Dated October 8, 1970, to become effective upon publication in the FEDERAL REGISTER.

PAUL A. NICHOLSON,
Acting Director,
Fruit and Vegetable Division,
Consumer and Marketing Service.

[F.R. Doc. 70-13216; Filed, Oct. 12, 1970; 8:47 a.m.]

Title 9—ANIMALS AND ANIMAL PRODUCTS

Chapter I—Agricultural Research Service, Department of Agriculture

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS AND POULTRY

[Docket No. 70-277]

PART 76—HOG CHOLERA AND OTHER COMMUNICABLE SWINE DISEASES

Areas Quarantined

Pursuant to provisions of the Act of May 29, 1884, as amended, the Act of February 2, 1903, as amended, the Act of March 3, 1905, as amended, the Act of September 6, 1961, and the Act of July 2, 1962 (21 U.S.C. 111-113, 114g, 115, 117, 120, 121, 123-126, 134b, 134f), Part 76, Title 9, Code of Federal Regulations, restricting the interstate movement of swine and certain products because of hog cholera and other communicable swine diseases, is hereby amended in the following respects:

1. In § 76.2, paragraph (e) (16) relating to the State of Kansas is amended to read:

(16) *Kansas.* That portion of Wyandotte County bounded by a line beginning at intersection of U.S. Highway 73, 40, 24, and Secondary Road 761; thence, following Secondary Road 761 and continuing on Secondary Road 1648 in a northeasterly direction to Donohoo Road; thence, following Donohoo Road in a southeasterly direction to the southernmost end of the Wyandotte County Lake; thence, following Hurrelbrink Street and East Cerneck Street in an easterly direction to the western boundary of Kansas City limits; thence, following the western boundary of Kansas City limits in a generally southerly direction to U.S. Highway 73, 40, 24; thence, following U.S. Highway 73, 40, 24 in a westerly direction to its junction with Secondary Road 761.

2. In § 76.2, in paragraph (e) (9) relating to the State of North Carolina, subdivision (v) relating to Pitt County is amended to read:

(9) *North Carolina.* * * *

(v) That portion of Pitt County bounded by a line beginning at the junction of Secondary Road 1426 and U.S. Highway 13, North Carolina Highway 11; thence, following U.S. Highway 13, North Carolina Highway 11 in a southeasterly direction to Secondary Road 1515; thence, following Secondary Road 1515 in a southeasterly direction to Secondary Road 1514; thence, following Secondary Road 1514 in a northeasterly direction to Secondary Road 1518; thence, following Secondary Road 1518 in a generally southeasterly direction to Secondary Road 1512; thence, following Secondary Road 1512 in a generally southeasterly direction to Secondary Road 1519; thence, following Secondary Road 1519 in an easterly direction to Secondary Road 1517; thence, following Secondary Road 1517 in a generally southeasterly direction to Secondary Road 1541; thence, following Secondary Road 1541 in a southwesterly direction to Secondary Road 1529; thence, following Secondary Road 1529 in a westerly direction to Secondary Road 1523; thence, following Secondary Road 1523 in a southwesterly direction to Secondary Road 1537; thence, following Secondary Road 1537 in a southwesterly direction to North Carolina Highway 30; thence, following North Carolina Highway 30 in a northwesterly direction to U.S. Highway 13, North Carolina Highway 11; thence, following U.S. Highway 13, North Carolina Highway 11 in a southwesterly direction to the Tar River; thence, following the north bank of the Tar River in a generally northwesterly direction to Secondary Road 1400; thence, following Secondary Road 1400 in a northeasterly direction to Secondary Road 1401; thence, following Secondary Road 1401 in a southeasterly direction to Secondary Road 1402; thence, following Secondary Road 1402 in an easterly direction to Secondary Road 1001; thence, following Secondary Road 1001 in a northwesterly direction to Secondary Road 1415; thence, following Secondary Road 1415 in a northeasterly direction to Secondary Road 1416; thence, following Secondary Road 1416 in a northeasterly direction to Secondary Road 1424; thence, following Secondary Road 1424 in a northerly direction to Secondary Road 1425; thence, following Secondary Road 1425 in a northeasterly direction to Secondary Road 1426; thence, following Secondary Road 1426 in a northeasterly direction to its junction with U.S. Highway 13, North Carolina Highway 11.

* * * * *

3. In § 76.2, the reference to the State of Arkansas in the introductory portion of paragraph (e) and paragraph (e) (15) relating to the State of Arkansas are deleted.

4. In § 76.2, in subparagraph (e) (7) relating to the State of Missouri, subdivisions (i) relating to Butler County; (iii) relating to Jackson County; and (iv) and (v) relating to Scott County are deleted.

(Secs. 4-7, 23 Stat. 32, as amended, secs. 1, 2, 32 Stat. 791-792, as amended, secs. 1-4, 33 Stat. 1264, 1265, as amended, sec. 1, 75 Stat. 481, secs. 3 and 11, 76 Stat. 130, 132; 21 U.S.C. 111, 112, 113, 114g, 115, 117, 120, 121, 123-126, 134b, 134f; 29 F.R. 16210, as amended)

Effective date. The foregoing amendments shall become effective upon issuance.

The amendments quarantine a portion of Pitt County, N.C., because of the existence of hog cholera. This action is deemed necessary to prevent further spread of the disease. The restrictions pertaining to the interstate movement of swine and swine products from or through quarantined areas as contained in 9 CFR Part 76, as amended, will apply to the quarantined portion of such county.

The amendments also exclude a portion of Wyandotte County, Kans.; portions of Jackson, Butler, and Scott Counties in Missouri; and a portion of Craighead County, Ark., from the areas quarantined because of hog cholera. Therefore, the restrictions pertaining to the interstate movement of swine and swine products from or through quarantined areas as contained in 9 CFR Part 76, as amended, will not apply to the excluded areas, but will continue to apply to the quarantined areas described in § 76.2. Further, the restrictions pertaining to the interstate movement of swine and swine products from nonquarantined areas contained in said Part 76 will apply to the areas excluded from quarantine.

Insofar as the amendments impose certain further restrictions necessary to prevent the interstate spread of hog cholera, they must be made effective immediately to accomplish their purpose in the public interest. Insofar as they relieve restrictions, they should be made effective promptly in order to be of maximum benefit to affected persons.

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 amendments are impracticable, unnecessary, and contrary to the public interest, and good cause is found for making them effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 7th day of October 1970.

F. MULHERN,
Acting Administrator,
Agricultural Research Service.

[F.R. Doc. 70-13745; Filed, Oct. 12, 1970; 8:49 a.m.]

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

MISCELLANEOUS AMENDMENTS TO CHAPTER

On May 16, 1970, there was published in the FEDERAL REGISTER (35 F.R. 7652) a notice of proposed rule making with respect to proposed amendments to the regulations relating to viruses, serums, toxins, and analogous products in Parts 109, 113, 114, and 121 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). A correction notice which also extended the period to submit written data, views, or arguments to August 9, 1970, was published in the June 10, 1970, issue of the FEDERAL REGISTER (35 F.R. 8945).

After due consideration of all relevant matters, including the proposals set forth in the aforesaid notice of rule making, 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 proposed amendments of Parts 109, 113, 114, and 121 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 in full herein, subject to the following noted modifications:

Section 109.2: Relaxed the requirements to permit approval of recordkeeping systems other than recording gauges.

Section 109.3: Changed to permit larger units if heated to the required temperature. For clarification, "The" is changed to "Each" and "separate" is changed to "separated" in § 109.3(b).

"Yeasts" has been deleted from §§ 113.25, 113.26, and 113.27, as being covered by the term "fungi." The index has been corrected accordingly. Also, "test vessels" has been substituted for the words "tubes" or "flasks" where they appear in the text of §§ 113.25, 113.26, and 113.27.

Section 113.25(a): Clarified by specifying where the formulas for culture media in §§ 113.26 and 113.27 can be found.

Section 113.25(b): Rewritten for clarification of the requirements for testing medium.

Section 113.25(d): Relaxed requirements to permit application of tests results to comparable products.

Sections 113.26(a) (1) and (2): Clarifies the intent by specifying 0.5 percent beef extract and relaxes the requirements by providing an option for its use in certain tests.

Section 113.26(b)(2): Changed to provide for samples containing less than 1 ml. Spelling of "sufficient" has been corrected.

Section 113.26(b)(3): Reworded for clarification and changed the required incubator temperature to 30°–35° C.

Section 113.26(b)(4): Changed "11th" to read "eleventh" and deleted the extra "and."

Section 113.26(c): Relaxes the requirements to permit additional tests; specifies a satisfactory and an unsatisfactory test.

Section 113.27: Relaxed the requirements by adding an opening paragraph authorizing the Director to permit exceptions when indicated.

Section 113.27(a): Lead paragraph has been clarified by using the phrase "parenteral injection" as being more descriptive and accurate.

Section 113.27(a)(3): Reworded for clarification.

Section 113.27(a)(4): Clarified by inserting the words "a minimum of" before 120 ml. Changed the required incubator temperature to 30° to 35° C.

Section 113.27(a)(5): Clarified by inserting the words "a minimum of" before 40 ml.

Section 113.27(a) (6) and (7): Relaxes the requirements to permit additional tests; specifies a satisfactory and an unsatisfactory test.

Section 114.10 (b) and (c): Corrected the spelling of "nystatin."

PART 109—STERILIZATION AND PASTEURIZATION AT LICENSED ESTABLISHMENTS

1. Part 109 is amended by changing the title, by amending the table of contents, by revising § 109.2, and adding a new § 109.3 to read:

Sec.
109.1 Equipment and the like.
109.2 Sterilizers.
109.3 Pasteurizers.

AUTHORITY: The provisions of this Part 109 issued under 37 Stat. 832–833; 21 U.S.C. 151–158.

§ 109.2 Sterilizers.

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

§ 109.3 Pasteurizers.

All pasteurizing equipment shall meet the requirements in paragraphs (a), (b), and (c) of this section and be acceptable to the Division.

(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.

PART 113—STANDARD REQUIREMENTS

2. Part 113 is amended by adding three new sections and amending the table of contents to read:

APPLICABILITY

Sec.
113.1 Compliance.
113.2 Ingredients of biological products.
113.3 Sampling of biological products.
113.4 Outline of production.
113.5 General testing.
113.6 Division testing.
113.7 Multiple fractions.
113.8 Virus titrations in lieu of test for antigenicity.

STANDARD PROCEDURES

113.25 Culture media for detection of bacteria and fungi.
113.26 Detection of viable extraneous bacteria and fungi in all biological products except live vaccines.
113.27 Detection of viable extraneous bacteria and fungi in live vaccines.

AUTHORITY: The provisions of this Part 113 issued under 37 Stat. 832–833; 21 U.S.C. 151–158.

STANDARD PROCEDURES

§ 113.25 Culture media for detection of bacteria and fungi.

(a) Ingredients for which standards are prescribed in The United States Pharmacopeia or The National Formulary shall conform to such standards. In lieu of preparing the media from the individual ingredients, they may be made from dehydrated mixtures which, when reconstituted with distilled water, have the same or equivalent composition as such media and have growth-promoting buffering, and oxygen tension-controlling properties equal to or better than such media. The formulas for the composition of the culture media prescribed in § 113.26 and § 113.27 are set forth in The United States Pharmacopeia, 18th Edition.

(b) The licensee shall test each quantity of medium prepared at one time from individual ingredients and the first quantity prepared from each lot of commercial dehydrated medium for growth-promoting qualities. If any portion of a lot of commercial dehydrated medium is held for 90 days or longer after being so tested, it shall be retested before use. Two or more strains of micro-organisms that are exacting in their nutritive requirements shall be used. More than one dilution shall be used to demonstrate the adequacy of the medium to support the growth of a minimum number of micro-organisms.

(c) The sterility of the medium shall be confirmed by incubating an adequate number of test vessels and examining each for growth. Additional control may be used by incubation of representative uninoculated test vessels for the required incubation period during each test.

(d) A determination shall be made by the licensee for each biological product of the proportion of inoculum to medium which shall result in sufficient dilution of such product to prevent bacteriostatic and fungistatic activity. The determination may be made by tests on a representative biological product for each group of comparable products containing identical preservatives at equal or lower concentrations.

§ 113.26 Detection of viable extraneous bacteria and fungi in all biological products except live vaccines.

Each serial and subserial of biological product except live vaccines shall be

tested for the presence of viable forms of bacteria and fungi as prescribed in this section unless otherwise specified by the Director.

(a) The media to be used shall be as follows:

(1) Fluid Thioglycollate Medium with 0.5 percent beef extract shall be used to test for bacteria in biological products containing clostridial toxoids, bacterins, and bacterin-toxoids.

(2) Fluid Thioglycollate Medium with or without 0.5 percent beef extract shall be used to test for bacteria in biological products other than clostridial toxoids, bacterins, and bacterin-toxoids.

(3) Soybean-Casein Digest Medium shall be used to test biological products for fungi.

(b) Test procedure:

(1) Ten final container samples from each serial and subserial shall be tested using the media as prescribed in paragraph (a) of this section.

(2) Inoculate 1 ml., or entire contents if less than 1 ml., of material from each final container sample to a corresponding individual test vessel of culture medium. The quantity of medium shall be sufficient to negate bacteriostatic or fungistatic activity in the biological product as determined in § 113.25(d).

(3) Incubation shall be for an observation period of 14 days at 30° to 35° C. for Fluid Thioglycollate Medium with or without 0.5 percent beef extract and 14 days at 20° to 25° C. for Soybean-Casein Digest Medium.

(4) If the inoculum renders the medium turbid so that the absence of growth cannot be determined by visual examination, subcultures shall be made on the seventh to eleventh day from biological products prepared from clostridial toxoids, bacterins, and bacterin-toxoids and the third to seventh day for other biological products. Portions of the turbid medium in amounts of not less than 1.0 ml. shall be transferred to 20 to 25 ml. of fresh medium, and incubated the balance of the 14-day period.

(c) Examine the contents of all test vessels for macroscopic microbial growth during the incubation period. When demonstrated by adequate controls to be invalid, the test may be repeated.

For each set of test vessels representing a serial or subserial in a valid test, the following rules shall apply:

(1) If no growth is found in any test vessel, the serial or subserial meets the requirements of the test.

(2) If growth is found in any test vessel, one retest to rule out faulty technique may be conducted using 20 unopened final container samples.

(3) If growth is found in any test vessel of the final test, the serial or subserial is unsatisfactory.

§ 113.27 Detection of viable extraneous bacteria and fungi in live vaccines.

Unless otherwise specified by the Director, live vaccines shall be tested for the presence of viable forms of bacteria and fungi as prescribed in this section.

(a) *Live viral vaccines.* Each serial and subserial of a biological product composed of live virus shall be tested for viable extraneous bacteria and fungi according to procedures prescribed in this paragraph if such product is recommended for parenteral injection. Tests for bacteria and fungi shall be conducted as follows:

(1) Soybean Casein Digest Medium shall be used.

(2) Ten final container samples from each serial and subserial shall be tested.

(3) Immediately prior to starting the tests, frozen liquid vaccine shall be thawed, and desiccated vaccine shall be rehydrated with the accompanying diluent as recommended on the label. Sterile distilled water shall be used for those desiccated vaccines packaged without diluents.

(4) To test for bacteria, 0.2 ml. of vaccine from each final container sample shall be placed into a corresponding individual vessel containing a minimum of 120 ml. of Soybean Casein Digest Medium. Additional medium shall be used if the determination made as required in § 113.25(d) indicates the need for a greater dilution of the biological product. Incubation shall be at 30° to 35° C. for 7 days.

(5) To test for fungi, 0.2 ml. of vaccine from each final container sample shall be placed into a corresponding individual vessel containing a minimum of 40 ml. of Soybean Casein Digest Medium. Additional medium shall be used if the determination made as required in § 113.25(d) indicates the need for a greater dilution of the biological product. Incubation shall be at 20° to 25° C. for 14 days.

(6) Examine the contents of all test vessels for macroscopic microbial growth during the incubation period. If growth in a vessel cannot be reliably determined by visual examination, judgment shall be confirmed by subcultures, microscopic examination, or both. When demonstrated by adequate controls to be invalid, the test may be repeated.

(7) For each set of test vessels representing a serial or subserial in a valid test, the following rules shall apply:

(i) If no growth is found in 9 or 10 of the test vessels in the initial test or a retest, the serial or subserial meets the requirements of the test.

(ii) If growth is found in 2 or 3 test vessels of the initial test, one retest to rule out faulty technique may be conducted using 10 unopened final container samples.

(iii) If growth is found in 4 or more test vessels in the initial test or 2 or more in a retest, the serial or subserial is unsatisfactory.

(b) *Live bacterial vaccines.* Each serial or subserial of live bacterial biological products shall be tested for purity by plating on appropriate medium depending upon the live bacteria contained in the product. A serial or subserial shall be considered unsatisfactory if there is any evidence of viable extraneous bacteria and fungi.

PART 114 — MISCELLANEOUS REQUIREMENTS FOR LICENSED ESTABLISHMENTS

3. Part 114 is amended by changing the title, by amending the table of contents, by adding a new § 114.6 and a new § 114.10 and by revising § 114.9 and § 114.12.

Sec.

AUTHORITY: The provisions of this Part 114 issued under 37 Stat. 832–833; 21 U.S.C. 151–158.

§ 114.6 Admission of biological products to licensed establishments.

Except as specifically authorized by the regulations in Parts 101 through 121 of this subchapter, no biological product which has not been prepared, handled, stored, and marked in accordance with such regulations and no biological product which is worthless, contaminated, dangerous, or harmful shall be brought onto the premises of any licensed establishment.

§ 114.9 Mixing biological products.

Each serial of biological product, when in liquid form, shall be mixed thoroughly in a single container and be constantly agitated during bottling operations at licensed establishments. A serial number, with any other markings that may be necessary for ready identification of the serial, shall be applied to identify it with the records of preparation and labeling.

§ 114.10 Antibiotics as preservatives.

Antibiotics are authorized for use as preservatives for biological products if used within the limitations as to kinds and amounts prescribed in this section.

(a) When an antibiotic or combination of antibiotics, with or without a fungistat is to be used in the preparation of a biological product, the kind(s) and amount(s) of each shall be specified in the outline for such product in such a way that the concentration in the final product may be calculated. Except as may be approved by the Director, only those individual antibiotics or combinations of antibiotics listed in paragraphs (b) and (c) of this section shall be used.

(b) Permitted individual antibiotics:

(1) The antibiotic level of a specified individual antibiotic in one ml. of a biological product, when prepared as recommended for use, shall not exceed the amounts listed in this paragraph: *Provided,* That in the case a desiccated

biological product is to be used with an indefinite quantity of water or other menstruum, the determination shall be based on 30 ml. per 1,000 dose vial or equivalent.

(2) Except as prescribed in paragraph (c) of this section, only one antibiotic shall be used as a preservative in a biological product. The kind and maximum amount per ml. of such antibiotic shall be restricted to:

Amphotericin B	2.5 mcg.
Nystatin (Mycostatin)	30.0 units
Tetracyclines	30.0 mcg.
Penicillin	30.0 units
Streptomycin	30.0 mcg.
Polymyxin B	30.0 mcg.
Neomycin	30.0 mcg.

(c) Permitted combinations:

(1) Either amphotericin B or nystatin, but not both, may be used with one of the other antibiotics listed in paragraph (b) of this section, or with a combination of penicillin and streptomycin, or with a combination of polymyxin B and neomycin.

(2) The maximum amount of each antibiotic in a combination shall be the amount prescribed for such antibiotic in paragraph (b) of this section.

(d) Antibiotics used in virus seed stock purification are not restricted as to kind or amounts provided carryover into the final product is controlled and specified in outlines of production.

§ 114.12 **Production of serums and antiserums.**

(a) Serums and antiserums prepared for inoculation into animals shall be obtained from the blood of healthy animals maintained at licensed establishments. Detailed records regarding tests made on the animals and the antigens given to the animals shall be maintained by the licensee.

(b) Serum and antiserum of equine origin shall be heated at 58.5° C. for 60 minutes, with a tolerance of 0.5° above and below that temperature. Serum and antiserum of bovine and porcine origin shall be heated in like manner for 30 minutes. Neither serum nor antiserum shall contain preservative at the time of heating.

(c) Serum and antiserum heated as provided in paragraph (b) of this section, shall be cooled immediately thereafter to 15° C. or lower, and thus held until properly preserved. It shall be preserved, mixed, and tested by methods described in the licensee's outline.

(d) Licensees shall keep detailed records relative to each batch of antiserum or serum pasteurized and each serial prepared for marketing. Recording thermometer charts shall bear full information concerning the antiserum or serum heated and tests made of the equipment.

PART 121—ADMISSION OF BIOLOGICAL PRODUCTS AND MATERIALS TO LICENSED ESTABLISHMENTS

4. Part 121 of Chapter I of Title 9 of the Code of Federal Regulations is revoked.

The reporting and/or recordkeeping requirements contained herein have been approved by the Bureau of the Budget in accordance with the Federal Reports Act of 1942.

Effective date: Thirty days after publication in the FEDERAL REGISTER, except with respect to sections 113.25, 113.26, 113.27, and 114.10, which shall become effective 180 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 7th day of October 1970.

F. J. MULHERN,
Acting Administrator,
Agricultural Research Service.

[F.R. Doc. 70-13744; Filed, Oct. 12, 1970; 8:49 a.m.]

Title 14—AERONAUTICS AND SPACE

Chapter I—Federal Aviation Administration, Department of Transportation

[Docket No. 70-CE-10-AD; Amdt. 39-1092]

PART 39—AIRWORTHINESS DIRECTIVES

Continental Models IO-520, IO-470, IO-470-J, -U, -V, -VO, TSIO-470 and IO-360 Engines

Amendment 39-1028 (35 F.R. 11384), AD 70-14-7, applicable to Teledyne Continental Models IO-520, IO-470, TSIO-470 and IO-360 engines, is an airworthiness directive which requires a visual inspection of the fuel bypass needle on these model engines and application of securing material to the needle. In addition, the AD requires replacement of the existing needle with a needle having a positive safety provision at the next engine or fuel injection pump overhaul, fuel inspection pump adjustment or before further flight if inspection reveals that the securing procedure will not provide an adequate level of safety.

The applicability statement of AD 70-14-7, as published, inadvertently did not include Teledyne Continental Models IO-470-J, -U, -V and -VO engines and must be amended to include these model engines.

Since this amendment corrects an error, it is found that notice and public procedure hereon are impracticable and good cause exists for making this amendment effective in less than thirty (30) days.

In consideration of the foregoing and pursuant to the authority delegated to me by the Administrator (31 F.R. 13697), Section 39.13 of Part 39 of the Federal Aviation Regulations, Amendment 39-1028 (35 F.R. 11384), AD 70-14-7, is amended as follows:

The applicability statement is amended to read as follows:

CONTINENTAL. Applies to Teledyne Continental Models IO-360-A, -C, -D; IO-520-A, -B, -C, -D, -E, -F, -J, -K; IO-470-C, -D, -E, -F, -H, -K, -L, -M, -N, -S, -J, -U, -V, -VO; TSIO-470-B, -C and -D engines.

NOTE: Compliance with AD 70-14-7 on the Model IO-470-J, -U, -V, and -VO engines added to the applicability statement commences on the effective date of this amendment.

This amendment becomes effective October 13, 1970.

(Secs. 313(a), 601 and 603 of the Federal Aviation Act of 1958; 49 U.S.C. 1354(a), 1421 and 1423, and sec. 6(c) of the Department of Transportation Act; 49 U.S.C. 1655(c))

Issued in Kansas City, Mo., on October 2, 1970.

DANIEL E. BARROW,
Acting Director, Central Region.

[F.R. Doc. 70-13707; Filed, Oct. 12, 1970; 8:46 a.m.]

[Docket No. 10078; Amdt. 121-67]

PART 121—CERTIFICATION AND OPERATIONS: DOMESTIC, FLAG, AND SUPPLEMENTAL AIR CARRIERS AND COMMERCIAL OPERATORS OF LARGE AIRCRAFT

Carriage of Persons Without Compliance With Passenger-Carrying Requirements; Correction

The document amending Part 121 of the Federal Aviation Regulations, published in the FEDERAL REGISTER on September 18, 1970 (35 F.R. 14611) is corrected by changing the paragraph designation "(d)" to "(e)" in the amendment to § 121.1.

Issued in Washington, D.C., on October 5, 1970.

J. H. SHAFFER,
Administrator.

[F.R. Doc. 70-13706; Filed, Oct. 12, 1970; 8:46 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart C—Food Additives Permitted in Feed and Drinking Water of Animals or for the Treatment of Food-Producing Animals

OXYTETRACYCLINE

The Commissioner of Food and Drugs has evaluated a new animal drug application (38-200V) filed by Diamond Shamrock Chemical Co., formerly Nopco Chemical Co., 60 Park Place, Newark, N.J. 07102, proposing the safe and effective use of oxytetracycline in the drinking water of turkeys for the control of hexamitiasis. The application is approved.

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512 (i), 82 Stat. 347; 21 U.S.C. 360b(i)), in accordance with § 3.517 (21 CFR 3.517), and under authority delegated to the Commissioner (21 CFR 2.120), § 121.251 is amended in Table 3 by designating the existing item therein as item 1 and adding a new item 2, as follows:

§ 121.251 Oxytetracycline.

* * * * *

(d) * * *

TABLE 3—OXYTETRACYCLINE IN DRINKING WATER

Principal ingredient	Grams per gallon	Combined with—	Grams per gallon	Limitations	Indications for use
1. Oxytetracycline	* * *	* * *	* * *	* * *	* * *
2. Oxytetracycline	0.2-0.4			For turkeys; administer for 2 weeks as follows:	For the control of hexamitiasis.
				Weeks of age — *Grams per gallon*: 0-8 — 0.2; 9-16 — 0.3; 17 to market age — 0.4	
				Withdraw 3 days before slaughter; as oxytetracycline hydrochloride.	

Any person who will be adversely affected by the foregoing order may at any time within 30 days after its date of publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-62, 5600 Fishers Lane, Rockville, Md. 20852, written objections thereto in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective on its date of publication in the FEDERAL REGISTER.

(Sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i))

Dated: October 2, 1970.

SAM D. FINE,
Associate Commissioner for Compliance.

[F.R. Doc. 70-13699; Filed, Oct. 12, 1970; 8:45 a.m.]

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

ADHESIVES

The Commissioner of Food and Drugs, having evaluated the data in a petition (FAP 0B2546) filed by Emery Industries, Inc., 4300 Carew Tower, Cincinnati, Ohio 45202, and other relevant material, concludes that the food additive regulations should be amended as set forth below to provide for the safe use of azelaic acid as a component of food packaging adhesives.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1)), and under the authority delegated to the Commissioner (21 CFR 2.120), § 121.2520(c)(5) is amended by alphabetically inserting in the list of substances the item azelaic acid and by revising the item "Polyamides derived from * * *" as follows:

§ 121.2520 Adhesives.

* * * * *

(c) * * *

(5) * * *

COMPONENTS OF ADHESIVES

Substances	*Limitations*
* * *	* * *
Azelaic acid	
* * *	* * *
Polyamides derived from reaction of one or more of the following acids with one or more of the following amines:	
Acids:	
Azelaic acid	
Dimerized vegetable oil acids	
Amines:	
Bis(hexamethylene) triamine and higher homologues	
Diethylenetriamine	
Diphenylamine	
Ethylenediamine	
Hexamethylenediamine	
Tetraethylenepentamine	
Triethylenetetramine	
* * *	* * *

Any person who will be adversely affected by the foregoing order may at any time within 30 days after its date of publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-62, 5600 Fishers Lane, Rockville, Md. 20852, written objections thereto in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective on its date of publication in the FEDERAL REGISTER.

(Sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1))

Dated: October 5, 1970.

R. E. DUGGAN,
Acting Associate Commissioner for Compliance.

[F.R. Doc. 70-13698; Filed, Oct. 12, 1970; 8:45 a.m.]

SUBCHAPTER C—DRUGS

PART 148a—AMPHOMYCIN

Effective on publication in the FEDERAL REGISTER, Part 148a is republished as follows to incorporate editorial and nonrestrictive technical changes. This order revokes all prior publications.

Sec.

148a.1 Calcium amphomycin.

148a.2 Calcium amphomycin-neomycin sulfate-hydrocortisone acetate cream.

AUTHORITY: The provisions of this Part 148a issued under sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357.

§ 148a.1 Calcium amphomycin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Calcium amphomycin is the calcium salt of amphomycin. It is so purified and dried that:

(i) Its potency is not less than 868 micrograms of amphomycin per milligram.

(ii) Its moisture content is not more than 10 percent.

(iii) Its pH in a 2 percent aqueous suspension is not less than 6.0 and not more than 7.5.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter.

(3) *Requests for certification.* In addition to the requirements of § 146.2 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, moisture, and pH.

(ii) Samples required on the batch: 10 packages, each containing approximately 300 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 141.110 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Allow this stock solution to stand overnight at room temperature to assure that the sample is dissolved completely. Further dilute the stock solution with solution 3 to the reference concentration of 10.0 micrograms of amphomycin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 141.502 of this chapter.

(3) *pH.* Proceed as directed in § 141.503 of this chapter, using a suspension