August 31, 1988

VETERINARY SERVICES MEMORANDUM NO. 800.54

Subject: Guidelines for the Preparation and Review of Labeling Materials

To: Biologics Licensees, Permittees, and Applicants
Director, National Veterinary Services Laboratories
Directors, VS Regions
Biologics Specialists, VS
Area Veterinarians in Charge, VS

1. PURPOSE

The purpose of this memorandum is to provide guidance in the preparation and review of labeling materials for biological products. Most labeling requirements are promulgated in Title 9, Code of Federal Regulations, Part 112 (9 CFR 112). The material in Part III below emphasizes or interprets areas of 9 CFR 112 that have, on occasion, caused problems. Parts IV and V cover labeling requirements for experimental biological products and biological products for further manufacture, respectively.

II. CANCELLATION

Veterinary Services Memorandum No. 800.54 dated October 16, 1985, is hereby rescinded.

III. PREPARATION AND SUBMISSION

A. Submission of Labeling Materials

The manner of labeling submission prescribed in 9 CFR 112.5(d) should be precisely followed. Close attention should be paid to the following points:

1. All labels and sketches submitted at the same time for the same product should be accompanied by a single VS Form 14-15.

2. The proper number of copies must be provided with each submission. Two copies of each sketch and at least three copies of each label are required.

3. When two final containers are packaged in the form of a combination package, the labels must be submitted together on a single sheet of paper.

B. Standards for Displaying True Name of Product on Labels

1. The true name of the product must appear as on the license. The term parainfluenza$_3$, however, may be presented as either parainfluenza$_3$ or parainfluenza 3.

2. Each term of the principal part of the true name must receive equal emphasis with regard to size, boldness, color, etc.

3. The true name must not be overshadowed.

a. The trade name must not appear above the true name.

b. The trade name lettering must not exceed that of the true name in size or boldness.

c. Colors used must not render the trade name more prominent than the true name.

d. The true name must not be overshadowed by any logo,trademark, design, or company name.

e. In summary, the most conspicuous feature of the label must be the true name.

C. Small Final Container Labels

Full instructions for use and all required warning/caution statements must appear on these labels unless the resultant print size renders them illegible. A reference to the box label or circular should then be included.

D. Nonbiologic Sterile Diluents

When a desiccated biological product is packaged with a nonbiologic sterile diluent, final container label submissions should consist of both the biologic and sterile diluent labels.

E. Special Additional Label Requirements

Additional label requirements are specified in 9 CFR 112.7 for the following:

1. Biological products containing live Newcastle disease virus.

2. Biological products containing infectious bronchitis virus.

3. Biological products containing rabies virus.

4. Vaccines containing modified live bovine rhinotracheitis virus.

5. Inactivated bacterial products with specific repeat dose recommendations for those containing *Clostridium haemolyticum*, *Erysipelothrix rhusiopathiae*, or *Clostridium botulinum* Type C.

6. Autogenous biologics.

7. Liquid products used as diluents in combination packages.

8. Wart Vaccines.

9. Feline Panleukopenia Vaccines.

10. Serum, antiserum, or antiserum derivatives.

11. Biological products containing modified live canine hepatitis virus or modified live adenovirus Type 2.

F. Foreign Language Labels

1. The foreign language portion of a bilingual label must be a direct translation of the English portion. If a label is entirely in a foreign language, the mounting sheets should state that the label is a direct translation of an approved English label (cite the label number) or a direct English translation of the foreign language text should be attached.

G. Distributor Labels

1. If distributor's logo is used, the manufacturer's logo must appear in equal or greater prominence .

2. The distributor s name and address must not be more conspicuous than the manufacturer's.

IV. EXPERIMENTAL BIOLOGICAL PRODUCTS

A. Labels for experimental biological products should not be submitted with a VS Form 14-15 but as a part of the package required in 9 CFR 103.3.

B. The following must appear on experimental biological product labels:

1. True name of the product.

2. Storage conditions.

3. Name and address of the manufacturer.

4. Volume of contents.

5. Number of doses.

6. The statement "Notice: For Experimental Use Only-Not For Sale" or the equivalent.

C. Three copies of all labels should be submitted with a request to initiate the field trial. The United States Veterinary License legend must not appear on these labels.

V. PRODUCTS FOR FURTHER MANUFACTURE

A. The following must appear on For Further Manufacture labels:

1. True name of the product.

2. "For Further Manufacture" phrase.

3. Serial number.

4. Name, address, and establishment license number of the manufacturer

5. Volume of contents.

6. Storage conditions.

/s/

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