AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

storing biological products, at a licensed establishment, except as otherwise prescribed herein, shall be thoroughly sterilized by live steam at a temperature of at least 120 °C. for not less than one-half hour, or by dry heat at a temperature of at least 160 °C. for not less than one hour. If for any reason such methods of sterilization are impracticable, then a process known to be equally efficacious in destroying microorganisms and their spores may be substituted after approval by the Administrator.

(b) Instruments which are found to be damaged by exposure to the degree of heat prescribed in this section, after having been thoroughly cleaned, may be sterilized by boiling for not less than 15 minutes.

[23 FR 10051, Dec. 23, 1958, as amended at 34 FR 18119, Nov. 11, 1969; 56 FR 66783, Dec. 26, 1991]

§ 109.2 Sterilizers.

Steam and dry-heat sterilizers used in connection with the processing of biological products at licensed establishments shall be equipped with automatic temperature recording gauges: *Provided*, That other record keeping systems may be used when approved by the Administrator. When gauges are used, they shall be periodically standardized to assure accuracy. Charts and other temperature records made during production shall be available at all times charts and records shall be kept in accordance with part 116 of this chapter.

[35 FR 16039, Oct. 13, 1970, as amended at 56 FR 66783, Dec. 26, 1991]

§ 109.3 Pasteurizers.

All pasteurizing equipment shall meet the requirements in paragraphs (a), (b), and (c) of this section and be acceptable to Animal and Plant Health Inspection Service.

(a) Metal serum containers shall be used in licensed establishments. During the heating process, each container shall be surrounded by a separate water jacket or equivalent so that the entire container, including its lid, is heated to the required temperature. Each serum container shall be equipped with a motor-driven agitator and a separate automatic recording thermometer.

(b) Each water bath shall have an automatic temperature control to limit the temperature of the water to a maximum of 62 °C., an automatic recording thermometer, an indicating thermometer set in a fixed position, and circulating mechanism adequate to insure equal temperatures throughout the bath. The heating unit for the bath shall be separated from the serum container and the water jacket.

(c) Accurate thermometers at licensed establishments shall be used at frequent intervals to check temperatures of the serum as registered by recording thermometers.

[35 FR 16039, Oct. 13, 1970, as amended at 56 FR 66783, Dec. 26, 1991]

PART 112—PACKAGING AND LABELING

Sec.

112.1 General.
112.2 Final container label, carton label, and enclosure.
112.3 Diluent labels.
112.4 Subsidiaries, divisions, distributors, and permittees.
112.5 Review and approval of labeling.
112.6 Packaging biological products.
112.7 Special additional requirements.
112.8 For export only.
112.9 Biological products imported for research and evaluation.
112.10 Special packaging and labeling.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 38 FR 12094, May 9, 1973, unless otherwise noted.

§ 112.1 General.

(a) Unless otherwise authorized or directed by the Administrator, each biological product prepared at a licensed establishment, or imported, shall be packaged and labeled as prescribed in this part before it is removed from the licensed establishment or presented for importation: *Provided*, That biological products to be imported for research and evaluation shall be subject to packaging and labeling requirements in § 112.9. *Provided further*, That, unless otherwise exempted, all preparation, including packaging and labeling, of biological products shall only be performed in a licensed establishment

under an approved Outline of Production.

(b) No person shall apply or affix to or include with, or cause to be applied or affixed to or included with, any carton or final container of a biological product, any label, stamp, mark or statement that is false or misleading in any particular, is not in compliance with the regulations, or is not approved by APHIS.

(c) No person shall alter, mark or remove any approved labeling affixed to or included with any biological product prior to selling or otherwise distributing such product. In addition, no person shall mark any carton, other container, or final container of a biological product so as to falsify the labeling, make it misleading, or cause it to be illegible.

(d) Labels that are stamped, printed or glued directly on cartons, other containers, or final containers shall be legible throughout the dating period. Biological products bearing labels, which have been altered, mutilated, destroyed, obliterated or removed, shall be withheld from the market.

[38 FR 12094, May 9, 1973, as amended at 59 FR 43445, Aug. 24, 1994]

§ 112.2 Final container label, carton label, and enclosure.

(a) Unless otherwise provided, final container labels, carton labels, and enclosures (inserts, circulars, or leaflets) shall include the information specified in this section.

(1) The principal part of the true name of the biological product which name shall be identical with that shown in the product license under which such product is prepared, or the permit under which it is imported, shall be prominently lettered and placed giving equal emphasis to each word composing it. Descriptive terms used in the true name on the product license or permit shall also appear. Abbreviations of the descriptive terms may be used on the final container label if complete descriptive terms appear on a carton label and enclosures;

(2) If the biological product is prepared in the United States, the name and address of the producer (licensee or subsidiary) or if the biological product is prepared in a foreign country, the name and address of the permittee and of the foreign producer.

(3) The license or permit number assigned by the Department which shall be shown only in one of the following forms respectively: ''U.S. Veterinary License No. _____,'' or ''U.S. Vet. License No. _____,'' or ''U.S. Vet Lic. No. _____,'' or ''U.S. Veterinary Permit No. _____,'' or ''U.S. Permit No. _____.''

(4) Storage temperature recommendation for the biological product stated as not over 45 °F. or stated as not over 7 °C. or stated as not over 45 °F. or 7 °C.

(5) Full instructions for the proper use of the product, including vaccination schedules, warnings, cautions, and the like: *Provided,* That in the case of very small final container labels or carton, a statement as to where such information is to be found, such as ''See enclosure for complete directions,'' ''Full directions on carton,'' or comparable statement;

(6) In the case of a multiple-dose final container, a warning to use entire contents when first opened: *Provided,* That a diagnostic or a desensitizing antigen packaged in a multiple-dose final container is exempt;

(7) If the biological product contains viable or dangerous organisms or viruses, a warning to ''Burn this container and all unused contents,'' except that in the case of a small one-dose container, the statement ''Burn this container'' or ''Burn this vial'' may be used.

(8) In the case of a biological product recommended for use in domestic animals, the edible portion of which may be used for food purposes, a withholding statement of not less than 21 days to read: ''Do not vaccinate within (insert number) days before slaughter'' or ''Do not vaccinate food-producing animals within (insert number) days before slaughter'': *Provided,* That longer periods shall be stated when deemed necessary by the Administrator. Very small final container labels are exempted from this requirement.

(9) The following information shall appear on the final container label and carton label, if any, but need not appear on the enclosure:

(i) A permitted expiration date;

(ii) The number of doses where applicable;

(iii) The recoverable quantity of the content of each final container stated in cubic centimeters (cc.) or milliliters (ml.) or units.

(iv) A serial number by which the product can be identified with the manufacturer's records of preparation: *Provided*, That when a liquid antigenic fraction is to be used instead of a water diluent for one or more desiccated antigenic fractions in a combination package, a hyphenated serial number composed of a serial number for the desiccated fraction and the serial number for the liquid fraction shall be used on the carton;

(10) In the case of a product which contains an antibiotic added during the production process, the statement ''Contains _____ as a preservative,'' or an equivalent statement indicating the antibiotic added shall appear on cartons and enclosures if used: *Provided*, That if cartons are not used, such information shall appear on the final container label;

(11) The number of final containers of biological product and the number of doses in each final container shall be stated on each carton label for all cartons containing more than one final container of biological product. The number of final containers of diluent, if any, and the quantity in each shall also be stated on each carton label.

(b) Labels may also include any other statement which is not false or misleading and may include factual statements regarding variable response of different animals when vaccinated as directed but may not include disclaimers of merchantability, fitness for the purpose offered, or responsibility for the product.

(c) Labels of biological products prepared at licensed establishments or imported shall not include any statement, design, or device, which overshadows the true name of the product as licensed or which is false or misleading in any particular or which may otherwise deceive the purchaser.

(d) Carton labels and enclosures shall be subject to paragraph (d)(1), (d)(2), and (d)(3) of this section.

(1) The statement, ''Restricted to use by or under the direction of a veterinarian'' or ''Restricted to use by a veterinarian,'' shall be used on all carton labels and enclosures when such restriction is prescribed on the product license.

(2) If the licensee states on the carton labels and enclosures of a product that its sales are restricted to veterinarians, then the entire production of that particular product in the licensed establishment shall be so restricted by the licensee.

(3) The statement ''For veterinary use only'' or an equivalent statement may appear on the carton labels and enclosures for a product if such statement is being used to indicate that the product is recommended specifically for animals, and not for humans.

(e) When label requirements of a foreign country conflict with the requirements as prescribed in this part, special labels may be approved for use on biological products to be exported to such country. When laws, regulations, or other requirements of foreign countries require exporters of biological products prepared in a licensed establishment to furnish official certification that such products have been prepared in accordance with the Virus-Serum-Toxin Act and regulations issued pursuant thereto, such certification may be made by Animal and Plant Health Inspection Service upon request of the licensee.

(f) If a carton label or an enclosure is required to complete the labeling for a multiple-dose final container of liquid biological product, only one final container shall be packaged in each carton: *Provided*, That if the multiple-dose final container is fully labeled without a carton label or enclosure, two or more final containers may be packaged in a single carton which shall be considered a shipping box. Labels or stickers for shipping boxes shall not contain false or misleading information but need not be submitted for approval.

(Approved by the Office of Management and Budget under control number 0579–0013)

[38 FR 12094, May 9, 1973, as amended at 39 FR 16856, May 10, 1974; 41 FR 44359, Oct. 8, 1976; 42 FR 11825, Mar. 1, 1977; 42 FR 29854, June 10, 1977; 42 FR 41850, Aug. 19, 1977; 48 FR 57473, Dec. 30, 1983; 56 FR 66784, Dec. 26, 1991]

§ 112.3 Diluent labels.

Each final container of diluent, other than a liquid biological product, packaged with desiccated biological products shall bear a label that includes the following:

(a) The name—Sterile Diluent.

(b) True name of the biological product with which the diluent is packaged, except that when the firm packages all desiccated biological products with the same diluent, or two or more types of diluent are used, and the licensees' methods of identification and storage insure that all products are packaged with the correct type of diluent, labels affixed to the containers of diluent are exempt from this provision.

(c) The recoverable quantity of contents in cubic centimeters (cc) or milliliters (ml).

(d) A serial number by which the diluent can be identified with the manufacturer's records of preparation;

(e) Name and address of the licensee or the permittee;

(f) In the case of a diluent with which a desiccated biological product is to come in contact while the diluent is in its original container; and,

(1) Is in a multiple-dose container, a positive warning that all of the biological product shall be used at the time the container is first opened; and/or

(2) The biological product is composed of viable or dangerous organisms or viruses, the notice, ''Burn this container and all unused contents,'' except that, in the case of a small one-dose container, the statement ''Burn this container'' or ''Burn this vial'' may be used.

(g) The establishment license number or the permit number, as the case may be, in one of the forms provided in § 112.2(a)(3).

[38 FR 12094, May 9, 1973; 38 FR 13476, May 22, 1973, and amended at 39 FR 16856, May 10, 1974]

§ 112.4 Subsidiaries, divisions, distributors, and permittees.

Labels used by subsidiaries, divisions, distributors, and permittees shall be affixed by the licensee in a licensed establishment where the product is produced. Such labels shall comply with requirements for their review, approval, and filing as provided in the regulations.

(a) *Subsidiaries*. Labels to be used on a licensed biological product prepared by a subsidiary operating in a licensed establishment shall be submitted in accordance with § 112.5. Only labels approved for use on such product shall be used by the subsidiary.

(b) *Divisions*. Labels to be used on a licensed biological product prepared in a licensed establishment for distribution by a division or marketing unit of the licensee shall be submitted in accordance with § 112.5. The name, address, and license number of the licensee shall be prominently placed on such labels. The relationship of the division or marketing unit to the licensee shall appear prominently on the label by use of the term ''division of'' or equivalent.

(c) *Distributors*. The name and address of the distributor or any statement, design, or device shall not be placed on the labels or containers of a licensed biological product in a manner which could be false or misleading or which could indicate that the distributor is the manufacturer of such product or operating under the license number shown on the label. The manufacturer shall be identified by name, address, and license number with the term ''manufactured by,'' ''produced by,'' or an equivalent term prominently placed in connection therewith. The name and address of the distributor may be placed on labels or containers if the term ''distributor,'' or ''distributed by,'' or an equivalent term is prominently placed in connection therewith.

(d) *Permittees*. The name and address of the permittee and any statement, design, or device shall not be placed on the labels or containers of a biological product imported for sale and distribution in accordance with § 104.5 in a manner which could be false or misleading or which could falsely indicate that the permittee is the manufacturer of such product. The manufacturer shall be identified by name and address with the term ''manufactured by,'' ''produced by,'' or an equivalent term prominently placed in connection therewith. Reference to the permittee shall be made by name, address, and

permit number with the term ''imported by,'' ''produced for,'' or an equivalent term prominently placed in connection therewith.

[50 FR 46417, Nov. 8, 1985, as amended at 59 FR 43445, Aug. 24, 1994]

§ 112.5 Review and approval of labeling.

Labels used with biological products prepared at licensed establishments or imported for general distribution and sale must be submitted to the Animal and Plant Health Inspection Service for review for compliance with the regulations and approval in writing prior to use, except as provided in paragraph (c) of this section and under the master label system provided in paragraph (d) of this section.

(a) Transmittal forms, furnished by Animal and Plant Health Inspection Service upon request, shall be used with each submission of sketches (including proofs) and labels. Separate forms shall be used for each biological product but only one copy of the form shall be used for all sketches and labels submitted at the same time for the same biological product.

(b) Sketches may be submitted for comment to Animal and Plant Health Inspection Service by the licensee or permittee before preparing the finished label. Such sketches shall be returned to the licensee or permittee with comments, if any. Failure of the reviewer to take exception to a sketch shall not constitute approval of a finished label subsequently prepared.

(c)(1) Labels must be submitted to the Animal and Plant Health Inspection Service for review and written approval. Only labels which are approved as provided in §112.5(d) may be used. When changes are made in approved labels, the new labels shall be subject to review and approval before use: *Provided*, That certain minor changes may be made in labels for products with approved labels or master labels, and the revised labels may be used prior to review by APHIS, with the provision that a new label or master label bearing these changes is submitted to APHIS for review and written approval within 60 days of label use, and that such minor changes do not render the product mislabeled or the label false and misleading in any particular.

(2) Minor label changes that may be made under the provision for products with approved labels or master labels are:

(i) Changes in the physical dimensions of the label provided that such change does not affect the legibility of the label;

(ii) Change in the color of label print, provided that such change does not affect the legibility of the label;

(iii) The addition or deletion of a Trade Mark (TM) or Registered (R) symbol;

(iv) The correction of typographical errors;

(v) Adding or changing label control numbers of bar codes; and

(vi) Revising or updating logos.

(d) Labels and sketches submitted shall be prepared in the number and manner prescribed in this paragraph.

(1) Copies required:

(i) For label sketches, submit two copies of each sketch of a final container label, carton label, and enclosure. Sketches must be legible, and must include all information specified in §112.2. One copy of each sketch will be returned with applicable comments, and one copy will be held on file by APHIS for no more than one year after processing, until replaced by a finished label: *Provided*, That sketches submitted in support of an application for a license or permit shall be held as long as the application is considered active.

(ii) For master label sketches, submit for each product two copies of each sketch of an enclosure, label for the smallest size final container, and carton label; *Provided*, That labels for larger size containers and/or cartons that are identical, except for physical dimensions, need not be submitted. One copy of each master label sketch will be returned with applicable comments, and one copy will be held on file by APHIS for one year after processing, until replaced by a finished master label that is submitted according to §112.5(d)(1)(iii): *Provided*, That master label sketches submitted in support of an application for license or permit shall be held as long as the application is considered active.

(iii) For finished labels, submit three copies of each finished final container label, carton label, and enclosure: *Provided*, That when an enclosure is to be used with more than one product, one extra copy shall be submitted for each additional product. Two copies of each finished label will be retained by APHIS. One copy will be stamped and returned to the licensee. Labels to which exceptions are taken shall be marked as sketches and handled under § 112.5(d)(1)(i).

(iv) For finished master labels, submit for each product three copies each of the enclosure and the labels for the smallest size final container and carton. Labels for larger sizes of containers or cartons of the same product that are identical, except for physical dimensions, need not be submitted. Such labels become eligible for use, concurrent with the approval of the appropriate finished master label: *Provided*, That the marketing of larger sizes of final containers is approved in the filed Outline of Production, and the appropriate larger sizes of containers or cartons are identified on the label mounting sheet. When a master label enclosure is to be used with more than one product, one extra copy for each additional product shall be submitted. Two copies of each finished master label will be retained by APHIS. One copy will be stamped and returned to the licensee. Master labels to which exceptions are taken will be marked as sketches and handled under § 112.5(d)(1)(ii).

(2) Mounting:

(i) Each label or sketch shall be securely fastened to a separate sheet of heavy bond paper (8½″ × 11″) in such a manner that all information is available for review.

(ii) Two-or three-part cartons, including ''sleeves,'' shall be considered as one label. All parts shall be submitted together.

(iii)(A) When two final containers are packaged together in a combination package, the labels for each shall be mounted on the same sheet of paper and shall be treated as one label. For diagnostic test kits, the labels for use on the individual reagent containers to be included in the kit shall be mounted together on a single sheet of paper, if possible; if necessary, a second sheet of paper may be used. The carton label and enclosure shall be mounted on separate individual sheets.

(B) If either final container label is also used alone or in another combination package, sets of separate labels for each biological product with which it is used shall be submitted for review.

(iv) When the same final container label is applied by different methods such as paper or screen printing, one of each shall be mounted on the same sheet of paper as one submission.

(3) To appear on the top of each page:

(i)(A) Name and product code number of the biological product as it appears on the product license or permit.

(B) Extra copies of enclosures to be used with another product shall bear the name and code number of the product affected.

(ii)(A) Designation of the specimen as a label or master label: sketch, final container label, carton label, or enclosure.

(B) If two final container labels or multiple parts are on one sheet, each shall be named, and the label or part being revised shall be designated.

(iii) Size of package (dose, ml., cc., or units) for which the labels or enclosures are to be used.

(4) To appear on the bottom of each page: The reason for and information relevant to the submission shall be stated in the lower left hand corner as:

(i) Master label dose sizes approved for code _____.

(ii) Replacement for label, master label, and/or sketch No. _____.

(iii) Reference to label or master label No. _____.

(iv) Addition to label No. _____.

(v) License Application Pending _____.

(vi) Foreign Language copy of Label No. _____.

(e) Special requirements for foreign language labels:

(1) If true, a statement that the label is a direct translation from a corresponding approved domestic label.

(2) If the foreign language label is not a direct translation of an approved domestic label, an English version shall be submitted with an explanation for the difference in texts.

(3) Foreign language portion of a bilingual label shall be a true translation of the English portion. Reference to additional information on the enclosure shall not be made unless that enclosure is also bilingual.

(f) When a request is received from Animal and Plant Health Inspection Service, the licensee or permittee shall submit a list of all approved labels currently being used. Each label listed shall be identified as to:

(1) Name and product code number as it appears on the product license or permit for the product; and

(2) Where applicable, the size of the package (doses, ml., cc., or units) on which the label shall be used; and

(3) Label number and date assigned; and

(4) Name of licensee or subsidiary appearing on the label as the producer.

(g) At the time of an inspection, or when requested by APHIS, licensees or permittees shall make all labels and master labels, including labels approved for use but exempted from filing under the master label system, available for review by authorized inspectors. Such labels shall be identical to the approved label or master label except for physical dimensions, reference to recoverable volume or doses and/or certain minor differences permitted in accordance with § 112.5(c).

(Approved by the Office of Management and Budget under control number 0579–0013)

[38 FR 12094, May 9, 1973, as amended at 48 FR 57473, Dec. 30, 1983; 49 FR 21044, May 18, 1984; 56 FR 66783, Dec. 26, 1991; 59 FR 43445, Aug. 24, 1994; 61 FR 29464, June 11, 1996; 61 FR 33175, June 26, 1996; 64 FR 43044, Aug. 9, 1999]

§ 112.6 Packaging biological products.

(a) Each multiple-dose final container of a biological product which requires a diluent for administration shall be packaged in an individual carton with a container of the proper volume of diluent for that dose as specified in the filed Outline of Production. Each multiple-dose final container of a product which does not require a diluent for administration need not be packaged in an individual carton unless the final container labeling does not contain all information required by the regulations. Such information must be included in or on a carton. Exceptions are provided in paragraphs (c) and (d) of this section and § 112.8.

(b) Single-dose final containers of a product need not be packaged one per carton. For single-dose products which require a diluent for administration, the number of containers of the proper amount of diluent specified in the filed Outline of Production for the number of doses contained in the carton shall be included in each carton.

(c) Poultry products for mass administration (including but not limited to administration through drinking water and spray) and products used in automatic vaccinating systems (including but not limited to pneumatic beak injectors and automated needle injectors) may be packaged in multiple-dose final containers as specified in the filed Outline of Production. Poultry products for manual administration to individual birds shall not exceed 1,000 doses in each final container. Diluent need not be packaged with the final container(s) of the product, but the licensee shall provide the required number of containers of diluent as specified in the filed Outline of Production. The following requirements apply to cartons containing more than one final container of poultry product:

(1) They shall be sealed prior to leaving the licensed establishment.

(2) The contents may not be repackaged.

(3) The contents of such cartons may not be sold in fractional units.

(4) The following statement must appear in a prominent place on the carton label: ''Federal regulations prohibit the repackaging or sale of the contents of this carton in fractional units. Do not accept if seal is broken.''

(d) Diluent for the following products need not be packaged with the final container(s) of the product, but the licensee shall provide the consumer with the required number of containers of the proper amount of diluent as specified in the filed Outline of Production:

(1) Marek's Disease Vaccine.

(2) Poultry vaccines administered to individual birds using automatic vaccinating equipment.

(e) Final containers of biological product prepared at a licensed establishment, or imported, in cartons or other containers shall not be removed

from such cartons or containers for sale or distribution, unless each final container bears, or is packaged in a carton with, complete and approved labeling which is affixed to or included with each container by the licensed establishment producing the product or by the producer in the case of imported product: *Provided*, That this paragraph is not intended to apply to licensed veterinary practitioners administering or dispensing biological products in the course of their practice under a veterinary-client-patient-relationship as that term is used in § 107.1.

(f) Labels which are affixed to or included with a biological product shall not be removed or altered in any manner.

[47 FR 8761, Mar. 2, 1982, as amended at 48 FR 12691, Mar. 28, 1983; 59 FR 43445, Aug. 24, 1994; 64 FR 43044, Aug. 9, 1999]

§ 112.7 Special additional requirements.

The label requirements in this section are additional to those prescribed elsewhere in this part.

(a) In the case of biological products containing live Newcastle Disease virus, a caution statement indicating that Newcastle Disease can cause inflammation of the eyelids of humans, and a warning to the user to avoid infecting his eyes shall be included on the enclosure.

(b) In the case of a biological product containing infectious bronchitis virus, all labels shall show the infectious bronchitis virus type or types used in the product. Abbreviation is permitted.

(c) In the case of a biological product containing inactivated rabies virus, carton labels, enclosures, and all but very small final container labels shall include a warning against freezing and the recommendations provided in this paragraph.

(1) That vaccine be administered to animals at 3 months of age or older, with a repeat dose 1 year later.

(2) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in § 113.209, paragraph (b) or (c), or both.

(d) In the case of a biological product containing modified live rabies virus, the carton labels, enclosures, and all but very small final container labels shall include the recommendations provided in this paragraph.

(1) For low egg-passage (below the 180th egg-passage level) the statement ''For Use in Dogs Only! Not For Use in Any Other Animal!''

(2) For other vaccines containing modified live rabies virus, the statement ''For Use In (designate animal(s)) Only! Not For Use In Any Other Animal!''

(3) Intramuscular injection at one site in the thigh shall be recommended.

(4) The statement ''In event of accidental exposure to the vaccine virus, the possible hazard to human health should be considered and State Public Health Officials should be consulted for specific recommendations'' shall be prominently placed on all carton labels and on enclosures, if used.

(5) That vaccine be administered to animals at 3 months of age or older, with a repeat dose 1 year later.

(6) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in § 113.312, paragraph (b) or (c), or both.

(e) In the case of bovine rhinotracheitis vaccine containing modified live virus, all labeling except small final container labels shall bear the following statement: ''Do not use in pregnant cows or in calves nursing pregnant cows.'': *Provided*, That such vaccines which have been shown to be safe for use in pregnant cows may be excepted from this label requirement by the Administrator.

(f) Unless otherwise authorized in a filed Outline of Production, labels for inactivated bacterial products shall contain an unqualified recommendation for a repeat dose to accomplish primary immunization to be given at an appropriate time interval: *Provided*, That, repeat dose recommendations prescribed in paragraphs (f)(1) through (3) of this section are required for products containing the fractions listed.

(1) *Clostridium haemolyticum*. ''Repeat the dose every 5 or 6 months in animals subject to reexposure.''

(2) *Erysipelothrix rhusiopathiae*. ''Swine: For breeding animals, repeat after 21 days and annually. Turkeys: Repeat dose every 3 months.''

(3) *Clostridium botulinum Type C.* ''Revaccinate breeders 1 month before breeding.''

(g) In the case of a liquid product authorized in a filed Outline of Production to be used as a diluent in a combination package, the carton labels and enclosures used for serials which are either not tested for bactericidal or viricidal activity or have been found unsatisfactory by such test shall contain the statement: ''CAUTION: DO NOT USE AS DILUENT FOR LIVE VACCINES.''

(h) In the case of wart vaccine, recommendations shall be limited to use in cattle. Indications for use shall be for prophylactic use only, as an aid in the control of viral papillomas (warts). All labels shall include a dosage recommendation of at least 10 ml to be given subcutaneously and the dose repeated in 3 to 5 weeks.

(i) Unless otherwise authorized in an Outline of Production filed subsequent to the effective date of these amendments, all but very small final container labels for Feline Panleukopenia Vaccines shall contain the following recommendations for use:

(1) *Killed virus vaccines.* Vaccinate healthy cats of any age with one dose except that if the animal is less than 12 weeks of age, a second dose should be given at 12 to 16 weeks of age. Annual revaccination with a single dose is recommended.

(2) *Modified live virus vaccines.* Vaccinate healthy cats of any age with one dose except that if the animal is less than 12 weeks of age, a second dose should be given at 12 to 16 weeks of age. Annual revaccination with a single dose is recommended. Do not vaccinate pregnant cats.

(j) In the case of normal serum, antiserum, or antiserum derivatives, the type of preservative used shall be indicated on all labels.

(k) Unless acceptable data has been filed with Animal and Plant Health Inspection Service, to show that development of corneal opacity is not associated with the product, carton labels and enclosures used with biological products containing modified live canine hepatitis virus or modified live canine adenovirus Type 2 shall bear the following statement: ''Occasionally, transient corneal opacity may occur following the administration of this product.''

(l) All labels for autogenous biologics shall bear the following statement: ''Potency and efficacy of autogenous biologics have not been established. This product is prepared for use only by or under the direction of a veterinarian or approved specialist.''

(m) In the case of biological products containing Marek's disease virus, all labels shall specify the Marek's disease virus serotype(s) used in the product.

(Approved by the Office of Management and Budget under control number 0579–0013)

[38 FR 12094, May 9, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 112.7, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 112.8 For export only.

The applicable regulations for packaging and labeling a biological product produced in the United States shall apply to such biological product if exported from the United States except as otherwise provided in this section. Only labels approved as provided in § 112.5 shall be used.

(a) Biological products which have been packaged and labeled for export or which have been exported, shall be subject to the applicable provisions in this paragraph.

(1) After leaving the licensed establishment, a biological product shall not be bottled, repackaged, relabeled, or otherwise altered in any way while in the United States; and

(2) An exported biological product shall not be returned to the United States: *Provided*, That, in the case of a biological product exported in labeled final containers, the Administrator may authorize by permit the importation of a limited number for research and evaluation by the producing licensee; and

(3) An exported biological product which is bottled, rebottled, or altered in any way in a foreign country shall not bear a label which indicates by establishment license number that it has been prepared in the United States.

(b) Desiccated and frozen liquid products, packaged and labeled as for domestic use, may be exported without the diluent required for rehydration or dilution, as the case may be, if the labeling includes adequate instructions for preparing the product for use and the words ''For Export Only''.

(c) Final containers of products, labeled or unlabeled, may be exported in sealed shipping boxes, adequately identified as to contents with an approved label, and plainly marked ''For Export Only'': *Provided*, That such products shall not be diverted to domestic use.

(d) Completed inactivated liquid products, antiserums, and antitoxins, may be exported in large multiple-dose containers identified with an approved label that contains the words ''For Export Only'' prominently displayed.

(e) Concentrated inactivated liquid product, completed except for dilution to the proper strength for use, may be exported in large multiple-dose containers identified with an approved label that contains the words ''For Export Only'' prominently displayed.

[38 FR 12094, May 9, 1973, as amended at 39 FR 19202, May 31, 1974; 40 FR 46093, Oct. 6, 1975; 43 FR 11145, Mar. 17, 1978; 56 FR 66784, Dec. 26, 1991]

§ 112.9 Biological products imported for research and evaluation.

A biological product imported for research and evaluation under a permit issued in accordance with § 104.4, with the exception of products imported under § 104.4(d), shall be labeled as provided in this section.

(a) The label shall identify the product and the name and address of the manufacturer and shall provide instructions for proper use of the product, including all warnings and cautions needed by the permittee to safely use the product.

(b) Labels on each product to be further distributed in accordance with § 103.3 shall bear the statement ''Notice! For Experimental Use Only—Not for Sale!''

(c) The labeling shall contain any other information deemed necessary by the Administrator and specified on the permit.

[50 FR 46417, Nov. 8, 1985, as amended at 56 FR 66784, Dec. 26, 1991]

§ 112.10 Special packaging and labeling.

A biological product, which requires special packaging and/or labeling not provided for in this part, shall be packaged and/or labeled in accordance with requirements written into the approved outline for such product.

PART 113—STANDARD REQUIREMENTS

APPLICABILITY

Sec.
113.1 Compliance.
113.2 Testing aids.
113.3 Sampling of biological products.
113.4 Exemptions to tests.
113.5 General testing.
113.6 Animal and Plant Health Inspection Service testing.
113.7 Multiple fractions.
113.8 In vitro tests for serial release.
113.9 New potency test.
113.10 Testing of bulk material for export or for further manufacture.

STANDARD PROCEDURES

113.25 Culture media for detection of bacteria and fungi.
113.26 Detection of viable bacteria and fungi except in live vaccine.
113.27 Detection of extraneous viable bacteria and fungi in live vaccines.
113.28 Detection of mycoplasma contamination.
113.29 Determination of moisture content in desiccated biological products.
113.30 Detection of Salmonella contamination.
113.31 Detection of avian lymphoid leukosis.
113.32 Detection of Brucella contamination.
113.33 Mouse safety tests.
113.34 Detection of hemagglutinating viruses.
113.35 Detection of viricidal activity.
113.36 Detection of pathogens by the chicken inoculation test.
113.37 Detection of pathogens by the chicken embryo inoculation test.
113.38 Guinea pig safety test.
113.39 Cat safety tests.
113.40 Dog safety tests.
113.41 Calf safety test.
113.42 Detection of lymphocytic choriomeningitis contamination.
113.43 Detection of chlamydial agents.
113.44 Swine safety test.
113.45 Sheep safety test.
113.46 Detection of cytopathogenic and/or hemadsorbing agents.
113.47 Detection of extraneous viruses by the fluorescent antibody technique.