SUPPLEMENTAL POLICIES

GENERAL POLICIES FOR ANIMAL DRUG LABEL REVIEW

Although the review of labels for compliance with certain mandatory requirements may appear to be somewhat mechanical, a knowledge of policy, precedent animal drugs, the Act and Regulations, currently accepted good veterinary medical procedures and the application of good judgment are all essential. Consultation with others within the Center/Agency and in other agencies is appropriate and necessary in some situations. (See CVM Guide 1240.2320, "Communication and Liaison with Other Centers and Agencies".)

1. Purpose:

   This guide sets forth the general policies to be used in the review and evaluation of labels for animal drug products.

2. Animal Drug Label Review Policies:

   a. The reviewing officer shall apply the appropriate criteria during the evaluation of animal drug labels, irrespective of the source or reason for their submission. (See Summary Table - Attachment A.)

   b. Precedent opinions found in formal statements of policy (Federal Register notices), public announcements, speeches, reports of informal conferences and meetings, or letters to manufacturers are generally not binding on manufacturers or distributors even though directed to a single issue. Labeling requirements set forth in the regulations have the effect of law.

      (1) Precedent unpublished opinions must be used with good judgment and are subject to revision and change in accordance with proper administrative procedures.

      (2) Comments to manufacturers, distributors, etc., must conform with Center/Agency policy and regulations and they must be uniformly applied.

   c. Minor or extremely technical violations require careful consideration of the

implications and resources involved in the choice of the corrective actions to be taken.

d. A company should not include advertising for other products on the label of an animal drug because a label should be neither promotional in tone nor false and misleading in any particular. This practice may cause the product to be misbranded.

e. Specific attention shall be given to a product's status as a new animal drug. Label reviews resulting in classification of the product as a new animal drug are to be made by the Division of Epidemiology and Surveillance in accordance with Program Policy and Procedures Manual, Guide 1240.3500, regarding New Animal Drug Determinations.

3. Foreign Languages:

Labels and labeling for drugs sold in the United States, its territories and possessions, must be in English except in Puerto Rico or in a territory where another language predominates. The exact information required by the Act and Regulations must be provided in the foreign language for distribution within U.S. jurisdiction. If more than one language is used, the same information is required in every language appearing in the labeling material. Spanish is the predominant language other than English used in some geographic areas under U.S. jurisdiction off the mainland.

4. Investigational New Animal Drugs:

Additional cautionary statements are required for investigational new animal drugs.

a. The label of new animal drugs intended for tests in vitro and in laboratory animals shall contain the statement:

> "Caution: Contains a new animal drug for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans."

b. The label of new animal drugs intended for clinical investigation in animals shall bear the statement:

> "Caution. Contains a new animal drug for use in investigational animals in clinical trials. Not for use in humans. Edible products of investigational

animals are not to be used for human food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture."

5. References:

The following sections of the Federal Food, Drug, and Cosmetic Act (FFDCA) and CFR provide the authority for the requirements listed in this guide:

a. Federal Food, Drug, and Cosmetic Act

(1) Section 502 - Misbranded Drugs and Devices
(2) Section 503(f) - Veterinary Prescription Drugs
(3) Section 508 - Authority to Designate Official Names
(4) Section 512 - New Animal Drugs
(5) Section 801 - Imports and Exports

b. Code of Federal Regulations

(1) 21 CFR 1 - General Regulations for the enforcement of the FFDCA and the Fair Packaging and Labeling Act.

(2) 21 CFR 201 - Labeling

(3) 21 CFR 299 - Drugs; Official Names and Established Names

(4) 21 CFR 500 - General

(5) 21 CFR 505 - Interpretative Statements regarding Warnings on Animal Drugs for the Over-the-Counter Sale

(6) 21 CFR 510 - New Animal Drugs

(7) 21 CFR 511 - Investigational New Animal Drugs

(8) 21 CFR 1302 - Labeling and Packaging Requirements for Controlled Substances

6. Foreign-made NADA Products:

U.S. Customs regulations require all products made outside the United States and its territories and possessions to include the country of origin to be listed on the labeling. The Customs requirement can be found in 19 CFR 134.11. Such phrases as "Made in----" or "Product of----" and other similar phrases are acceptable.

7. Label Requirements for Small Containers:

A drug packaged in a container too small to accomodate all the required information is exempt from the label requirements under Section 502(e)(1)(A)(ii) and (B) of the Act under 21 CFR 201.10(h)(2)(i).

The product label must contain the following:

- The proprietary and established name of the drug;
- lot control number;
- name of manufacturer, packer (if any) or distributor, country of origin (if applicable);
- expiration date;
- statement to refer to any accompanying leaflet for use of the product;

Complete drug use information must be provided in an accompanying leaflet or insert.

SUMMARY TABLE

REQUIREMENTS FOR LABELS AND LABELING OF ANIMAL DRUG PREPARATIONS

R = REQUIRED,
CR = CONDITIONALLY REQUIRED (REQUIRED UNDER CERTAIN CIRCUMSTANCES),
NA = NOT APPLICABLE,
NR = NOT REQUIRED

DOSAGE FORM	ORAL		PARENTERALS		TYPE B & C MEDICATED FEEDS	ALL OTHERS	
TYPE	OTC	RX	OTC	RX	OTC	OTC	RX
Product Name R		R	R	R	R	R	R
** Net Quantity of Contents 21 CFR 201.62	R	R	R	R	R	R	R
Name and Address of Manufacturer, Packer or Distributor 21 CFR 201.1	R	R	R	R	R	R	R
Established Name (if any) 21 CFR 201.50 & 201.61	R	R	R	R	R	R	R
General Pharmacological Category 21 CFR 201.61	R	NR	R	NR	NR	R	NR
Ingredients:							
Active - Name	R	R	R	R	R	R	R
- Amount	CR	R	CR	R	CR	CR	R
21 CFR 201.10 502(E)(1)(a) FD&C							
Inactive - Name	CR	NR	CR	R***	R	CR	R

- Amount 21 CFR 201.105	CR	NR	CR	R***	CR	CR	CR

NOTE: "ALL OTHERS" includes products such as implants, aerosols, etc.

* Includes Type A Medicated Articles

** OTC labeled products should include both avoirdupois and metric equivalents.

*** Except for water for injection when used as a vehicle

					TYPE B&C MEDICATED FEEDS		
DOSAGE FORM	ORAL		PARENTERALS			ALL OTHERS	
TYPE	OTC	RX	OTC	RX	OTC	OTC	Rx
Dosage Recommendation 21 CFR 201.5 & 201.105	R	R	R	R	R	R	R
Indications for Safe Use 21 CFR 201.5 & 201.105	R	R	R	R	R	R	R
Directions for Use 21 CFR 201.5 & 201.105	R	CR	R	CR	R	R	CR
Route of Administration 21 CFR 201.5 & 201.105	R	CR	R	R	R	R	R
Warning and Cautions 21 CFR 201.5 & 201.105	R	R	R	R	R	R	R
Side Effects 21 CFR 201.5 & 201.105	R	R	R	R	R	R	R
Expiration Dates 21 CFR 201.17	R	R	R	R	CR	R	R

Manufacturers Control Number 21 CFR 201.18 & 201.105	R	R	R	R	R	R	R
Effects (Drug Actions) 21 CFR 201.105	NA	R	NA	R	NA	NA	R
Prescription Legend 21 CFR 201.105	NA	R	NA	R	NA	NA	R
Date of Labeling Issuance 21 CFR 201.105	NA	R	NA	R	NA	NA	R
Country of Origin 19 CFR 134.11 (U.S. Customs Requirements)	R	R	R	R	R	R	R

NOTE: Any Qualitative or Quantitative Declaration Necessary for Safety and Efficacy may be required in processing INADs and/or NADAs.

* Includes Type A Medicated Articles