

Animal and Plant Health Inspection Service, USDA

§ 112.2

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

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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)

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shall include the information specified in this section.

(1) The complete 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 the carton label and enclosure. The following exceptions are applicable to small final containers, and containers of interchangeable reagents included in diagnostic test kits:

(i) For small final containers, an abbreviated true name of the biological product, which shall be identical with that shown in the product license under which the product is prepared or the permit under which it is imported, may be used: *Provided*, That the complete true name of the product must appear on the carton label and enclosures;

(ii) In addition to the true name of the kit, the functional and/or chemical name of the reagent must appear on labeling for small final containers of reagents included in diagnostic kits: *Provided*, That the true name is not required on labeling for small final containers of interchangeable (non-critical) components of diagnostic kits.

(2) For biological product prepared in the United States or in a foreign country, the name and address of the producer (licensee, or subsidiary) or permittee and of the foreign producer, and an appropriate consumer contact telephone number: *Provided*, That in the case of a biological product exported from the United States in labeled final containers, a consumer contact telephone number is not required; however, small single dose containers marketed in the United States must include contact telephone information on carton and enclosures.

(3) The United States Veterinary Biologics Establishment License Number (VLN) or the United States Veterinary Biological Product Permit Number (VPN), and the Product Code Number

(PCN) assigned by the Department, which shall be shown only as “VLN/PCN” and “VPN/PCN,” respectively, except that:

(i) Only the VLN or VPN is required on container labels of interchangeable (non-critical) components of diagnostic kits and container labels for individual products packaged together for co-administration.

(ii) The PCN may be used in lieu of the true name of the kit on small container labels for critical components of diagnostic kits.

(iii) Container labels for individually licensed biological products, when marketed as components of combination packages, must include a statement referring the consumer to the carton or enclosure for the PCN of the combination package.

(4) Storage temperature recommendation for the biological product stated as 2 to 8 °C or 35 to 46 °F, or both.

(5) Full instructions for the proper use of the product, including indications for use, target species, minimum age of administration, route of administration, vaccination schedule, product license restriction(s) that bear on product use, warnings, cautions, and any other vital information for the product's use; except that in the case of limited space on final container labels, 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) The following warning statements, or equivalent statements, shall appear on the labeling as applicable:

(i) Products other than diagnostic kits: “Do not mix with other products, except as specified on this label.”

(ii) Injectable products and other products containing hazardous components: “In case of human exposure, contact a physician.”

(iii) Products containing viable organisms: “Inactivate unused contents before disposal.”

(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.

(v) A statement similar to "For more information regarding efficacy and safety data, go to productdata.aphis.usda.gov."

(10) In the case of a product that contains a preservative that is added during the production process and is not reduced to undetectable levels in the completed product through the production process, the statement "Contains [name of preservative] as a preservative" or an equivalent statement must appear on cartons and enclosures, if used. If cartons are not used, such information must 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.

(12) An indications statement to read, "This product has been shown to be effective for the vaccination of healthy (insert name of species) _____ weeks of age or older against _____." *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.

(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 use in animals only" may appear on the labeling as appropriate for a product to indicate that the product is recommended specifically for animals and not for humans.

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(e) When label requirements of a foreign country differ from the requirements as prescribed in this part, special labels may be approved by APHIS for use on biological products to be exported to such country upon receipt of written authorization, acceptable to APHIS, from regulatory officials of the importing country, provided that:

(1) If the labeling contains claims or indications for use not supported by data on file with APHIS, the special labels for export shall not bear the VLN.

(2) All other labels for export shall bear the VLN unless the importing country provides documentation that the VLN is specifically prohibited. 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 to the Act, such certification may be made by APHIS.

(f) Multiple-dose final containers of liquid biological product and carton tray covers showing required labeling information are subject to the requirements in this paragraph.

(1) 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, with a container of diluent if applicable, 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, and a corresponding number of diluent 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 to APHIS for approval.

(2) When required labeling information is shown on a carton tray cover, it must be printed on the outside face of such tray cover where it may be read without opening the carton. The inside

face of the tray cover may contain information suitable for an enclosure.

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[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; 80 FR 39674, July 10, 2015; 81 FR 59433, Aug. 30, 2016; 81 FR 78500, Nov. 8, 2016]

§ 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, "Inactivate unused contents before disposal."

(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; 81 FR 59434, Aug. 30, 2016]

§ 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 (d) of this section and under the master label system provided in paragraph (e) of this section.

(a) Transmittal forms, available on the APHIS Web page at <http://www.aphis.usda.gov/animalhealth/cvb/forms>, 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) A data summary, available on the Internet at productdata.aphis.usda.gov, shall be used with each submission of efficacy and safety data in support of a label claim. Manufacturers will submit the efficacy and safety data information with either the efficacy and safety studies or at the time of label submission. This information will be posted at productdata.aphis.usda.gov to allow public disclosure of product performance.

(c) 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

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constitute approval of a finished label subsequently prepared.

(d)(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 paragraph (e) of this section 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) Changes in the color of label print or background, provided that such changes do 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, changing, deleting, or repositioning label control numbers, universal product codes, or other inventory control numbers;

(vi) Revising or updating logos;

(vii) Changing the telephone contact number;

(viii) Adding, changing, or deleting an email and/or Web site address;

(ix) Changing the establishment license or permit number assigned by APHIS, and/or changing the name and/or address of the manufacturer or permittee, provided that such changes are identical to information on the current establishment license or permit; and

(x) Adding or changing the name and/or address of a distributor.

(e) 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 paragraph (e)(1)(iii) of this section: *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 two 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. One copy of each finished label will be retained by APHIS. One copy will be stamped and returned to the licensee or permittee. Labels to which exceptions are taken shall be marked as sketches and handled under paragraph (e)(1)(i) of this section.

(iv) For finished master labels, submit for each product two 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 size 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. One copy of each finished master label will be retained by APHIS. One copy will be stamped and returned to the licensee or permittee. Master labels to which exception are taken will be marked as sketches and handled under paragraph (e)(1)(ii) of this section.

(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 in the lower left hand corner, if applicable:

(i) The dose size(s) to which the master label applies.

(ii) The APHIS assigned number for the label or sketch to be replaced.

(iii) The APHIS assigned number for the label to be used as a reference for reviewing the submitted label.

(f) Special requirements for foreign language labels:

(1) An accurate English translation must accompany each foreign language label submitted for approval. A statement affirming the accuracy of the translation must also be included.

(2) 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.

(g) 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.

(h) 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

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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 paragraph (d) of this section.

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[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; 75 FR 20772, Apr. 21, 2010; 80 FR 39675, July 10, 2015; 81 FR 47005, July 20, 2016; 81 FR 59435, Aug. 30, 2016]

§ 112.6 Packaging biological products.

(a) Multiple-dose final containers of a biological product with final container labeling including all information required under the regulations may be packaged one or more per carton with a container(s) of the proper volume of diluent, if required, for that dose as specified in the filed Outline of Production: *Provided*, That cartons containing more than one final container of product must comply with the conditions set forth in paragraphs (c)(1) through (4) of this section. Multiple-dose final containers of a product that require a carton or enclosure in order to provide all information required under the regulations shall be packaged one container per carton with the proper volume of diluent, if required, for that dose as specified in the filed Outline of Production.

(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 mul-

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; 81 FR 59435, Aug. 30, 2016]

§ 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) Labeling for all products for use in mammals must bear an appropriate statement concerning use in pregnant animals.

(1) For bovine rhinotracheitis vaccine or bovine virus diarrhea 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.

(2) For other modified live and inactivated vaccine, labeling shall bear a statement appropriate to the level of safety that has been demonstrated in pregnant animals.

(i) Products known to be unsafe in pregnant animals shall include statements such as "Do not use in pregnant animals," or "Unsafe for use in pregnant animals," or an equivalent statement acceptable to APHIS.

(ii) Products without safety documentation acceptable to APHIS, but not known to be unsafe, labeling shall include the statement "This product has not been tested in pregnant animals" or an equivalent statement acceptable to APHIS.

(3) For modified live vaccines containing agents with potential reproductive effects but having acceptable pregnant animal safety data on file with APHIS, labeling still must bear the following statement concerning residual risk: "Fetal health risks associated with the vaccination of pregnant animals with this vaccine cannot be unequivocally determined during clinical

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trials conducted for licensure. Appropriate strategies to address the risks associated with vaccine use in pregnant animals should be discussed with a veterinarian.”

(f) For biological products recommending annual booster vaccinations, such recommendations must be supported by data acceptable to APHIS. In the absence of data that establish the need for booster vaccination, labeling must bear the following statement: “The need for annual booster vaccinations has not been established for this product; consultation with a veterinarian is recommended.”

(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) 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 with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given no earlier than 16 weeks of age.

(2) *Modified live virus vaccines.* Vaccinate healthy cats with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given no earlier than 16 weeks of age.

(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 must specify the name of the microorganism(s) or antigen(s) that they contain, and 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.

(n) All labels for conditionally licensed products shall bear the following statement: “This product license is conditional; efficacy and potency have not been fully demonstrated.”

(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 at www.fdsys.gov.

§ 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.