search prior to formal publication when such release would adversely affect the public interest.

(e) Interagency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. This would include but would not be limited to:

(1) Records involving any pending or expected claim actions against the Government resulting from property damage or personal injury.

(2) Documents covering agency plans which may be subject to revision before presentation.

(3) Reports of internal deliberations where premature release could harm the authorized and appropriate purpose for which they are being used.

(4) Preparatory budget material.

(f) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(g) Investigatory files compiled for law enforcement purposes except to the extent available by law to a party other than an agency.

§ 510.14 Determinations.

The appropriate official, depending upon whether the request is regional or national in origin, shall promptly make available any ARS records requested in accordance with § 510.10, unless he determines that it is an exempt record. He shall give prompt written notice of any such determination together with the reasons therefor.

§ 510.15 Appeals.

The denial of any request for an ARS record or records may be appealed by the person who made the request to the Administrator of ARS. The appeal shall be made in writing within 30 days of the date of the notice of denial. The Administrator will give written notice of the final determination of ARS.

The foregoing action is taken to reflect organizational changes within the Department of Agriculture, Agricultural Research Service, and does not substantially affect the rights or obligations of any member of the public.

This amendment shall become effective May 9, 1973.

Done at Washington, D.C., this third day of May 1973.

T. W. EDMINSTER,
Administrator,
Agricultural Research Service.

[FR Doc.73-9214 Filed 5-8-73;8:45 am]

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Valencia Orange Reg. 430]

PART 908—VALENCIA ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

Limitation of Handling

This regulation sets a minimum size requirement for the period May 11, 1973, through January 15, 1974, applicable to the handling of Valencia oranges grown in the production areas of California and Arizona Valencia oranges were regulated Arizona. Shipments of California-by size through April 26, 1973, pursuant to Orange Regulation 423. The regulatory requirements for California-Arizona Valencia oranges specified herein are the same as those published in the FEDERAL REGISTER on April 6, 1973, under notice of proposed rulemaking, except for the later effective date of May 11, 1973.

Notice was published in the FEDERAL REGISTER on April 6, 1973 (38 FR 8749), that consideration was being given to a continuation of the size regulation for Valencia oranges grown in Arizona and designated part of California, pursuant to the applicable provisions of the marketing agreement, as amended, and order No. 908, as amended (7 CFR part 908) regulating the handling of Valencia oranges grown in Arizona and designated part of California. This regulatory program is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The proposed regulation was recommended by the Valencia Orange Administrative Committee, established under said amended marketing agreement and order as the agency to administer the terms and provisions thereof. The notice provided that all written data, views, or arguments in connection with the proposed amendment be submitted by April 18, 1973. None were received.

The recommendation by the Valencia Orange Administrative Committee reflects its appraisal of the crop and current and prospective marketing conditions. The Committee now estimates that the 1972–73 season crop of Valencia oranges will be 58,500 carlots. It further estimates that the demand in regulated market channels will require about 38 percent of this volume, and the remaining 62 percent will be available for utilization in export and processing. The volume and size composition of the corp are such that ample supplies of the more desirable sizes are available to satisfy the demand in regulated channels. Equivalent fresh on-tree returns for California-Arizona Valencia oranges averaged $1.92 per carton for the season through April 1973 or 79 percent of the equivalent parity price. The regulation herein specified is designed to permit shipment of ample supplies of fruit of the more desirable sizes in the interest of both growers and consumers. The action is necessary to maintain orderly marketing conditions, provide consumer satisfaction and guard against the shipment of undesirable sizes of Valencia oranges which tend to demoralize the market for later shipments of such fruit. The regulation therefore is consistent with the objective of the act of promoting orderly marketing, maintaining grower returns, and protecting the interest of consumers.

After consideration of all relevant matter presented, including the proposal set forth in the aforesaid notice and other available information, it is hereby found that the limitation of shipments of Valencia oranges, as hereinafter set forth, is in accordance with said amended marketing agreement and order and will tend to effectuate the declared policy of the act.

It is hereby further found that good cause exists for making this regulation effective at the time hereinafter set forth and for not postponing the effective date hereof until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 553) in that (1) notice of proposed rulemaking concerning this regulation was published in the FEDERAL REGISTER on April 6, 1973 (38 FR 8749), and no objection to it was received; (2) except for the later effective date of May 11, 1973, the regulatory provisions are the same as those contained in said notice; (3) the recommendation and supporting information for regulation of Valencia oranges were submitted to the Department after an open meeting of the committee on March 20, 1973, which was held to consider recommendations for regulation, after giving due notice of such meeting, and interested persons were afforded an opportunity to submit their views at this meeting; (4) information concerning such provisions and effective time has been disseminated among handlers of such oranges; and (5) compliance with the regulation will not require any special preparation on the part of the persons subject thereto which cannot be completed by the effective time hereof.

§ 908.730 Valencia Orange Regulation 430.

(a) *Order.*—During the period May 11, 1973, through January 15, 1974, no handler shall handle any Valencia oranges grown in the production area which are of a size smaller than 2.20 inches in diameter, which shall be the largest measurement at a right angle to a straight line running from the stem to the blossom end of the fruit: *Provided,* That not to exceed 5 percent, by count, of the Valencia oranges contained in any type of container may measure smaller than 2.20 inches in diameter.

(b) As used in this section, "handle", "handler", and "production area", shall have the same meaning as when used in said amended marketing agreement and order.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.)

Dated May 4, 1973, to become effective May 11, 1973.

CHARLES R. BRADER,
Acting Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.73-9212 Filed 5-8-73;8:45 am]

PART 930—CHERRIES GROWN IN MICHIGAN, NEW YORK, WISCONSIN, PENNSYLVANIA, OHIO, VIRGINIA, WEST VIRGINIA, AND MARYLAND

Free and Restricted Percentages of Cherries for the 1972–73 Fiscal Period

This amendment releases 75 percent of the reserve pool which was established under the order's 1972 crop free and restricted percentage regulation. Handlers, eligible under the order, will be offered such an amount during the 10-day period May 8 through May 18, 1973. A

determination as to the need for such a release was based upon all available information on market prices for frozen cherries, level of supplies currently available to the market, and expected product usage to new crop.

Findings. (1) Pursuant to Marketing Order No. 930 (7 CFR Part 930), regulating the handling of cherries grown in Michigan, New York, Wisconsin, Pennsylvania, Ohio, Virginia, West Virginia, and Maryland, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1973, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations of the Cherry Administrative Board, established under the aforesaid amended marketing order, and upon other available information, it is hereby found that the release of reserve pool cherries, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) The recommendation by the Cherry Administrative Board for the release of frozen cherries from the reserve pool is consistent with the remaining supply of frozen cherries available to commercial channels and prospective demand for such cherries.

(3) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking procedure, and postpone the effective date of this amendment until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 553) because of the time intervening between the date when information upon which this amendment is based became available and the time when this amendment must become effective in order to effectuate the declared policy of the act is insufficient; and this amendment relieves restrictions on the handling of cherries grown in the production area included under Marketing Order No. 930.

Order. A new subparagraph (1) be added to paragraph (a) of § 930.501 (Free and restricted percentages for the 1972–73 fiscal period; 37 FR 13789) to read as follows:

§ 930.501 Free and restricted percentages for the 1972–73 fiscal period.

(a) * * *

(1) Seventy-five (75) percent of the volume of the reserve pool, established pursuant to § 930.54, with the aforementioned restricted percentage cherries, shall be offered for sale to eligible handlers by the Cherry Administrative Board during the period starting at 12:01 p.m. May 8, 1973, and ending 12 noon May 18, 1973, in accordance with the conditions governing the sale of reserve pool cherries.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.)

Dated May 2, 1973.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.73-9112 Filed 5-8-73;8:45 am]

Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS; EXTRAORDINARY EMERGENCY REGULATION OF INTRASTATE ACTIVITIES

PART 82—EXOTIC NEWCASTLE DISEASE; AND PSITTACOSIS OR ORNITHOSIS IN POULTRY

Area Quarantined

This amendment quarantines a portion of San Diego County in California because of the existence of exotic Newcastle disease. Therefore, the restrictions pertaining to the interstate movement of poultry, mynah and psittacine birds, and birds of all other species under any form of confinement, and their carcasses and parts thereof, and certain other articles from quarantined areas, as contained in 9 CFR part 82, as amended, apply to the quarantined area.

Pursuant to the provisions of sections 1, 2, 3, and 4 of the act of March 3, 1905, as amended, sections 1 and 2 of the act of February 2, 1903, as amended, sections 4, 5, 6, and 7 of the act of May 29, 1884, as amended, and sections 3 and 11 of the act of July 2, 1962 (21 U.S.C. 111, 112, 113, 115, 117, 120, 123, 124, 125, 126, 134b, 134f), part 82, title 9, Code of Federal Regulations, is hereby amended in the following respects:

In § 82.3, in paragraph (a)(1) relating to the State of California, new paragraph (a)(1)(ix) relating to San Diego County is added to read:

(ix) The premises of Nicholas Van Dam, d.b.a. Rainbow Egg Ranch, 5405 5th Street, City of Fallbrook (Rainbow Community), in San Diego County.

(Secs. 4–7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791–792, as amended; secs. 1–4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132; 21 U.S.C. 111–113, 115, 117, 120, 123–126, 134b, 134f; 37 FR 28464, 28477.)

Effective date.—The foregoing amendment shall become effective May 3, 1973.

The amendment imposes certain restrictions necessary to prevent the interstate spread of exotic Newcastle disease, a communicable disease of poultry, and must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable, unnecessary, and contrary to the public interest, and good cause is found for making it effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 3d day of May 1973.

G. H. WISE,
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc.73-9114 Filed 5-8-73;8:45 am]

PART 82—EXOTIC NEWCASTLE DISEASE; AND PSITTACOSIS OR ORNITHOSIS IN POULTRY

Areas Released From Quarantine

This amendment excludes portions of Starr and Hidalgo Counties in Texas from the areas quarantined because of exotic Newcastle disease. Therefore, the restrictions pertaining to the interstate movement of poultry, mynah, and psittacine birds, and birds of all other species under any form of confinement, and their carcasses and parts thereof, and certain other articles from quarantined areas, as contained in 9 CFR part 82, as amended, will not apply to the excluded areas. No areas in Texas remain under quarantine.

Pursuant to the provisions of sections 1, 2, 3, and 4 of the act of March 3, 1905, as amended, sections 1 and 2 of the act of February 2, 1903, as amended, sections 4, 5, 6, and 7 of the act of May 29, 1884, as amended, and sections 3 and 11 of the act of July 2, 1962 (21 U.S.C. 111, 112, 113, 115, 117, 120, 123, 124, 125, 126, 134b, 134f), part 82, title 9, Code of Federal Regulations, is hereby amended in the following respects.

In § 82.3, the introductory portion of paragraph (a) is amended by deleting the name of the State of Texas after the reference to "California,"; and paragraph (a)(2) relating to the State of Texas is deleted.

(Secs. 4–7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791–792, as amended; secs. 1–4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132; 21 U.S.C. 111–113, 115, 117, 120, 123–126, 134b, 134f; 37 FR 28464, 28477.)

Effective date.—The foregoing amendment shall become effective May 3, 1973.

The amendment relieves certain restrictions presently imposed but no longer deemed necessary to prevent the spread of exotic Newcastle disease, and must be made effective immediately to be of maximum benefit to affected persons. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and unnecessary, and good cause is found for making it effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this third day of May 1973.

G. H. WISE,
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc.73-9113 Filed 5-8-73;8:45 am]

SUBCHAPTER E—VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS; ORGANISMS AND VECTORS

PART 112—PACKAGING AND LABELS

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

Miscellaneous Amendments to Subchapter

On December 8, 1972, there was published in the FEDERAL REGISTER (FR Doc.

72-21141) a notice of proposed rulemaking with respect to proposed amendments to the regulations relating to viruses, serums, toxins, and analogous products in part 112 of title 9, Code of Federal Regulations, issued pursuant to the provisions of the Virus-Serum-Toxin Act of March 4, 1913 (21 U.S.C. 151-158).

These amendments to part 112 were proposed to update the current label requirements for biological products by restating the applicability of such requirements in a revised § 112.1; by specifying the basic requirements for the three label components, namely, final container labels, carton labels, and enclosures in a revised § 112.2; by clarifying diluent label requirements in a revised § 112.3; by adding requirements for subsidiary labels in a revised § 112.4; by codifying instructions for submission of labels currently found in administrative directives in a revised § 112.5; by revising the packaging and labeling requirements in § 112.6 for desiccated products to conform to present day needs; and by codifying administrative directives containing special label requirements for specified products. Special packaging and label requirements for products to be exported and for products to be imported for research and evaluation have been added in two new sections—§§ 112.8 and 112.9. Authority to issue label and/or packaging requirements for special products has been provided in a new section § 112.10.

Obsolete requirements, such as prelabeling restrictions in § 112.1(b) have been removed. Modern labeling methods, such as screen printing, make such restrictions inadvisable. Definitions of "label and labeling" have been recodified in a new § 101.4.

After due consideration of all relevant matters, including the proposals set forth in the aforesaid notice of rulemaking, and the comments and views submitted by interested persons, and pursuant to the authority contained in the Virus-Serum-Toxin Act of March 4, 1913 (21 U.S.C. 151-158), the amendments of part 112 of subchapter E, chapter I, title 9 of the Code of Federal Regulations, as contained in the aforesaid notice are hereby adopted and are set forth herein, subject to the following noted modifications:

Identification requirements for biological products while in course of preparation now contained in the second sentence of paragraph 112.1(c) have been redesignated as § 114.5. This amendment is merely editorial and makes no substantive change in the regulations.

The words "prepared" and "producer" have been substituted for "manufacturer," respectively, as being more appropriate terminology.

Section 112.2(a)(3) has been changed to permit the use of "U.S. Vet. Lic. No." as an abbreviation for "United States Veterinary License Number."

The storage temperature requirement in § 112.2(a)(4) has been rewritten to authorize use of either 45°F., or 7°C., or both.

To prevent unnecessary label revision, the requirements in §§ 112.2(a)(6) and 112.2(a)(7) have been reworded to conform to current labels. An abbreviated statement has been added to § 112.2 (a)(7) to accommodate small labels.

Section 112.2(a)(8) has been reworded to limit the requirement to food-producing animals when the product is for more than one species.

Section 112.2(a)(9)(iii) has been reworded for clarity.

Section 112.2(a)(10)(ii) has been rewritten to relax the requirements in the proposal but retain those now in effect.

The lead paragraph in § 112.3 has been rewritten to provide for products other than bacterins used as diluents by substituting "liquid biological product" for "bacterin." § 112.3(c) has been reworded for clarity. An abbreviated statement has been added to § 112.3(f)(2) to accommodate small labels.

In § 112.4(a) reference to "subsidiary" has been reworded for clarification. "Veterinary Services" has been substituted for "Deputy Administrator" for administrative efficiency.

Section 112.5 in the lead paragraph has been rewritten to limit review of labels to compliance with regulations and approval by Veterinary Services.

Sections 112.5(b) and 112.5(c) have been reworded to require submission of sketches and labels to be made to Veterinary Services. "Written" has been inserted in front of "approval" in § 112.5 (c) for completeness.

"Veterinary Services" has been inserted into § 112.5(d)(1)(i) to designate the file referred to and "At least" has been inserted in two places in § 112.5(d)(1)(ii) to permit processing of additional labels, if required. "According to § 112.5 (d)(1)(i)" has been substituted for "accordingly."

"Screen printing" has been substituted for "silk screen" in § 112.5(d)(2)(iv) for accuracy.

The words "by Veterinary Services" has been inserted in § 112.5(d)(4) for clarity.

Section 112.5(f) has been reworded to have a request for label list come from Veterinary Services for administrative efficiency.

"Except as provided in § 112.8," has been inserted in § 112.6(d) for completeness.

Section 112.7(c)(1) "Nerve" has been substituted for "neural" for accuracy and the dosage to be recommended limited to that in the approved outline of production. In both subparagraphs, § 112.7(c)(1) and (2), "dog and cat" have been substituted for "puppy" to provide for cat vaccination. "Approved Outline of Production" has been substituted for "outline" in § 112.7(c)(2).

The following substitutions of words have been made for accuracy: "modified live rabies virus" for "live rabies virus" in the lead paragraph in § 112.7(d) and in § 112.7(d)(3); "below 180th" for "40th—50th" in § 112.7(d)(2); and "Vaccination" for "Dosage" in § 112.7(d)(4). Section 112.7(d)(4)(iii) has been reworded to correspond with published recommendations for vaccinating cats.

Recommendation requirements for use of rabies vaccine in animals other than dogs and cats have been relaxed in § 112.7 (d)(4)(iii) by permitting licensees to make other claims for their products if such claims are in the approved outline of production.

Section 112.7(d)(5) has been reworded for clarity.

Section 112.7(e) has been rewritten to exempt inactivated vaccines from the pregnant cow label requirement and to authorize other exceptions to be made by the Deputy Administrator. Exception to § 112.7(f) has been provided if authorized in the approved outline of production for administrative purposes.

Section 112.7(f)(1) has been changed to provide for products containing *Clostridium septicum Bacterin* because it is used only in combination with *Clostridium chauvoei Bacterin*.

The proposed § 112.8(a)(3) has been relaxed to prohibit the use of only the establishment license number to comply with foreign requirements.

Section 112.8(c) has been reworded to limit the regulations to desiccated products identified with an approved label.

1. Section 114.5 is amended to read:

§ 114.5 Identification of biological products.

Suitable tags or labels of a distinct design shall be used for identifying all biological products while in course of preparation at licensed establishments.

2. Part 112 is amended to read:

Sec.

AUTHORITY: The provisions of this Part 112 issued under 37 Stat. 832-833; 21 U.S.C. 151-158.

§ 112.1 Applicability.

Unless otherwise authorized or directed by the Deputy 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 as may be issued pursuant to § 112.9.

(a) No person shall apply or affix, or cause to be applied or affixed, any label, stamp, or mark, to any carton or final container of a biological product prepared or received in a licensed establishment or imported that is false or misleading in any particular or is not in compliance with the regulations.

(b) No person shall alter, mark, or remove any label or mark on any carton or final container of a biological product

so as to falsify the label or make it misleading.

(c) Labels stamped, printed, or glued directly on cartons and final containers, shall be legible throughout the dating period. Biological products shall be withheld from the market if such labels have been altered, mutilated, destroyed, obliterated, or removed.

§ 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 or special 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, special 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. Vet. Permit No. ------;" the word (Special) shall be added to indicate a special license when applicable.

(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 Deputy Administrator.

(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 The following information shall appear on cartons and enclosures if used: *Provided*, That if cartons are not used, such information shall appear on the final container label;

(i) In the case of a biological product for which a standard requirement for evaluating potency has not been established, a statement, "No U.S. Standard of Potency." In the case of a multiple fraction product for which a standard requirement for potency has been established for one or more fractions of such product, the statement, "U.S. Standard of Potency for (name fraction) Fraction(s) Only," shall so appear;

(ii) 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.

(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) Restricted sales to veterinarians may be so stated on the labels: *Provided*, That the entire production of the product by the licensee involved shall be so restricted. The phrase, "For Veterinary Use Only," or an equivalent statement may be used to indicate a 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.

(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.

§ 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 (cm^3) 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.

§ 112.4 Subsidiaries, distributors, permittees.

Labels used by subsidiaries, distributors, and permittees shall comply with requirements for filing and approval of labels used for biological products distributed and sold by the licensee and as provided in this section.

(a) *Subsidiaries.*—Labels to be used on biological products prepared in a licensed establishment by a domestic subsidiary shall be submitted to Veterinary Services in accordance with § 112.5 and only labels approved for use on such product shall be used by the subsidiary.

(b) *Distributors.* The name and address of a distributor of a biological product (who is not the licensed producer of such product) shall not be placed on the labels or containers of such product in a manner as to indicate that he is the producer of such product or operating under the license number shown on the label. The name and address of such 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: *Provided,* The terms are not so used as to be false or misleading. Reference to such distributor shall be by name and address only.

(c) *Permittees.* The name and address of a permittee shall not be placed on the labels or containers of an imported biological product in such manner as to indicate that he is the manufacturer of such product. Reference to such permittee shall be made by name, address, and permit number only.

§ 112.5 Review and approval of labeling.

Labels used with biological products prepared at licensed establishments or imported for general distribution and sale shall be reviewed for compliance with the regulations and approved in writing by Veterinary Services prior to use.

(a) Transmittal forms, furnished by Veterinary Services 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 Veterinary Services 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) All labels shall be submitted to Veterinary Services for review and written approval. Only labels which are approved shall be used. When changes are made in approved labels, the new labels shall be subject to review and approval before use.

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

(1) Copies required:

(i) Three copies of each sketch shall be submitted. Two copies shall be returned to the licensee or permittee with applicable comments. One copy shall be held in the Veterinary Services label file until replaced by a finished label but for not more than 1 year after processing: *Provided,* That sketches submitted in support of an application for a product license or permit shall be held as long as the application is considered active.

(ii) At least five copies of a label shall be submitted: *Provided,* That when an enclosure is to be used with more than one biological product, two extra copies shall be required for each additional product. At least two copies of items submitted shall be returned to the licensee or permittee. Labels to which exceptions are taken shall be marked as sketches and handled according to § 112.5 (d) (1) (i).

(2) Mounting:

(i) Each label or sketch shall be securely fastened to a separate sheet of heavy bond paper (8½" x 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.

(*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, special 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 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 (doses, 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 the submission shall be stated in the lower left hand corner as:

(i) To replace Label and/or Sketch No. _____;
(ii) Addition to Label No. _____;
(iii) Refer to Label No. _____;
(iv) License Application Pending _____;
(v) Foreign Language Copy of Label No. _____

A 2-inch space shall be reserved in the lower right hand corner. A label number shall be assigned by Veterinary Services to each sketch and label reviewed. It shall be stamped in the space reserved and shall be used for reference to such label or sketch in all subsequent correspondence.

(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 Veterinary Services, the licensee or permitee 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.

§ 112.6 Packaging desiccated products.

(a) Except as provided in § 112.8, each final container of a desiccated biological product, produced by a licensee or a subsidiary, or presented for importation by a permittee shall be packaged in a carton with accompanying container of diluent if such diluent is required for rehydration of the product before administration.

(b) Except as prescribed in paragraph (d) of this section and § 112.8, only one multiple-dose final container of a desiccated product with accompanying final container of diluent, if needed for rehydration, shall be packaged in an appropriately labeled carton.

(c) Several single-dose final containers of desiccated products and an equal number of containers of diluent, if needed for rehydration, may be marketed in an appropriately labeled carton.

(d) Except as provided in § 112.8, when a biological product is designed to be administered to poultry, multiple-dose final containers, not to exceed 1,000 doses per container and not to exceed 10 final containers per package, may be marketed with accompanying containers of diluent, if needed for rehydration, in a single appropriately labeled carton: *Provided,* That the statement, "Federal regulations prohibit the repackaging or sale of the contents of this carton in fractional units. Do not accept if seal is broken," shall be prominently placed on the carton label.

§ 112.7 Special additional requirements.

(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 and enclosures shall include a warning against freezing; and for

(1) Nerve tissue origin rabies vaccine, a minimum dose recommendation shall be as stated in the approved Outline of Production; *Provided*, That a recommendation shall be made that a dog or cat under 3 months or age shall be revaccinated at 3 months and yearly thereafter; and for

(2) Tissue culture origin rabies vaccine, the minimum dose recommendation shall be as stated in the approved Outline of Production and recommended to be repeated in 30 days and yearly thereafter: *Provided*, That, if the second dose is given to a dog or cat under 3 months of age, a third dose to be given in 6 months shall also be recommended.

(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 except as provided in subparagraph (5) of this paragraph.

(1) The statement "In high risk areas, revaccinate annually all animals for which this vaccine is recommended."

(2) For low egg-passage (below 180th) egg-passage level), the statement "For Use In Dogs Only! Not For Use In Any Other Animal!"

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

(4) Vaccination recommendations as provided in this paragraph.

(i) Dogs: One dose at age 3 months or older recommended to be repeated every 3 years: *Provided*, That for dogs less than 6 months of age at the time of the initial vaccination, the recommendation shall be for a repeat dose at 1 year of age. Subsequent vaccinations shall be not less frequently than every 3 years thereafter.

(ii) Cats: One dose at 3 months of age and annually thereafter.

(iii) Recommendation for use in animals other than dogs and cats shall be as stated in the approved Outline of Production.

(5) A statement, prominently placed on the enclosure, containing the recommended action to be taken in cases of exposure to the vaccine virus. Satisfactory recommendations may be found in the U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control Weekly Report, June 24, 1972.

(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 Deputy Administrator.

(f) Unless otherwise authorized in an approved Outline of Production, labels for inactivated bacterial products shall contain an unqualified recommendation for a repeat dose to accomplish primary immunization be given at an optimum time interval if such has been established; otherwise, a second dose within 7 days for aqueous products and in 14 days for those containing adjuvants shall be recommended: *Provided*, That repeat dose recommendations prescribed in the subparagraphs of this paragraph are required for products containing the fractions listed:

(1) *Clostridium chauvoei* and/or *Clostridium septicum*. Calves vaccinated under 3 months of age should be revaccinated at weaning or 4 to 6 months of age."

(i) If in combination with *Pasteurella*, add: "Revaccination with Pasteurella Bacterin is recommended at 2 to 4 weeks."

(ii) If in combination with *Clostridium sordellii*, add: "Revaccination with Clostridium Sordellii Bacterin is recommended at 2 to 4 weeks."

(2) *Clostridium Hemolyticum Bacterin*. "Repeat the dose every 5 to 6 months in animals subject to reexposure."

(3) *Clostridium Novyi Bacterin*. "Repeat the dose every 5 to 6 months in animals subject to reexposure."

(4) *Erysipelas Bacterin*. "Swine: For breeding animals, repeat after 21 days and annually." "Turkeys: Repeat dose every 3 months."

(5) *Clostridium Botulinum Type C Toxoid and combinations*. "Revaccinate breeders 1 month before breeding."

§ 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 Deputy 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 products, packaged and labeled as for domestic use, may be exported without the diluent required for rehydration, if the labeling includes adequate instructions for rehydrating the product prior to use and the words "For Export Only".

(c) Final containers of desiccated products, labeled or unlabeled, with or without required diluent, 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.

§ 112.9 Biological products to be imported for research and evaluation.

A biological product imported into the United States for research and evaluation under a permit issued in accordance with Part 102 of this subchapter shall be labeled as provided in this section.

(a) The label shall identify the product, shall furnish a dosage table and full instructions for the proper use of the product, shall include all warnings and cautions needed by the permittee to safely use the product, and shall bear a statement "Notice! For Experimental Use Only—Not For Sale!"

(b) The labeling shall contain any other information deemed necessary by the Deputy Administrator and included on the permit.

§ 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.

Effective dates.—These amendments take effect June 11, 1973, except the rabies vaccine label requirements prescribed in § 112.7 (c) and (d), which shall become effective November 6, 1973.

Done at Washington, D.C., this fourth day of May, 1973.

G. H. WISE,
Acting Administrator, Animal and Plant Health Inspection Service.

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Title 12—Banks and Banking

CHAPTER II—FEDERAL RESERVE SYSTEM

SUBCHAPTER A—BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

[Reg. T]

PART 220—CREDIT BY BROKERS AND DEALERS

Treatment of Simultaneous Long and Short Positions in a Margin Account With Respect to Options

Simultaneous long and short positions in the same security in the same margin account (often referred to as a short sale "against the box") may not be used to supply the place of the deposit of margin ordinarily required in connection with the guarantee by a creditor of a put or