Republic of the Philippines
Ministry of Health
OFFICE OF THE SECRETARY
Manila

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DEPARTMENT OF AGRICULTURE
Administrative Order No. 11
Series of 1991

DEPARTMENT OF HEALTH
Administrative Order No. 105
Series of 1991

SUBJECT : **REQUIREMENT FOR LABELLING MATERIALS OF VETERINARY DRUGS AND PRODUCTS**

Pursuant to R.A. No. 3720, as amended by Executive Order No. 175 otherwise known as the "Foods, Drugs and Devices, and Cosmetics, R.A. NO. 6675, otherwise known as the "Generic Act of 1988", R.A. 1556, otherwise known as the "Livestock and Poultry Drugs Act", R.A. 1071, an act to regulate the sale of veterinary biologics and medicinal preparation and R.A. 3101, an Act authorizing the Director of Animal Industry, subject to the approval of the Secretary of Agriculture and National Resources to promulgate regulations for the preparation, sale, traffic in shipment and importation of viruses, sera, toxins or analogous products used for the treatment of domestic animals, the following requirements for the labeling of veterinary drugs and products are hereby promulgated for the information, guidance and compliance of all concerned:

SECTION 1. DEFINITION OF TERMS

For purposes of this Regulation the terms:

1.1 ***"Labeling materials"*** refer to the label on the immediate container and package and other printed materials that are made available with the veterinary drug and product at the time of purchase and/or where the veterinary drug and product is used, such as the outer wrapper cartons, leaflet/package insert accompanying the product, which provide the accurate and necessary detailed information for the identification and proper use of the veterinary drug and product.

1.2 ***"Veterinary drugs and products"*** refer to any substance, including biological products, applied or administered to food producing, companion, aquatic, laboratory and exotic animals. Whether used for therapeutic prophylactic or diagnostic purposes or for modification of physiological functions or behavior.

1.3 ***"Brand Name"*** refers to the proprietary/trade name assigned to the veterinary drug and products by the veterinary drug and product establishment.

1.4 ***"Generic Terminology***" refers to the identification of veterinary drugs and products by their scientifically and internationally recognized active ingredient as determined by the Bureau of Food and Drugs of the DOH/Bureau of Animal Industry of the DA. In case of feed products containing veterinary drugs and products, generic name refers to the internationally recognized technical name of the feeds as determined by the Bureau of Animal Industry of the Department of Agriculture.

1.5 "***Philippine National Veterinary Drug Formulary (PNVDF)***" refers to the classification and listings of the veterinary drug and product.

1.6 "***Formulation***" refers to the name(s) and amount(s) of ingredients per unit quantity expressed in the metric system.

1.7 "***Indication***" refers to the approved clinical and non-clinical use of the veterinary drug and product in terrestrial and aquatic animals based on substantial scientific evidence of the safety and efficacy in the given dosage form.

1.8 "***Dosage Form***" refers to the pharmaceutical form of the preparation based on an official pharmacopoeia.

1.9 "***Mode of Administration***" refers to the site and manner by which the product is to be introduced to animal.

1.10"***Warning***" refers to statements regarding the withdrawal period of the product before the animal is slaughtered for food and/or the occurrence of potential hazard and side effects associated with the use of the product and the limitation of its use.

1.11"***Contraindications***" refer to statements of conditions under which veterinary drug and product should not be used.

1.12"***Caution***" refers to the instructions and special procedures required in the use and handling of the veterinary drug and product to avoid undesired effects and to ensure the safety and effective use of the veterinary drugs and products.

1.13"***Antidote***" refers to a specific substance or combination of substances that would counteract the effect of any undue reaction and overdosage.

1.14"***Veterinary Prescription or Ethical Drugs***" refer to any drug preparation that is to be dispensed only upon written order of a duly-licensed veterinarian for the treatment of a condition or a diagnosed disease of animals.

1.15"***Medicated Feed***" refers to any feed which contains drug ingredients intended or represented for the cure, mitigation, treatment or prevention of diseases of animal other than man or which contains drug ingredients intended to affect the structure or any function of the body of animal other than man.

1.16"***Medicated Feed Premix***" refers to a uniform mixture of one or more drug micro-ingredients with diluent, and/or carrier. Premixes are used to facilitate uniform dispension of the micro-ingredients in a larger mix.

1.17"***Medicated Feed Supplement***" refers to a drug ingredient or mixture of drug ingredients intended to supply the deficiencies in a ration or improve the nutritive balance or performance of the total mixture. It is intended to be:

a) fed undiluted as a supplement to other feeds;
b) offered free choice with other parts of the ration separately available; and
c) further diluted and mixed to produce a complete feed.

1.18"***Medicated Feed Additive***" refers to a drug ingredient or combination of drug ingredients added to the basic feed mix or parts thereof to fulfill a specific need. Usually mixed in micro quantities and requires careful handling and mixing.

1.19"***Medicated Water Additive***" refers to a drug ingredient or combination of drug ingredients added to basic drinking water or parts thereof to fulfill a specific need.

1.20"***Date of Manufacture of Veterinary Drugs and Products other than Veterinary Biological Products and Medicated Feeds***" refers to the month and year during which the

processing of the bulk product, from which the veterinary drug and product are packaged, is completed. “Bulk product” refers to the batch of the finished product.

1.21“***Batch number***” refers to any distinctive combination of letters and/or numbers, assigned to a particular batch

SECTION 3. <u>SPECIFIC REQUIREMENTS</u>

3.1.**Name of product**

3.1.1. In all cases, the generic name shall be the prominently printed element on the label, defined as the one with the highest point size among the various printed elements on the label. It shall be enclosed exclusively by an outlined box rendered in the same color as the generic name. the background color inside the box, should be the same color as the background color outside the box, against which the brand name is rendered.

3.1.2. In all cases, the generic name shall be printed in full, not abbreviated and in accordance with the International Non-proprietary Name (INN) in case the salt is to be indicated this must be included inside the box but in smaller point size.

3.1.3. If a product is identified by generic name together with its brand name the following shall be required in addition to 3.1.1. and 3.1.2.

3.1.3.1. The generic name and brand name shall be rendered using the same typeface, boldness, font and color, with the generic name appearing immediately above the brand name and rendered in a point size bigger than the brand name.

3.1.3.2. If a brand name is presented using a special typeface exclusively designed and used for it the generic name shall be rendered in Helvetica or Universe typeface while complying with the other pertinent provisions above.

3.2. Dosage form shall be specified such as tablets, suspensions, ointments including special delivery system such as sustained release, etc.

3.3. Pharmacologic category shall conform to the category used in the Philippine National Veterinary Drug Formulary (PNVDF) attached as Annex “A” provided that drugs which cannot be classified under these categories may be given a pharmacologic category other than what appears in the Annex, subject to the approval of BFAD/BAI taking into consideration current acceptable standards for therapeutic categories.

3.4. Rx Symbol

3.4.1. The Rx symbol must be printed in a contrasting color to the background on which it appears.

3.4.2. Overprinting or superimposition of the Rx symbol is allowed provided that such will not result in obliterating or rendering less legible the other required label requirements.

3.4.3. The Rx symbol shall be printed in a type size no less than one-fifth (1/5) of the height of the principal display panel.

3.4.4. The Rx symbol shall appear conspicuously on the principal display panel.

3.5. Complete Name and address of manufacturer and also trader, when applicable, must appear on the principal display panel of the label.

3.6. Net content shall indicate the total amount/quantity/number of the dosage form in a given container of the product expressed in metric systems.

3.7. Formulation

3.7.1. Active ingredient(s) must be stated in their generic names (INN)

3.7.2. The amount(s) of the active ingredient(s) shall be expressed in the metric system or units of potency, when applicable, as specified in an official compendium.

3.7.3. The salt or chemical form(s) of active ingredient(s) must be stated, when applicable.

3.7.4. The color agent and other excipients used in the formulation that may cause hypersentivity and/or other adverse reaction (s) must be indicated.

3.7.5. The alcohol content when present must be expressed in percent (%).

3.8 Indication(s)

3.8.1. Indications shall state only approved clinical/non-clinical use(s) and the approved use on species and/or classes of animals such as stated in the approved BFAD/BAI registration.

3.8.2. For anti-infectives and biological products disease conditions shall be indicated by scientific names of the causative agent to be printed on the product insert or accompanying labeling material.

3.9. Contraindication(s), Precaution(s) and Warning(s)

3.9.1. Full information regarding contraindication(s) to the use of drugs, as well as precaution(s) to be observed in its administration and use must be provided.

3.9.2. Caution statements, as required; and specified by BFAD/BAI must be stated (Annex B)

3.9.3. In case of Biological products, warning statements on the proper disposal of container shall be stated.

3.9.4. Warnings: Withdrawal period must be stated based on the PNVDF.

3.9.5. Antidote shall indicate the specific drug to be given to the animal to immediately counteract the drug reaction and/or overdosage.

3.10. Directions for Use

3.10.1. Full information must be provided for the recommended dosage, including the initial dose, the optimal use or usual dose, route of administration and frequency interval, the duration of treatment, dosage adjustment or other pertinent aspects of drug therapy.

3.10.2. Relevant information regarding dilution, reconstitution, preparation and administration must be included.

3.11. Batch/Lot Number

3.11.1. If the entire batch is marketed under one company, only the batch number needs to be indicated. If however, a batch is divided into several lots and the lots are marketed by different companies, the lot number and its corresponding batch number shall be indicated for every lot.

3.11.2. The batch number must be printed or embossed in the wrapper for every ten (10) blister units and the lot number must be printed on the wrapper for every two (2) blister units.

3.12. Expiry/Expiration Date

3.12.1. The expiry or expiration date shall be expressed in terms of the month and the year. In such cases, the last day of the month is assumed as the expiration date.

3.12.2. For a drug that is reconstituted prior to use, a period of guaranteed efficacy must be specified at a given storage condition.

3.12.3. The expiration date shall be printed or embossed on the tin foil, blister and/or strip packages.

3.13. Registration number shall indicate the drug registration number and code assigned by BFAD/BAI.

3.14. Storage conditions appropriate for the product must be stated.

SECTION 4. <u>BIOLOGICAL PRODUCTS</u>

For biological products, the label must include, an addition to the requirements of Section 2 and 3:

4.1. The name and proportion of any antimicrobial agent in the product.

4.2. The name of any adjuvant in the product or any substance which, when administered with an antigen, modifies the immune response to that antigen.

4.3. The name of the species of animal or organism from which the product has been prepared.

4.4. For monoclonal antisera, the name of the species source or name of the species of origin of the hybridoma cell line used in the preparation of the product.

4.5. For viral vaccines produced in animal cells or cell cultures, the name of the cell culture substrate or the name of the species of animal and tissue used in the manufacture of the product, as well as the name of any residual antibiotic present in the product, must be stated when applicable.

4.6. The potency of biological products which needs to be prepared before use, shall be expressed as potency units or weight of active substance per dose or unit volume or the volume which contains the recommended dose.

4.7. The potency unit to be used shall be the International Unit established by the FAO/World Health Organization or where no such International Unit has been established, the potency unit to be used shall be that approved by the BAI taking into consideration current acceptable standards.

SECTION 5. <u>INJECTIONS</u>

In addition to the requirements referred to in Section 2 and when the product is an injection, the label shall include:

5.1. The name and quantity of all excipients in the product except where Section 6 applies.

5.2. A statement of the recommended route or routes of administration, such as “intravenous”, “intramuscular”, “subcutaneous use only”.

5.3. When applicable the statement “use only once” “discard any remaining portion” or “use within 24 hours” or words to that effect must be included.

5.4. Where the contents of the container are to be used on one occasion only, the words “single use” or “single dose” must be included.

5.5. Where the product consists of a concentrated solution for injection, a direction not to administer the solution undiluted and a direction to dilute the solution with the specified diluent to the appropriate volume before use must be included.

SECTION 6. LARGE VOLUME INJECTION

In addition to the requirements referred to a Section 2 and 3, the label shall include:

6.1. The names and quantities of all excipient and active substances in the nominal volume of fluid in the container, listed in descending order of magnitude within each group of chemically similar substances.

6.2. Where one or more substances are amino acids and/or protein, a statement of the total amount of nitrogen in the nominal volume of fluid in the container.

6.3. The nominal osmolality.

6.4. A statement which specifies whether the solution is nominally “hypotonic” or “hypertonic”.

6.5. The nominal pH range of the solution.

6.6. The words “single use” or “single dose”.

SECTION 7. <u>MEDICATED FEED PRODUCTS</u>

In addition to the requirement referred to in Section 2 and when the product is a medicated feed, the label shall include:

7.1. The definite guarantee of the manufacturer relative to the quality of the veterinary drug and product.

7.2. The accepted or official name of each ingredient used in the manufacture.

7.3. The percent of such ingredients as corn cobs oat hulls, rice hulls, barley hulls, mongo bean hulls, cocoa shells, or similar materials when such constitute a portion of the feed or feedstuffs in quantities in excess of what is normally found in such feedstuffs.

SECTION 8. <u>TOPICAL PRODUCTS</u>

In addition to the requirements referred to in Section 2 and 3, the label shall include the name and proportion of any antimicrobial agent present in the product.

SECTION 9. PRODUCTS FOR EXTERNAL USE

In addition to the requirements referred to in Section 2 and 3, the statement "FOR EXTERNAL USE ONLY" printed in red color must appear on the principal display panel of the label.

SECTION 10. SMALL CONTAINERS

Where the product is enclosed in a container which has a capacity of 10 milliliters or less and the container is enclosed in a primary pack;

10.1. The label of the container must contain the requirement of 2.1.1, company logo, strength, mode of administration, species and type of animal indication batch number, expiry date and registration number of BAI/BFAD.

10.2. The label of the primary pack or other labeling materials must contain the requirements referred to in Section 2 and 3, and Sections 4 and 5, when applicable.

10.3. When it is not practical to set out particulars in full on the label of the container, the particulars referred to 10.1 may be abbreviated, upon the approval of the BAI/BFAD.

SECTION 11. INDIVIDUALLY WRAPPED PRODUCTS, STRIP AND BLISTER PACKS

Where the product consists of individual dosage units, and each such dosage unit is individually wrapped or contained in strip or blister packs, after which each individual dosage unit is enclosed in a primary pack:

11.1. The individual wrapper unit must contain the requirement of 2.1.1, company name or logo, strength, expiry date, lot number and for veterinary use only.

11.2. For products contained in strip or blister packs, the requirement of 2.1.1, strength, expiry date, lot number for every 2 units and company name and batch number for strip of 10 units.

11.3. The primary pack or other labeling materials must contain the requirement referred to in Section 2 and 3.

SECTION 12. EXEMPTIONS

12.1. Where products are made up or compounded by pharmacist in accordance with the individual prescription of a veterinarian.

12.2. Where products are used solely for investigational purpose.

12.3. Where products are donated by foreign agencies/persons, the requirements of generic labeling may be waived except that the expiry date must be indicated.

The requirements of this Regulation do not apply in relation to goods under 12.2, 12.3 and in exceptional cases where the labeling provisions of this regulation are not appropriate, but in these cases exemption must be applied for and approved by BFAD/BAI on a case to case basis.

SECTION 13. VIOLATIVE/PROHIBITED ACTS

13.1. Any product that is not labeled in accordance with the requirement of this Regulation shall be deemed misbranded.

13.2. The following acts and the causing thereof are hereby prohibited:

13.2.1. The manufacture, sale, offering for sale or transfer of any product that is misbranded.

13.2.2. Forging/counterfeiting, simulating or falsely representing or using any mark, stamp, label or other identification device required under the Regulation without proper authority.

13.2.3. The alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of product, if such act is done while such product is held for sale and results in such article being misbranded.

13.2.4. The use in labeling of reference to any BFAD/BAI Report or documents (analysis) without clearance from BFAD and or BAI.

SECTION 14. SANCTIONS

For violation of this Regulation, any or all of the following sanctions after due notice and summary hearing may be imposed by the Secretary of Health/Secretary of Agriculture, whenever applicable.

14.1. Suspension or revocation of the License to Operate (LTO) of veterinary drug and product establishments and outlets and cancellation of Certificate of Product Registration.

14.2. Imposition of administrative fines not less than P1,000.00 not more than P5,000.00.

14.3. Recall from the market of misbranded product(s)

14.4. Confiscation of the violative product(s)

SECTION 15. CRIMINAL LIABILITY

The imposition of the above sanctions does not preclude the institution of appropriate criminal proceeding pursuant to Section 26 of R.A. 3720, as amended, Section 12 of R.A. No. 6675, Section 10 of R.A. No. 1556 and Section 3 of R.A. 1071 and Section 5 of R.A. 3101.

SECTION 16. PROCEDURE FOR CHANGING OVER TO NEW LABELS

The procedure and timetable for changing over to the new labels will be as follows:

16.1. All drug establishments that own registered drug products with single active ingredients covered by this A.O. shall present the above for review and approval by BFAD not later than June 15, 1991. Multiple active ingredient products will follow the guidelines and timetable which shall be the subject of another subsequent A.O.

16.2. All satisfactory applications or new generic label covered by this A.O. submitted within June 15, 1991 deadline shall be approved by BFAD no later than August 15, 1991.

16.3 Starting sixty (60) days after approval but not later than October 15, 1991, only such approved generic labels shall be used for these products in new production. The drug establishment is required to submit the last batch number bearing the old and the first batch number bearing the new generic label before the start of actual product with the new label.

16.4. After December 31, 1991 all covered products with the old labels shall be deemed misbranded and subject to seizure by BFAD.

16.5. It shall be the responsibility of the drug establishment to ascertain the coverage of this A.O. on its product.

16.6. Remedial generic labeling according to the provisions of A.O. 79 s. 1989 is available to products covered by this A.O.

SECTION 17. SEPARABILITY CLAUSE

In case any provision of these rules and regulations is declared contrary to law or unconstitutional, other provisions which are not affected thereby shall continue to be in force and in effect.

SECTION 18. REPEALING CLAUSE

All Administrative orders, rules and regulations and other administrative issuances or parts thereof, inconsistent with the provisions of this Regulation, are hereby repealed and modified accordingly.

SECTION 19. EFFECTIVITY

This regulation shall take effect fifteen (15) calendar days after publication in two newspapers of general circulation or in Official Gazette.

(Sgd.) SENEN C. BACANI
Secretary of Agriculture

(Sgd.) ALFREDO R.A. BENGZON
Secretary of Health