef, Chicken and Rice



Net Wt. 5 lb. (2.26 Kg.)

Don't know!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 15%

Crude fiber, max 5%

Moisture, max 10%

Calorie content:
3450 kcal/mg,
300 kcal/cup

Point X-1

X. Calorie Content - Regulation PF9

4. Has it been determined by calculation or animal testing procedure?
Yes _____ No _____
5. If calculated, does the word "calculated" appear in parenthesis after the calorie statement? Yes _____ No _____
6. Do calorie contents determined by animal testing procedures compare to calculated values by 15% or less? Yes _____ No _____
7. Are affidavits available upon request to support calorie content statement?
Yes _____ No _____

Noel's
Favorite Dog Food
With Beef, Chicken and Rice



Net Wt. 5 lb. (2.26 Kg.)

NO!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 15%

Crude fiber, max 5%

Moisture, max 10%

Calorie content:
3450 kcal/kg

Point X-1

Noel's
Favorite Dog Food
With Beef, Chicken and Rice



Net Wt. 5 lb. (2.26 Kg.)

YES!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 15%

Crude fiber, max 5%

Moisture, max 10%

Calorie content ME
(calculated): 3450 kcal/kg,
300 kcal/cup

Point X-1

X. Calorie Content - Regulation PF9

4. Has it been determined by calculation or animal testing procedure?
Yes _____ No _____
5. If calculated, does the word "calculated" appear in parenthesis after the calorie statement? Yes _____ No _____
6. Do calorie contents determined by animal testing procedures compare to calculated values by 15% or less? Yes _____ No _____
7. Are affidavits available upon request to support calorie content statement?
Yes _____ No _____

Noel's
Favorite Dog Food
With Beef, Chicken and Rice



Net Wt. 5 lb. (2.26 Kg.)

Maybe

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 15%

Crude fiber, max 5%

Moisture, max 10%

Calorie content ME:
3800 kcal/kg,
300 kcal/cup

Point X-1

X. Calorie Content - Regulation PF9

The label contains a calorie content statement which is separate and distinct from the GA.

The statement has the heading 'Calorie content' and is metabolizable energy in units of kcal/kg and optionally in terms of common household units.

When determined via calculation as stipulated in the OP, the word 'calculated' is inserted into the statement.

The caloric content determined by animal feeding trial is 15% or less of the calculated value.

Point X- Summary

XI. Descriptive Terms – Regulation PF10(a)(1)

A. If the product label contains a “light”, “lite” or “low calorie” claim:

1. Does it meet the following requirements?
Yes _____ No _____

Light - PF10(a)(1)(A) - Dog Food

$\leq 3100 \text{ kcal/kg}$ < 20% moisture

$\leq 2500 \text{ kcal/kg}$ < 65% and > 20% moisture

$\leq 900 \text{ kcal/kg}$ > 65% moisture

Light - PF10(a)(1)(B) - Cat Food

$\leq 3250 \text{ kcal/kg}$ < 20% moisture

$\leq 2650 \text{ kcal/kg}$ < 65% and > 20% moisture

$\leq 950 \text{ kcal/kg}$ > 65% moisture

Noel's
Favorite Lite Dog Food



Net Wt. 5 lb. (2.26 Kg.)

NO!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 15%

Crude fiber, max 5%

Moisture, max 10%

Calorie content ME:

3800 kcal/kg,

300 kcal/cup

Point X-1

Noel's
Favorite Lite Dog Food



Net Wt. 5 lb. (2.26 Kg.)

YES!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 9.5%

Crude fiber, max 12%

Moisture, max 10%

Calorie content ME:

3090 kcal/kg,

300 kcal/cup

Point X-1

XI. Descriptive Terms - Regulation PF10(a)(1)

A. If the product label contains a “light”, “lite” or “low calorie” claim:

A2. Does the label contain a calorie content statement? Yes _____ No _____

A3. Does the label follow labeling format for calorie content? Yes _____ No _____

A4. Are feeding directions consistent with reduced calorie intake? Yes _____ No _____

Point X-A2&3

Noel's
Favorite **Lite** Dog Food



Net Wt. 5 lb. (2.26 Kg.)

YES!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 10%

Crude fiber, max 5%

Moisture, max 10%

Calorie content ME:

3090 kcal/kg,

300 kcal/cup

Point X-A2&3

XI. Descriptive Terms - Regulation PF10(a)(1)

A. If the product label contains a “light”, “lite” or “low calorie” claim:

A2. Does the label contain a calorie content statement? Yes _____ No _____

A3. Does the label follow labeling format for calorie content? Yes _____ No _____

A4. Are feeding directions consistent with reduced calorie intake? Yes _____ No _____

Point X-A4

Noel's
Favorite **Lite** Dog Food



Net Wt. 5 lb. (2.26 Kg.)

YES!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 10%

Crude fiber, max 5%

Moisture, max 10%

Feeding directions: 25 lb
adult dog, feed 2 cups
per day.

Calorie content ME:

3090 kcal/kg,

300 kcal/cup

Point X-A4

XI. Descriptive Terms -

B. Less or Reduced Calories – Regulation PF10(a)(B)(2)

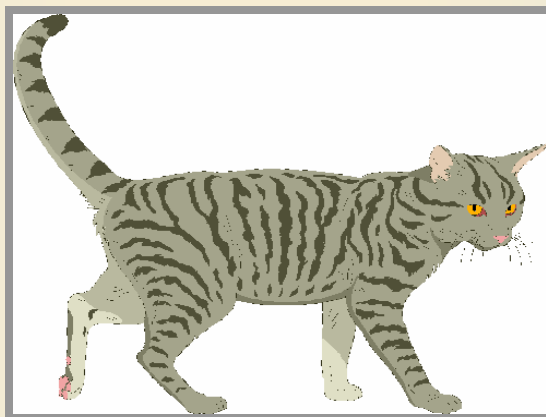
If the label makes a less or reduced calorie claim:

- B1. Is there a product of comparison named?
Yes _____ No _____
- B2. Is there a percentage of calorie reduction stated on label?
Yes _____ No _____
- B3. Is it expressed on an equal weight basis?
Yes _____ No _____

Point XI-B1-3

NO!

Noel's
Reduced Calorie
Adult Cat Food



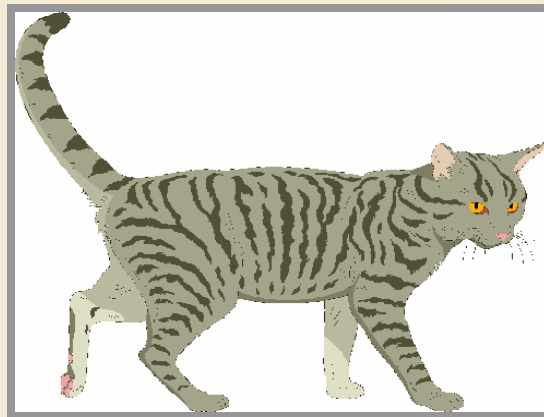
Fewer calories by far

Net Wt. 3.5 lb. (1.58 kg.)

Point XI-B1-3

NO!

Noel's
Reduced Calorie
Adult Cat Food



Fewer calories than
Noel's Super Premium

Net Wt. 3.5 lb. (1.58 kg.)

Point XI-B1-3

XI. Descriptive Terms -

B. Less or Reduced Calories – Regulation PF10(a)(B)(2)

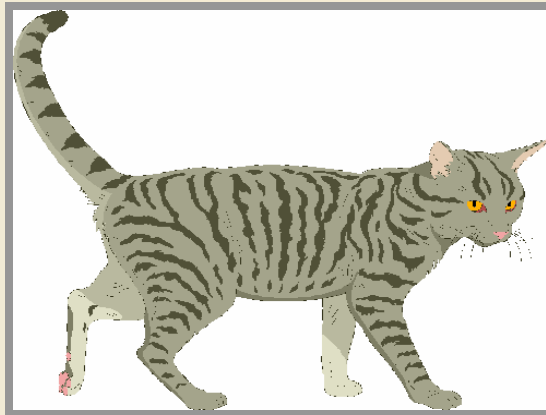
If the label makes a less or reduced calorie claim:

B4. Is this information included with the most prominent use of this claim on each panel?
Yes _____ No _____

B5. Is print of comparative statement in same color and style and at least 1/2 type size of claim?
Yes _____ No _____

Point XI-B4

Noel's
Reduced Calorie
Adult Cat Food

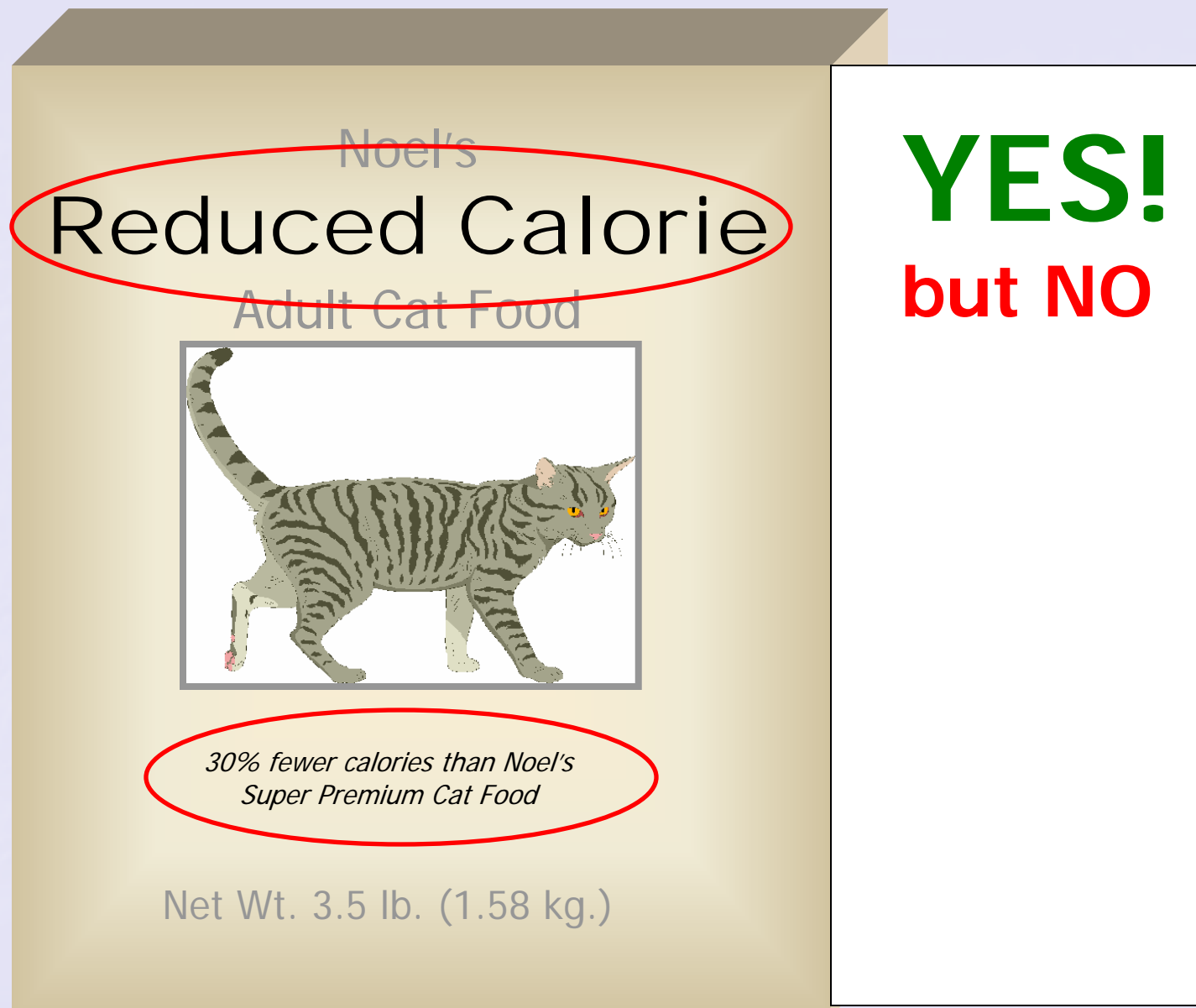


Net Wt. 3.5 lb. (1.58 kg.)

NO!

30% fewer calories
than Noel's Super
Premium Cat Food

Point XI-B4



Point XI-B5

XI. Descriptive Terms -

B. Less or Reduced Calories – Regulation PF10(a)(B)(2)

If the label makes a less or reduced calorie claim:

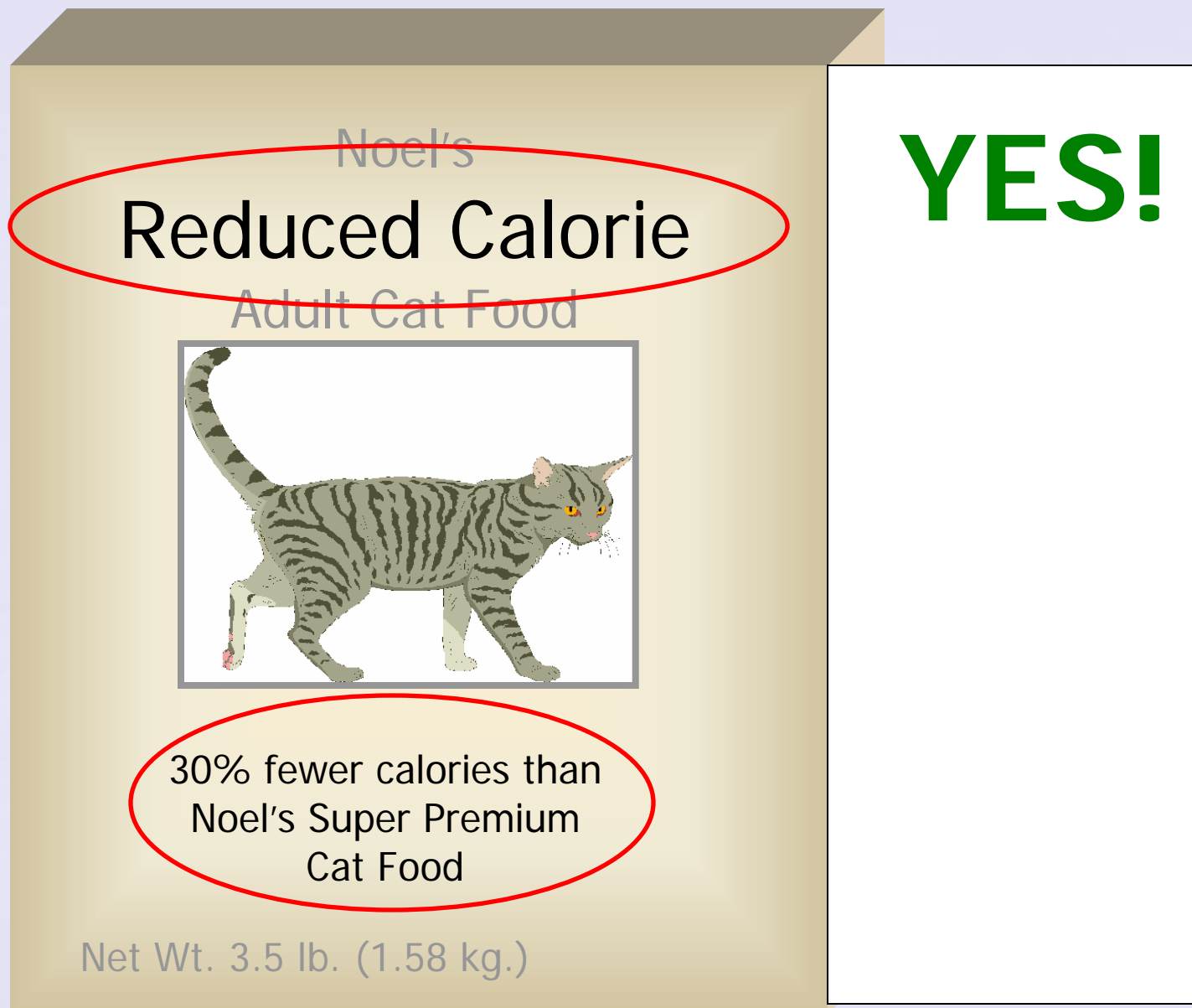
B4. Is this information included with the most prominent use of this claim on each panel?

Yes _____ No _____

B5. Is print of comparative statement in same color and style and at least 1/2 type size of claim?

Yes _____ No _____

Point XI-B5



Point XI-B5

XI. Descriptive Terms -

B. Less or Reduced Calories - Regulation PF10(a)(B)(2)

B6. Is there a calorie content statement on label?

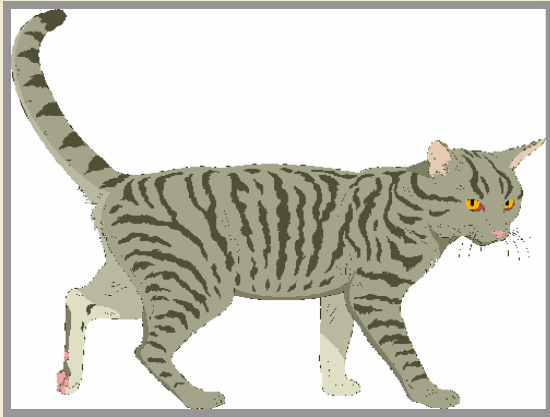
Yes _____ No _____

B7. Do feeding directions reflect reduction in calories? Yes _____ No _____

B8. Are comparisons of products within the same moisture category? Yes _____ No _____

Point XI-B6

Noel's
Reduced Calorie
Adult Cat Food



30% fewer calories than
Noel's Super Premium
Cat Food

Net Wt. 3.5 lb. (1.58 kg.)

YES!

Calorie Content ME
(Calculated):
3150 kcal/kg

Point XI-B6

XI. Descriptive Terms -

B. Less or Reduced Calories - Regulation PF10(a)(B)(2)

- B6. Is there a calorie content statement on label?
Yes _____ No _____
- B7. Do feeding directions reflect reduction in calories? Yes _____ No _____
- B8. Are comparisons of products within the same moisture category? Yes _____ No _____

Point XI-B7&8

Noel's
Super Premium
Cat Food



Complete Nutrition

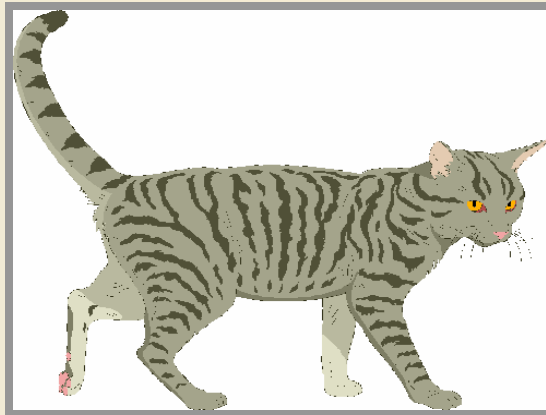
Net Wt. 5 lbs. (2.26 Kg.)

Feeding Directions: Feed your 6-10 pound adult cat $\frac{3}{4}$ - 1 cup of food per day. May split into two feedings. Adjust according to age and activity.

Feed weaned kittens $\frac{1}{2}$ - 1 cup per day. Feed pregnant or lactating queens 3 - 4 times their regular adult amounts per day.

Point XI-B7&8

Noel's
Reduced Calorie
Adult Cat Food



30% fewer calories than
Noel's Super Premium
Cat Food

Net Wt. 3.5 lb. (1.58 kg.)

YES!

Feeding Directions:
Feed your adult cat
 $\frac{1}{2}$ to $\frac{3}{4}$ cups
per day.

Calorie Content ME
(Calculated):
3150 kcal/kg

Point XI-B7 &8

XI. Descriptive Terms -

C. Fat Terms - Regulation PF10(b)(1)(A)

If there is a lean or low-fat claim on label:

C1. Does it meet the following requirements?

Yes _____ No _____

Lean - PF10(b)(1)(A) - Dog Food:

$\leq 9\%$ fat	$< 20\%$ moisture
$\leq 7\%$ fat	$< 65\%$ and $\geq 20\%$ moisture
$\leq 4\%$ fat	$\geq 65\%$ moisture

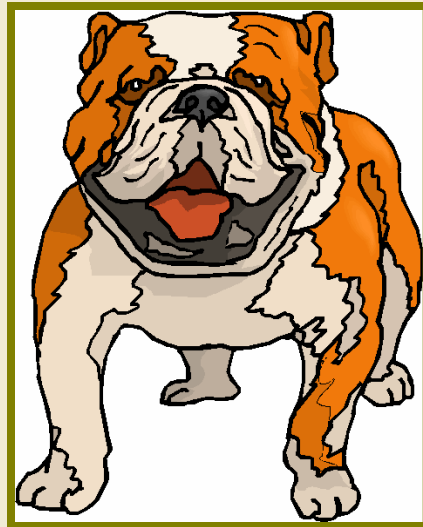
Lean - PF10(b)(1)(B) - Cat Food:

$\leq 10\%$ fat	$< 20\%$ moisture
$\leq 8\%$ fat	$< 65\%$ and $\geq 20\%$ moisture
$\leq 5\%$ fat	$\geq 65\%$ moisture

C2. Is there both a maximum and minimum crude fat guarantee? Yes _____ No _____

Point XI-C1&2

Noel's
Lean Mean
Dog Food



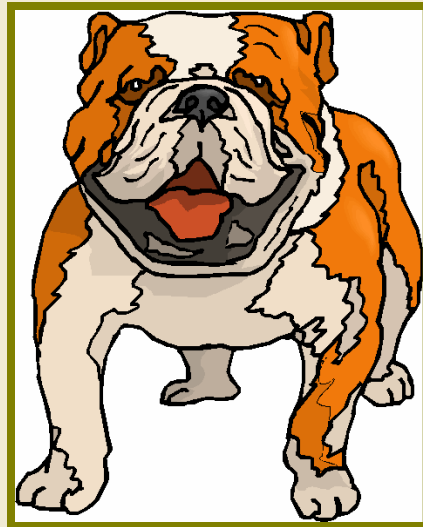
Net Wt. 5 lb. (2.26 Kg.)

NO!

Guaranteed analysis:
~~Crude Protein, min. 27%~~
Crude Fat, max. 10%
Crude Fiber, max. 4%
Moisture, max. 10%

Point XI-C1&2

Noel's
Lean Mean
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

YES!

Guaranteed analysis:
Crude Protein, min. 27%
Crude Fat, min. 8%
Crude Fat, max. 9%
Crude Fiber, max. 4%
Moisture, max. 10%

Point XI-C1&2

XI. Descriptive Terms -

D. Less or Reduced Fat - PF10(b)(2)(A)

If there is a reduced fat, less fat or similar claim on label:

D1. Is a product of comparison stated?

Yes _____ No _____

D2. Is there a percentage of reduction based on an equal weight basis stated?

Yes _____ No _____

Brand B
Reduced Fat Formula
Dog Food



Contains 10% less fat than
Brand B Dog Food

Net Wt. 5 lb. (2.26 Kg.)

YES!

but

Point XI-1&2

XI. Descriptive Terms -

D. Less or Reduced Fat - PF10(b)(2)(A)

D3. Is percentage of reduction determined using the following example:

Yes _____ No _____

Guarantees	Brand A	Brand B	Brand C
% fat (min.)	10	5	5
% fat (max.)	not declared	9	7

Calculation used when there is no maximum fat listed for product to which claim is compared	Brand B has 10% less fat than Brand A	Brand B(max) - Brand A(min) / Brand A(min) = $(9-10)/10 = -1/10 = -10\%$
Calculation used when both products have maximum fat guaranteed	Brand C has 22% less fat than Brand B	Brand C(max) = Brand B(max) / Brand B(max) = $(7-9)/9 = -2/9 = -22\%$

Point XI-D1&2

XI. Descriptive Terms -

D. Less or Reduced Fat - PF10(b)(2)(A)

- D4. Is this information juxtaposed with most prominent use of claim on each panel?
Yes _____ No _____
- D5. Is statement in the same style, color and at least 1/2 size type as claim?
Yes _____ No _____
- D6. Are there both a maximum and a minimum crude fat guarantee? Yes _____ No _____
- D7. Are comparisons of products within same moisture categories? Yes _____ No _____

Point XI-D4&5

Brand B
Reduced Fat Formula
Dog Food

Contains 10% less fat than
Brand B Dog Food



Net Wt. 5 lb. (2.26 Kg.)

YES!

Point XI-D4&5

XI. Descriptive Terms -

D. Less or Reduced Fat - PF10(b)(2)(A)

- D4. Is this information juxtaposed with most prominent use of claim on each panel?
Yes _____ No _____
- D5. Is statement in the same style, color and at least 1/2 size type as claim?
Yes _____ No _____
- D6. Are there both a maximum and a minimum crude fat guarantee? Yes _____ No _____
- D7. Are comparisons of products within same moisture categories? Yes _____ No _____

Point XI-D6&7

Brand B
Reduced Fat Formula
Dog Food

Contains 10% less fat than
Brand B Dog Food



Net Wt. 5 lb. (2.26 Kg.)

YES!

Guaranteed analysis:

Crude protein, min 24%

Crude fat, min 5%

Crude fat, max 9%

Crude fiber, max 5%

Moisture, max 10%

Point XI-D6&7

XI. Descriptive Terms -

Light, Lite, Low Calorie –

Meets the calorie content limitation, has a calorie content statement in the right format, has feeding directions consistent with reduced calorie intake.

Less, Reduced, Fewer Calories –

State the percentage reduction and the name of the product of comparison (in the same moisture category) juxtaposed to the largest use of the claim and in the proper type, has a correct calorie content statement, and consistent feeding directions.

Point XI - Summary

XI. Descriptive Terms -

Lean, Low Fat –

Meets the fat content limitation, has both a minimum and a maximum fat guarantee.

Less Fat, Reduced Fat –

State the percentage reduction (properly calculated) and the name of the product of comparison (in the same moisture category) juxtaposed to the largest use of the claim and in the proper type, has both a minimum and a maximum fat guarantee.

Point XI - Summary

XII. Manufacturer or Distributor - PF11

aka responsible person/party or guarantor

Is there a name and address,
including zip code, of manufacturer or
distributor on label?

Yes _____ No _____

Point XII

Noel's
Super Formula
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

YES!

Manufactured by:
Noel's Super Duper
Pet Food Company
West Lafayette, IN 47907

Point XI-D6&7

Noel's
Super Formula
Dog Food



Net Wt. 5 lb. (2.26 Kg.)

YES!

Distributed by:
~~Noel's Super Duper~~
Pet Food Company
West Lafayette, IN 47907

Point XI-D6&7

XII. Manufacturer or Distributor - PF11

If the responsible person manufactures the product in their own facility, then it says manufactured by: followed by actual company name and address, including zip code, of manufacturer. Street address is not required if it is in the telephone directory.

If responsible person is not the manufacturer, then the contact information is prefaced by either manufactured for: or distributed by:

If the product is manufactured in a place other than the principle place of business, then the information may be the principle place rather than the actual place.

Point XII - Summary

XIII. Attachments

If brochures, pamphlets,
promotional material, etc.,
accompany this product, does all
of the information comply with the
AAFCO Pet Food Regulations?

Yes _____ No _____

XIV. Additional Comments

Regulation PF7 Nutritional Adequacy

PF7(g)(1)(C) - The following AAFCO-recognized nutritional authority...shall be acceptable as the basis for a claim of nutritional adequacy:...For specialty pets, the nutrient recommendations approved by the Committee on Animal Nutrition of the National Research Council of the National Academy of Sciences, provided that, this nutrient recommendation is recognized only for the specific specialty pet for which the profile is intended.

NRC Publications

2003 Nutrient Requirements of Non-Human Primates

1995 Nutrient Requirements of Laboratory Animals (rats, mice, hamsters, guinea pigs, gerbils)

1994 Nutrient Requirements of Poultry (chickens, turkeys, ducks, geese, pheasant, quail)

1993 Nutrient Requirements of Fish (catfish, trout, salmon, carp, tilapia)

Noel's Parrot Food

NO!



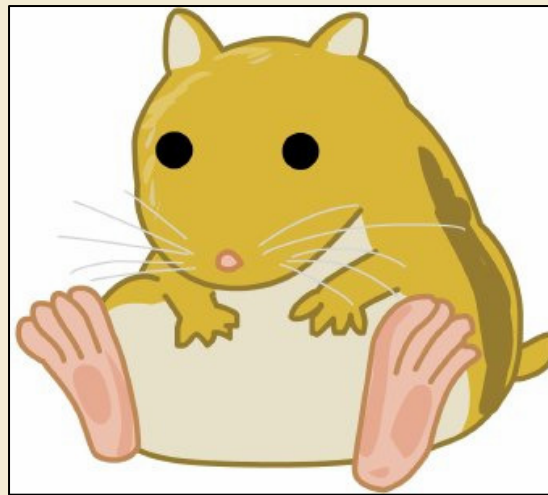
Complete &
Balanced!

Noel's Parrot Food is formulated to meet the nutritional
levels recommended by the National Research Council
for all life stages

Net Wt. 5 lb (2.26 kg)

Noel's Hamster Food

YES!



Complete &
Balanced!

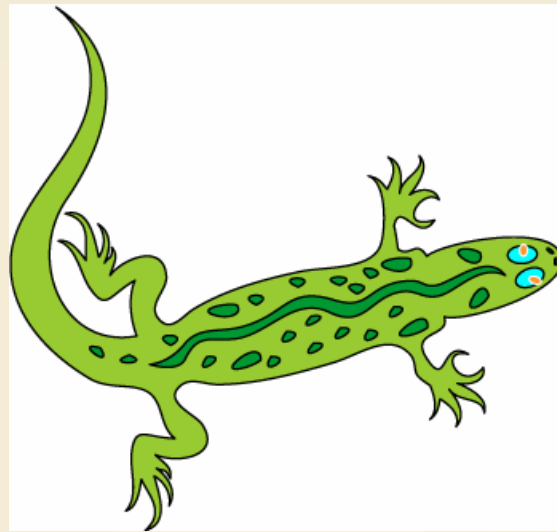
Noel's Hamster Food is formulated to meet the nutritional
levels recommended by the National Research Council

for all life stages

Net Wt. 5 lb (2.26 kg)

Noel's
Gecko Food

YES!



Basic (daily, healthy,
nutritious) diet

Net Wt. 5 lb (2.26 kg)

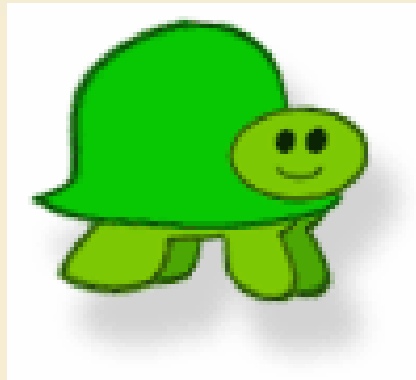
Regulation PF4 Expression of Guarantees

PF4(a)(4) - A specialty pet food shall list other required or voluntary guarantees as required by **Model Regulation 3(a)(4)X**.

PF4(c)(2) - The label of a...specialty pet food which is formulated as and represented to be a mineral supplement shall include...minimum guarantees for all minerals...expressed as the element in units specified in **Model Regulation 4(b)** when no species-specific nutrient profile has been recognized by AAFCO.

PF4(d)(2) - The label of a...specialty pet food which is formulated as and represented to be a vitamin supplement shall include...minimum guarantees for all minerals...expressed as the element in units specified in **Model Regulation 4(c)** when no species-specific nutrient profile has been recognized by AAFCO.

Noel's Turtle Treats



With Vitamins &
Minerals

Net Wt. 8 oz (227 g)

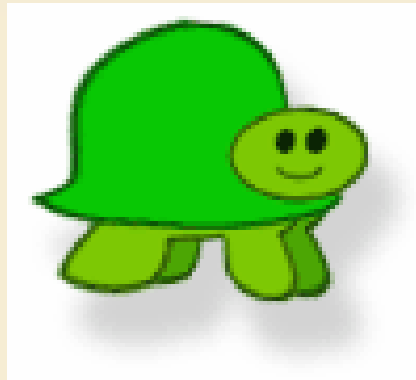
NO!



Guaranteed Analysis

Crude protein (min)	40%
Crude fat (min)	5%
Crude fiber (max)	2%
Potassium (min)	1%
Zinc (min)	200 mg/kg
Vitamin A (min)	10,000 IU/kg
Ascorbic acid (min)	100 mg/kg

Noel's Turtle Treats



With Vitamins &
Minerals

Net Wt. 8 oz (227 g)

YES!

Guaranteed Analysis

Crude protein (min)	40%
Crude fat (min)	5%
Crude fiber (max)	2%
Moisture (max)	10%
Potassium (min)	2%
Zinc (min)	200 ppm
Vitamin A (min)	4,500 IU/lb
Ascorbic acid (min)	45 mg/lb

Regulation PF9 Statements of Calorie Content

Regulation PF10 Descriptive Terms

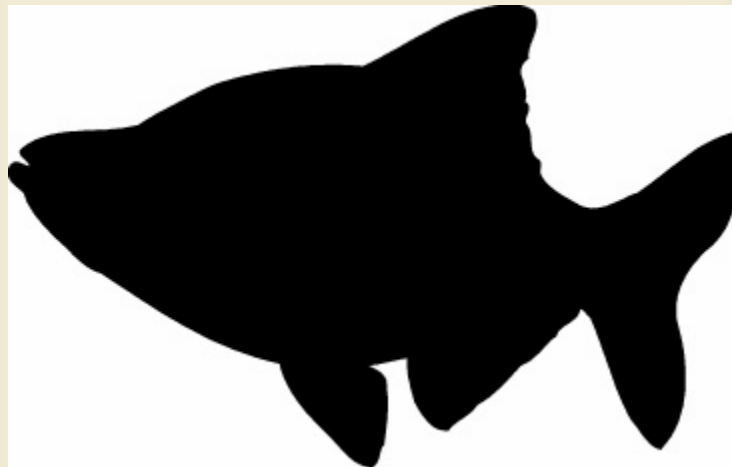
PF9(a) - ...the label of a **dog or cat food** may bear....

PF10(a)(1)A - A **dog food** product which bears...

PF10(a)(1)B - A **cat food** product which bears...

PF10(a)(2) - A **dog or cat food** product which bears...

Noel's Lite Fish Food



For Tubby Tetras and
Pudgy Platties!

Net Wt. 5 lb (2.26 kg)

NO!

Calorie Content
ME (calculated)

3000 kcal/kg
5 kcal/tsp

Regulation PF4 Expression of Guarantees

PF4(c) - The label of a pet food...which is formulated as and represented to be a **mineral supplement** shall include minimum guarantees for all minerals from sources declared in the ingredient statement...expressed as the element in units specified in the [AAFCO Dog or Cat Food] nutrient profile...[or] may be expressed in milligrams (mg) per unit (e.g., tablets, capsules, granules, liquids) consistent with those employed in the quantity statement and directions for use.

PF4(d) - The label of a pet food...which is formulated as and represented to be a **vitamin supplement** shall include minimum guarantees for all vitamins from sources declared in the ingredient statement...expressed in units specified in the [AAFCO Dog or Cat Food] nutrient profile...[or] may be expressed in approved units (e.g., IU, mg, g) per unit (e.g., tablets, capsules, granules, liquids) consistent with those employed in the quantity statement and directions for use.

Regulation PF4 Expression of Guarantees

PF4(g) - Guarantees for crude protein, crude fat, and crude fiber are not required when the pet food or specialty pet food is intended for purposes other than to furnish these substances or they are of minor significance relative to the primary purpose of the product, such as a **vitamin or mineral supplement**

NO!

Noel's
Supplement for Dogs
with Vitamins & Minerals



Net Wt. 8 oz (227 g)

Ingredients:

Dicalcium phosphate, maltodextrins, natural beef flavor, ferrous sulfate, stearic acid, zinc oxide, manganous oxide, copper chloride, vitamin E supplement, vitamin A palmitate, thiamine hydrochloride, cholecalciferol, selenium yeast, vitamin B12 supplement.

Guaranteed analysis:

Thiamine (min)....10 mg
Vitamin D (min)...10 IU
Calcium (min).....100 mg
Copper (min).....10 mg

Noel's **YES!**
Supplement for Dogs
With Vitamins & Minerals



Net Wt. 8 oz (227 g)

Ingredients:

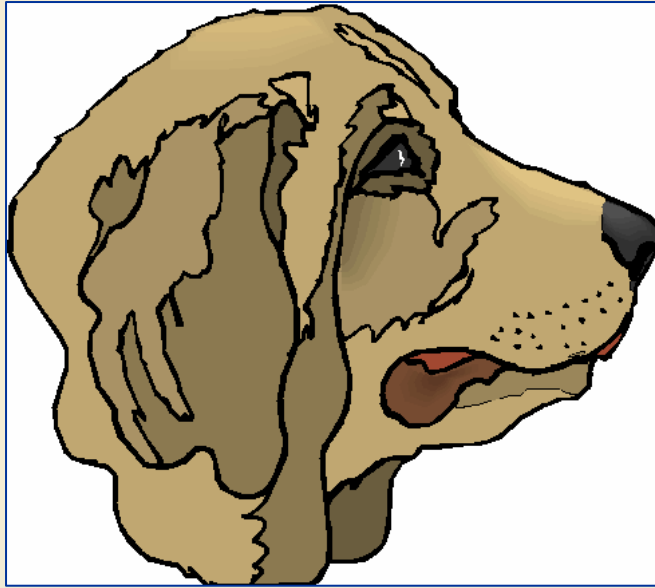
Dicalcium phosphate, maltodextrins, natural beef flavor, ferrous sulfate, stearic acid, zinc oxide, manganous oxide, copper chloride, vitamin E supplement, vitamin A palmitate, thiamine hydrochloride, cholecalciferol, selenium yeast, vitamin B12 supplement.

Guaranteed analysis:

Moisture (max).....	8%
Calcium (min).....	10%
Phosphorus (min).....	8%
Iron (min).....	100 mg/kg
Copper (min).....	20 mg/kg
Manganese (min).....	20 mg/kg
Zinc (min).....	60 mg/kg
Selenium (min).....	0.05 mg/kg
Vitamin A (min)...	10,000 IU/kg
Vitamin D3 (min)...	1000 IU/kg
Vitamin E (min).....	100 IU/kg
Thiamine (min).....	6 mg/kg
Vitamin B12 (min)....	0.2 mg/kg

YES!

Noel's Supplement for Dogs With Vitamins & Minerals



100 tablets

Ingredients:

Dicalcium phosphate, maltodextrins, natural beef flavor, ferrous sulfate, stearic acid, zinc oxide, manganous oxide, copper chloride, vitamin E supplement, vitamin A palmitate, thiamine hydrochloride, cholecalciferol, selenium yeast, vitamin B12 supplement.

Guaranteed analysis:

(per 1.0 g tablet)

Moisture (max).....	8%
Calcium (min).....	100 mg
Phosphorus (min).....	80 mg
Iron (min).....	0.1 mg
Copper (min).....	0.02 mg
Manganese (min).....	0.02 mg
Zinc (min).....	0.06 mg
Selenium (min).....	0.00005 mg
Vitamin A (min).....	10 IU
Vitamin D3 (min).....	1.0 IU
Vitamin E (min).....	0.1 IU
Thiamine (min).....	0.006 mg
Vitamin B12 (min).....	0.0002 mg

Noel's Fatty Acid Supplement for Dogs

With Omega-3 and 6 Fatty Acids
Plus Vitamin E



Net 8 fl oz (236 mL)

YES!

Ingredients:

Fish oil, corn oil, a-tocopherol acetate, BHA (preservative)

Guaranteed analysis:

per teaspoon

(1 teaspoon = 4.5 g)

Crude fat (min).....99%

Moisture (max).....0.5%

Vitamin E (min).....100 IU

Omega-3 fatty acids*

(min).....150 mg

Omega-6 fatty acids*

(min).....400 mg

*Not recognized as an essential nutrient by the AAFCO Dog Food Nutrient Profiles

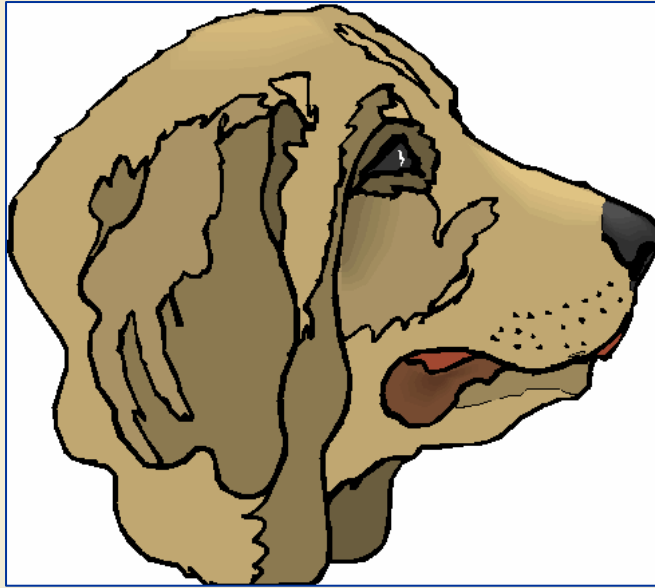
Policy Statement 27 Chews, Bones and Toys for Pets and Specialty Pets

The following products, whether flavored-coated or uncoated, shall be exempt from registration and labeling, unless the manufacturer, in its product labeling or advertising, makes any claim that the product is intended for use as an animal food, or that the product provides anything of nutritional value to the animal (e.g., "digestible" or "high protein"). NOTE: Labeling information required by the Code of Federal Regulations are applicable to the labeling of all these products.

All chews, bones, toys and exercisers made of animal skin, hide, wood, or man-made materials, Hooves, Ears, Animal Bones, Ligaments, [Snouts, Pizzles]

Rawhide generally refers only to beef, and many of these chews use other types of animal skins and hides.

Noel's
Rawhide Chews for Dogs
With Vitamins



Net wt 5 lb (2.26 kg)

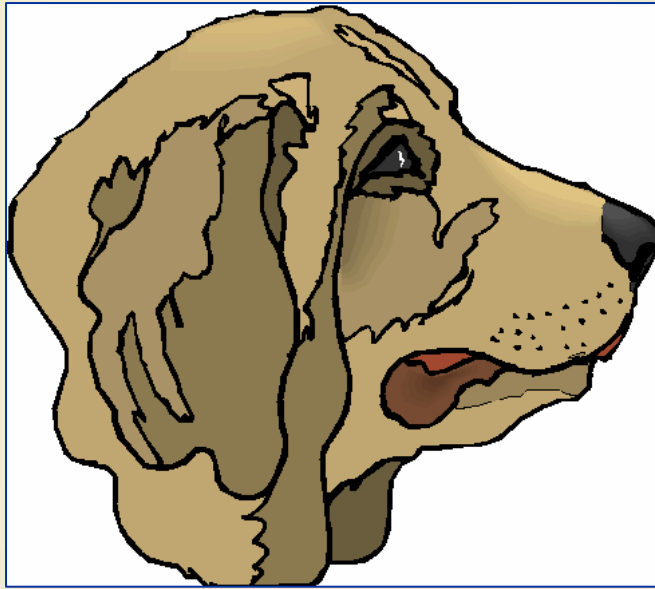
NO!

Ingredients:

Wheat flour, rawhide, natural
beef flavor, thiamine
hydrochloride. vitamin E
supplement

YES!

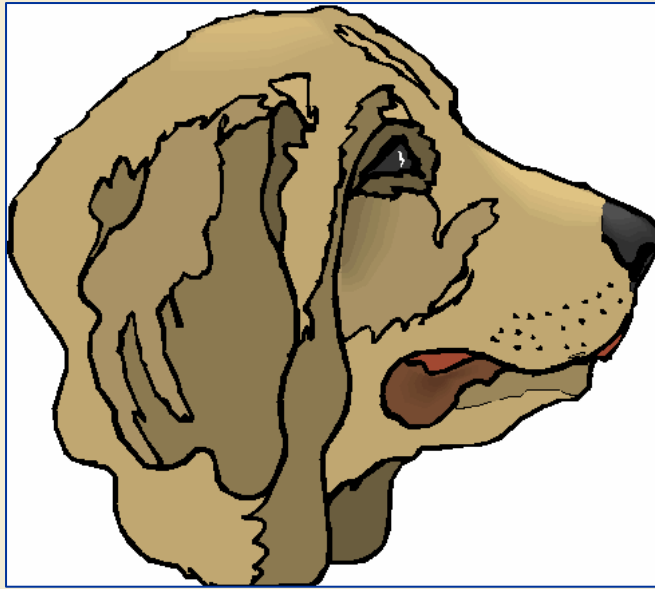
Noel's Rawhide Chews for Dogs



Ingredients:
Rawhide, natural
beef flavor

Net wt 5 lb (2.26 kg)

Noel's
Rawhide Chews for Dogs
With Vitamins



Net wt 5 lb (2.26 kg)

YES!

Ingredients:

Wheat flour, rawhide, natural
beef flavor, thiamine
hydrochloride. vitamin E
supplement

Guaranteed analysis:

Crude protein (min).....50%
Crude fat (min).....10%
Crude fiber (max).....1%
Moisture (max).....10%
Vitamin E (min).....200 IU/kg
Thiamine (min)..... 5 mg/kg

Goals of NASC Presentation

- Provide Facts & Clarify Information for Dietary Supplements for Pets
- Address Misperceptions of NASC
- Let You Know What We are Doing

Facts!

FFDCA §201 (f) The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any other such article.

Facts!

FFDCA §201 (g)(1) The term “drug” means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or the official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals

Facts!

The Dietary Supplements, Health and Education Act of 1994 (DSHEA) amended the Federal Food, Drug, and Cosmetic Act and falls under the jurisdiction of the Federal Food and Drug Administration.

Facts!

**DSHEA does NOT
apply to animals**

(Federal Register Notice, 4/22/96)

Early Regulatory Challenges

- Dietary Supplements for Animals
- Functional Pet Foods
- Both are Really Products Utilizing:
 - Undefined or Unrecognized Ingredients
 - Defined or Recognized Ingredients, but Being Marketed for Unapproved Purposes

Ingredient Approval Process

- AAFCO Ingredient Definition Process
- Food Additive Petition
- Generally Recognized as Safe (GRAS)
- Common or Usual Name
- Approval by Secretary, Director, or Commissioner
- New Animal Drug Application (NADA)
- Other options (EPA/Pesticides, USDA/Biologicals, FDA/Color Additives, etc.)

AAFCO Responses

- Feed Labeling Subcommittee on Nutritional Health and Nutrient Function Claims (1998)
- Nutraceutical Regulatory Advisory Panel (NRAP, 1998 - 1999)
- Novel Ingredients Regulatory Framework Task Force (NIRFTF, 1999 - 2000)
- Botanicals and Herbs Committee (2000 - 2002)
- Enforcement Strategy for Marketed Ingredients (ESMI, 2001 - 2004)

NASC Considered These Possible Pathways to Address the Issue

- Three ways to Achieve an Outcome:
 - Legislation
 - Litigation
 - Cooperation
 - ❖ Work with AAFCO to Establish New Model Bill
 - ❖ Work with FDA/CVM

Cooperation is Better than Confrontation

- Submitted 10 April 2002 as a starting point to work Cooperatively with Regulatory Agencies
- Considered the Objectives Emphasized by the Regulatory Agencies & AAFCO
- Approach – What Can We Do
- Applies to Non-HFC Animals Only
 - Adverse Event Reporting System
 - Member Directed Research – attempted the feed route which was unsuccessful
 - Define & Implement Labeling Guidelines
 - Define & Implement Quality Systems (BMPs)

Approach

- Feed Ingredient Submissions:
Attempted Approval as Feed
Ingredients
 - Glucosamine & MSM Ingredient Definitions
submitted – neither was approved by FDA
- Feed Pathway NOT An Option, so what
is left?
- The Drug Pathway!

Approach

- The Drug Pathway - FFDCA §211
- Approach: What CAN we do, NOT what we CAN'T do
 - Focus ONLY on Non-Human Food Chain Animals
 - Form & Intended Use of the Product is Important
 - ❖ Dosage Form Products
 - ❖ Intended for Non-Nutritional Purposes
 - Feed / Food Regulations not Addressed

A Few Accomplishments

- Risk Management: Establish AE System to Maintain Vigilance - Completed August 2003
- Establish cGMP Guidelines – Completed April 2004, w/revisions
(See FDA Requirements for Human Dietary Supplements Part 111)
- Establish & Implement Labeling Guidelines for Dosage Form Products – Completed May 04, w/revisions
- Established Independent Scientific Oversight
- Implemented Independent Audit Verification Program

NASC Provides a TQM System

- NASC Requirements (NOT Optional):
 - Quality Control for Controlling Your Companies Processes
 - Maintaining Continued Vigilance
 - Properly Labeling & Describing Products Consistent with Intended Use
 - Passing an Independent Audit
 - Embracing a Philosophy of Continuous Improvement
 - Becoming Part of the Solution ...

Thank You

