the Commission on the basis of the facts stated therein and other information contained in the official files of the Commission pertaining thereto.

For the Commission (pursuant to delegated authority).

[SEAL] ORVAL L. DUBOIS,
Secretary.

[F.R. Doc. 64-11899; Filed, Nov. 20, 1964; 8:45 a.m.]

[File No. 1-4722]

TASTEE FREEZ INDUSTRIES, INC.

Order Suspending Trading

NOVEMBER 17, 1964.

The common stock, 67 cents par value, of Tastee Freez Industries, Inc., being listed and registered on the American Stock Exchange, pursuant to provisions of the Securities Exchange Act of 1934; and

It appearing to the Securities and Exchange Commission that the summary suspension of trading in such securities on such Exchange and otherwise than on a national securities exchange is required in the public interest and for the protection of investors;

It is ordered, Pursuant to sections 15(c)(5) and 19(a)(4) of the Securities Exchange Act of 1934, that trading in such securities on the American Stock Exchange and otherwise than on a national securities exchange be summarily suspended, this order to be effective for the period November 18, 1964 through November 27, 1964, both dates inclusive.

By the Commission.

[SEAL] ORVAL L. DUBOIS,
Secretary.

[F.R. Doc. 64-11900; Filed, Nov. 20, 1964; 8:45 a.m.]

SMALL BUSINESS ADMINISTRATION

[Delegation of Authority 30-III, Amdt. 4]

PHILADELPHIA REGIONAL AREA

Delegation of Authority To Conduct Program Activities

Pursuant to the authority delegated to the Regional Director by Delegation of Authority (Revision 9) 29 F.R. 11777, as amended, 29 F.R. 12570, 13354 and 14093; Delegation of Authority No. 30-III, 29 F.R. 13125, as amended, 29 F.R. 13415, 13989 and 14556, is hereby further amended by revising Item I.L. to read as follows:

L. The following authority is hereby redelegated to the Branch Manager at Newark, N.J.

1. To approve the following:

a. Direct loans not exceeding $50,000.

b. Participation loans not exceeding $150,000.

c. Simplified Bank Participation loans not exceeding $250,000.

d. Simplified Early Maturities Participation loans not exceeding $250,000.

e. Direct disaster loans not exceeding $100,000.

f. Participation disaster loans not exceeding $150,000.

2. To decline as follows:

a. Business loans not exceeding $200,000.

b. Disaster loans in any amount.

3. To disburse unsecured disaster loans.

4. Items I.C. 6 through 11.

5. Item I.C. 12—only the authority for servicing, administration and collection, including subitems a. and b., but not c.

6. To (a) make emergency purchases chargeable to the administrative expense fund, not in excess of $25 in any one object class in any one instance but not more than $50 in any one month for total purchases in all object classes; (b) make purchases not in excess of $10 in any one instance for "one-time use items" not carried in stock subject to the total limitations set forth in (a) of this paragraph; (c) to contract for the repair and maintenance of equipment and furnishings in an amount not to exceed $25 in any one instance; and (d) purchase printing from the General Services Administration where centralized reproduction facilities have been established by GSA.

7. Item I.A. (size determinations for financial assistance only).

8. Item I.B. (eligibility determinations for financial assistance only).

Effective date: November 9, 1964.

EDWARD N. ROSA,
Regional Director,
Philadelphia Regional Office.

[F.R. Doc. 64-11919; Filed, Nov. 20, 1964; 8:46 a.m.]

DEPARTMENT OF LABOR

Wage and Hour Division

CERTIFICATES AUTHORIZING EMPLOYMENT OF LEARNERS AT SPECIAL MINIMUM RATES

Notice is hereby given that pursuant to section 14 of the Fair Labor Standards Act of 1938 (52 Stat. 1060, as amended, 29 U.S.C. 201 et seq.), and Administrative Order No. 579 (28 F.R. 11524) the firms listed in this notice have been issued special certificates authorizing the employment of learners at hourly wage rates lower than the minimum wage rates otherwise applicable under section 6 of the act. The effective and expiration dates, occupations, wage rates, number or proportion of learners and learning periods, for certificates issued under general learner regulations (29 CFR 522.1 to 522.9), and the principal product manufactured by the employer are as indicated below. Conditions provided in certificates issued under the supplemental industry regulations cited in the captions below are as established in those regulations.

Apparel Industry Learner Regulations (29 CFR 522.1 to 522.9, as amended, and 29 CFR 522.20 to 522.25, as amended).

The following learner certificates were issued authorizing the employment of 10 percent of the total number of factory production workers for normal labor turnover purposes. The effective and expiration dates are indicated.

The Arrow Company, a division of Cluett, Peabody & Co., Inc., Carbon Hill, Pa.; effective 10-15-64 to 10-14-65 (boys' shirts).

Michael Berkowitz Co., Inc., Barton Mill Road, Uniontown, Pa.; effective 11-4-64 to 11-3-65 (men's, ladies' and children's pajamas).

Blue Ridge Manufacturers, Inc., Christiansburg, Va.; effective 10-31-64 to 10-30-65 (men's and boys' denim jeans).

Blue Ridge Shirt Manufacturing Co., Box 801, Fayetteville, Tenn.; effective 10-31-64 to 10-30-65 (men's and boys' sport shirts).

J. H. Bonck Co., Inc., 1100 South Jefferson Davis Parkway, New Orleans, La.; effective 10-31-64 to 10-30-65 (men's sport shirts).

Carbondale Children's Dress Co., 30 7th Avenue, Carbondale, Pa.; effective 11-1-64 to 10-31-65 (children's and girls' dresses and playsuits).

The Carthage Corp., Carthage, Miss.; effective 11-1-64 to 10-31-65 (men's and boys' pants).

Cowden Manufacturing Co., 124 Apperson Heights, Mount Sterling, Ky.; effective 10-23-64 to 10-22-65 (men's denim work shirts and coats).

Crystal Springs Shirt Corp., Crystal Springs, Miss.; effective 10-21-64 to 10-20-65 (boys' shirts).

Dantan Co., Inc., Rankin Street, Dumas, Ark.; effective 10-18-64 to 10-17-65 (ladies' sportswear-slim jims, jamaicas, etc.).

Eureka Pants Manufacturing Co., Madison Street, Shelbyville, Tenn.; effective 10-27-64 to 10-26-65 (work pants, work shirts).

Fly Manufacturing Co., 204 South Main Street, Shelbyville, Tenn.; effective 10-27-64 to 10-26-65 (work pants, overalls, dungarees and jackets).

Form-O-Uth Brassiere Co., d.b.a. Marie Foundations Branch, Pampa, Tex.; effective 10-14-64 to 10-13-65 (women's brassieres and girdles).

Freeland Shirt Co., 1015 Dewey Street, Freeland, Pa.; effective 11-4-64 to 11-3-65 (men's and children's jackets and vests).

Gibson Garment Co., Inc., Gibson, Ga.; effective 10-31-64 to 10-30-65 (boys' and men's trousers).

Harrisburg Children's Dress Co., 1380 Howard Street, Harrisburg, Pa.; effective 10-26-64 to 10-25-65 (children's and girls' dresses and playsuits).

Heavy Duty Manufacturing Co., Gainesboro, Tenn.; effective 10-28-64 to 10-27-65 (men's and boys' sport shirts).

Joyner-Fields, Inc., Sherman, Miss.; effective 10-15-64 to 10-14-65 (men's and boys' sport shirts).

Key Work Clothes, Inc., Fort Scott, Kansas; effective 10-31-64 to 10-30-65 (men's and boys' bib overalls, work jackets, coveralls).

Key Work Clothes of Missouri, Nevada, Mo.; effective 11-1-64 to 10-31-65 (men's work pants, work shirts).

Lansford Apparel Co., West Patterson Street, Lansford, Pa.; effective 10-31-64 to 10-30-65 (children's dresses).

Luverne Slacks Corp., Luverne, Ala.; effective 10-19-64 to 10-18-65 (men's cotton and synthetic slacks).

McPenn Manufacturing Co., Washington and Walnut Streets, Nanticoke, Pa.; effective 10-25-64 to 10-24-65 (men's and boys' sport shirts).

Samuel Meltzer d.b.a. The Liberty Co., Royalty Manufacturing Co., Inc., East Front Street, Dyer, Tenn.; effective 10-22-64 to 10-21-65 (men's and boys' pajamas).

Charles Meyers & Co., First and Harrison Streets, Belleville, Ill.; effective 11-1-64 to 10-31-65 (men's trousers-semi-dress slacks).

Newport News Children's Dress Co., 824 39th Street, Newport News, Va.; effective 10-12-64 to 10-11-65 (children and girls' dresses and playsuits).

Penn Childrens Dress Co., 831 Lackawanna Avenue, Mayfield, Pa.; effective 10–26–64 to 10–25–65 (children's and girls' dresses and playsuits).

Press Dress and Uniform Co., Hummelstown, Pa.; effective 10–29–64 to 10–28–65 (maids' and nurses' uniforms and cotton dresses).

Quality Sewn Products, Inc., Post Office Box 126, Royston, Ga.; effective 10–15–64 to 10–14–65 (men's sport shirts, ladies' blouses).

S & S Manufacturing Co., Inc., 200 West Main Street, Spartanburg, S.C.; effective 11–1–64 to 10–31–65 (ladies' and children's blouses).

Shelburne Shirt Co., Inc., 69 Alden Street, Fall River, Mass.; effective 11–1–64 to 10–31–65 (men's dress shirts).

Smith & Company, 102 West Kaskaskia, Paola, Kans.; effective 10–12–64 to 10–11–65 (robes and loungewear).

Sparta Garment Co., Inc., Sparta, Ga.; effective 10–31–64 to 10–30–65 (boys' and men's trousers).

Warner Brothers Company, Post Office Box 682, Aiken, S.C.; effective 10–20–64 to 10–19–65 (corsets and brassieres).

Washington Overall Manufacturing Co., South Court Street, Scottsville, Ky.; effective 10–26–64 to 10–25–65 (men's and boys' trousers).

Weldon Manufacturing Co. of Pennsylvania, 1307 Park Avenue, Williamsport, Pa.; effective 10–29–64 to 10–28–65 (men's, women's, boys' pajamas).

Wilgree Manufacturing Co., North Harney Street, Camilla, Ga.; effective 10–21–64 to 10–20–65 (men's sport and dress shirts).

The following learner certificates were issued for normal labor turnover purposes. The effective and expiration dates and the number of learners authorized are indicated.

Anderson Brothers Consolidated Co's., Inc., Floyd and High Streets, Danville, Va.; effective 10–31–64 to 10–30–65; 10 learners (men's work clothes).

Athens Garment Co., 208 North Marion Street, Athens, Ala.; effective 10–24–64 to 10–23–65; 10 learners (work shirts).

Burgaw Manufacturing Co., Burgaw, N.C.; effective 10–12–64 to 10–11–65; 10 learners (women's dresses).

C & M Sportswear Manufacturing Corp., Meshoppen, Pa.; effective 10–14–64 to 10–13–65; 10 learners. Learners may not be employed at special minimum wage rates in the production of jackets of suit type construction (girls' jackets, men's ski jackets).

Boonville Manufacturing Corp., 302–316 North Second Street, Boonville, Ind.; effective 11–1–64 to 10–31–65; 10 learners (men's woven pajamas).

Dunmore Sewing Co., 105 Corner Street, Dunmore, Pa.; effective 10–29–64 to 10–28–65; 5 learners (children's dresses).

Good-I-Kin Sportswear Corp., 331 Main Street, Lilly, Pa.; effective 10–14–64 to 10–13–65; 10 learners (children's skirts, blouses and jumpers).

Eileen Hope, Inc., 209 Market Street, Halifax, Pa.; effective 10–19–64 to 10–18–65; 10 learners (women's dresses).

Lacy Manufacturing Co., Inc., 901 Adele Street, Martinsville, Va.; effective 10–16–64 to 10–15–65; 5 learners in the production of outerwear jackets (men's and boys' outerwear jackets).

Marshall Clothing Manufacturing Co., Inc., 115 East Main Street—118–122 Broadway, Butler, Ind., effective 10–19–64 to 10–18–65; 10 learners (insulated garments, jackets, uniforms, etc.).

Oswego Foundations, Inc., 185 East Seneca Street, Oswego, N.Y.; effective 11–1–64 to 10–31–65; 10 learners (girdles and corsets).

Roanoke Manufacturing Co., Anniston, Ala.; effective 10–12–64 to 10–11–65; 10 learners (men's sport shirts).

W. E. Stephens Manufacturing Co., Inc., Carthage, Tenn.; effective 10–14–64 to 10–13–65; 10 learners (men's and boys' dungarees).

Washington Garment Co., Inc., Washington, N.C.; effective 10–24–64 to 10–23–65; 10 learners (children's dresses).

The following learner certificates were issued for plant expansion purposes. The effective and expiration dates and the number of learners are indicated.

Michael Berkowitz Co., Inc., Route No. 2, Waynesburg, Pa.; effective 10–15–64 to 4–14–65; 15 learners (ladies' and men's pajamas).

Blue Bell, Inc., Homer, Ga.; effective 10–14–64 to 4–13–65; 25 learners (dungarees).

Burgaw Manufacturing Co., Burgaw, N.C.; effective 10–20–64 to 4–19–65; 65 learners (women's cotton dresses).

Collinwood Manufacturing Co., Collinwood, Tenn.; effective 10–19–64 to 4–18–65; 50 learners (women's washable cotton service uniforms).

The Dantan Co., Inc., Rankin Street, Dumas, Ark.; effective 10–23–64 to 4–22–65; 35 learners (ladies' sportswear-slim jeans, jamaicas, etc.).

Form-O-Uth Brassiere Co., d.b.a. Marie Foundations Branch, Pampa, Tex.; effective 10–14–64 to 4–13–65; 45 learners (women's brassieres and girdles).

H. D. Lee Co., Inc., Jasper, Ga.; effective 10–15–64 to 4–14–65; 75 learners (men's casual pants).

Oswego Foundations, Inc., 185 East Seneca Street, Oswego, N.Y.; effective 10–26–64 to 4–25–65; 15 learners (women's girdles and corsets).

Tracy City Manufacturing Co., Tracy City, Tenn.; effective 10–16–64 to 4–15–65; 100 learners (men's and boys' sport shirts).

Warner Brothers Co., Post Office Box 682, Aiken, S.C.; effective 10–20–64 to 4–19–65; 30 learners (corsets and brassieres).

Washington Garment Co., 2020 Main Street Extension, Washington, Pa.; effective 10–24–64 to 4–23–65; 80 learners. Learners may not be employed at special minimum wages in the production of skirts (ladies' sportswear pants and shorts).

Glove Industry Learner Regulations (29 CFR 522.1 to 522.9, as amended, and 29 CFR 522.60 to 522.65, as amended).

Good Luck Glove Co., Carbondale, Ill.; effective 10–30–64 to 10–29–65; 10 percent of the total number of machine stitchers for normal labor turnover purposes (cotton, jersey and leather combination).

Granet Glove Corp., Box 188, South Royalton, Vt.; effective 10–15–64 to 10–14–65; 5 learners for normal labor turnover purposes (work gloves).

Richmond Glove Corp., 601 North D Street, Richmond, Ind.; effective 10–10–64 to 4–9–65; 10 learners for plant expansion purposes (work gloves).

Richmond Glove Corp., 601 North D Street, Richmond, Ind.; effective 10–10–64 to 10–9–65; 10 percent of the total number of machine stitchers for normal labor turnover purposes (work gloves).

Hosiery Industry Learner Regulations (29 CFR 522.1 to 522.9, as amended, and 29 CFR 522.40 to 522.43, as amended).

Beaver Hosiery Co., Hickory, N.C.; effective 10–23–64 to 10–22–65; 5 learners for normal labor turnover purposes (seamless).

Burlington Balfour Mills, Post Office Box 610, Asheboro, N.C.; effective 10–19–64 to 10–18–65; 5 percent of the total number of factory production workers for normal labor turnover purposes (seamless).

Danville Knitting Mills, Inc., Danville, Va.; effective 10–15–64 to 10–14–65; 5 percent of the total number of factory production workers for normal labor turnover purposes (seamless).

C. D. Jessup & Co., Claremont, N.C.; effective 10–15–64 to 10–14–65; 5 learners for normal labor turnover purposes (seamless).

Union Manufacturing Co., 500 Sibley Avenue, Union Point, Ga.; effective 10–21–64 to 10–20–65; 5 percent of the total number of factory production workers for normal labor turnover purposes (seamless).

Wayne Knitting Mills, Humboldt, Tenn.; effective 10–24–64 to 10–23–65; 5 percent of the total number of factory production workers for normal labor turnover purposes (full-fashioned, seamless).

Wyatt Knitting Co., 1006 Goldsboro Avenue, Sanford, N.C.; effective 11–1–64 to 10–31–65; 5 learners for normal labor turnover purposes (full-fashioned, seamless).

Knitted Wear Industry Learner Regulations (29 CFR 522.1 to 522.9, as amended, and 29 CFR 522.30 to 522.35, as amended).

Boonville Manufacturing Corp., 302–316 North Second Street, Boonville, Ind.; effective 11–1–64 to 10–31–65; 5 learners for normal labor turnover purposes in the manufacture of men's woven underwear (men's woven underwear).

Lacy Manufacturing Co., Inc., 901 Adele Street, Martinsville, Va.; effective 10–16–64 to 10–15–65; 10 learners for normal labor turnover purposes (men's and boys' swim trunks).

Lacy Manufacturing Co., Inc., 901 Adele Street, Martinsville, Va.; effective 10–16–64 to 4–15–65; 10 learners for plant expansion purposes (men's and boys' swim trunks).

Rockwell Manufacturing Corp., St. Paul, Va.; effective 10–23–64 to 10–22–65; 5 percent of the total number of factory production workers for normal labor turnover purposes (ladies' sleepwear, lingerie).

Sherman Underwear Mills, Inc., Hawley, Pa.; effective 10–23–64 to 10–22–65; 5 percent of the total number of factory production workers for normal labor turnover purposes (ladies' and children's panties).

The following student-worker certificate was issued pursuant to the regulations applicable to the employment of student-workers (29 CFR 527.1 to 527.9). The effective and expiration dates, occupations, wage rates, number of student-workers, and learning periods for the certificates issued under Part 527 are as indicated below.

Atlantic Union College, Main Street, South Lancaster, Mass.; effective 10–13–64 to 8–31–65; authorizing the employment of: (1) 15 student-workers in the printing industry in the occupations of compositor, pressman and related skilled and semiskilled occupations for a learning period of 1000 hours at the rates of $1.10 an hour for the first 500 hours and $1.15 an hour for the remaining 500 hours; (2) 35 student-workers in the bookbinding industry in the occupations of bookbinder, bindery workers, and related skilled and semiskilled occupations for a learning period of 600 hours at the rates of $1.10 an hour for the first 300 hours and $1.15 an hour for the remaining 300 hours; and (3) 40 student-workers in the broom manufacturing industry in the occupations of broom maker, stitcher, sorter, winder, and related skilled and semiskilled occupations for a learning period of 360 hours at the rates of $1.10 an hour for the first 180 hours and $1.15 an hour for the remaining 180 hours.

The student-worker certificate was issued upon the applicant's representations and supporting material fulfilling the statutory requirements for the issuance of such certificates, as interpreted and applied by Part 527.

Each learner certificate has been issued upon the representations of the employer which, among other things, were that employment of learners at special minimum rates is necessary in order to prevent curtailment of opportunities for employment, and that experienced workers for the learner occupations are not available. Any person aggrieved by the issuance of any of these certificates may seek a review or reconsideration thereof within fifteen days after publication of this notice in the FEDERAL REGISTER pursuant to the provisions of 29 CFR 522.9. The certificates may be annulled or withdrawn, as indicated therein, in the manner provided in 29 CFR, Part 528.

Signed at Washington, D.C., this 6th day of November 1964.

ROBERT G. GRONEWALD,
Authorized Representative of the Administrator.

[F.R. Doc. 64-11904; Filed, Nov. 20, 1964; 8:45 a.m.]

INTERSTATE COMMERCE COMMISSION

[Rev. S. O. 562, Taylor's I.C.C. Order 176]

MIDLAND VALLEY RAILROAD CO.

Rerouting or Diversion of Traffic

In the opinion of Charles W. Taylor, Agent, the Midland Valley Railroad Co., due to bridge damage near Arkansas City, Kans., is unable to transport traffic routed over its lines.

It is ordered, That:

(a) Rerouting traffic: The Midland Valley Railroad Co. and its connections, being unable to transport traffic in accordance with shippers routing because of bridge damage, near Arkansas City, Kans., is hereby authorized to divert or reroute such traffic moving over its line over any available route to expedite the movement, regardless of the routing shown on the waybill. The billing covering all such cars rerouted shall carry a reference to this order as authority for the rerouting.

(b) Concurrence of receiving roads to be obtained: The railroad desiring to divert or reroute traffic under this order shall confer with the proper transportation officer of the railroad or railroads to which such traffic is to be diverted or rerouted, and shall received the concurrence of such other railroads before the rerouting or diversion is ordered.

(c) Notification to shippers: The carrier rerouting cars in accordance with this order shall notify each shipper at the time each car is diverted or rerouted and shall furnish to such shipper the new routing provided under this order.

(d) Inasmuch as the diversion or rerouting of traffic by said Agent is deemed to be due to carrier's disability, the rates applicable to traffic diverted or rerouted by said Agent shall be the rates which were applicable at the time of shipment on the shipments as originally routed.

(e) In executing the directions of the Commission and of such Agent provided for in this order, the common carriers involved shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to such traffic; divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(f) Effective date: This order shall become effective at 10:00 a.m., November 17, 1964.

(g) Expiration date: This order shall expire at 11:59 p.m., December 17, 1964, unless otherwise modified, changed, suspended or annulled.

It is further ordered, That this order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and per diem agreement under the terms of that agreement and by filing it with the Director, Division of the Federal Register.

Issued at Washington, D.C. November 17, 1964.

INTERSTATE COMMERCE COMMISSION,
[SEAL] CHARLES W. TAYLOR,
Agent.

[F.R. Doc. 64-11913; Filed, Nov. 20, 1964; 8:46 a.m.]

[Notice 1080]

MOTOR CARRIER TRANSFER PROCEEDINGS

NOVEMBER 18, 1964.

Synopses of orders entered pursuant to section 212(b) of the Interstate Commerce Act, and rules and regulations prescribed thereunder (49 CFR Part 179), appear below:

As provided in the Commission's special rules of practice any interested person may file a petition seeking reconsideration of the following numbered proceedings within 20 days from the date of publication of this notice. Pursuant to section 17(8) of the Interstate Commerce Act, the filing of such a petition will postpone the effective date of the order in that proceeding pending its disposition. The matters relied upon by petitioners must be specified in their petitions with particularity.

No. MC-FC 67239. By order of November 13, 1964, the Transfer Board approved the transfer to L. F. Berry, Easton, Md., of a portion of the operating rights issued by the Commission August 24, 1964, under Certificate No. MC 29969, to Rex "N" Don Van Lines, Inc., Charleston, Ill., authorizing the transportation, over irregular routes, of household goods, as defined by the Commission, between points in Macon County, Ill., on the one hand, and, on the other, points in Illinois, Indiana, Iowa, Kentucky, Michigan, Missouri, Ohio, Tennessee, and Wisconsin; between points in Clark, Coles, Cumberland, Douglas, Edgar, Moultrie, and Shelby Counties, Ill., on the one hand, and, on the other, points in Arkansas, Indiana, Kansas, Kentucky, Missouri, Oklahoma, and Texas. Harry C. Ames, Jr., 529 Transportation Building, Washington, D.C., 20006, attorney for applicants.

No. MC-FC-67329. By order of November 16, 1964, the Transfer Board approved the transfer to Moritz O. Gochenour, doing business as Gochenour Bus Service, Woodstock, Va., of Certificate in No. MC 116234, issued June 6, 1957, in the name of Alston Richard La Follette, doing business as L. & M. Transportation Service, Winchester, Va., authorizing the transportation of passengers and their baggage, and express and newspapers in the same vehicle with passengers, over regular routes, between Winchester, Va., and Charles Town, W. Va., serving all intermediate points except points on U.S. Highway 11; and between Charles Town, W. Va., and junction U.S. Highway 340 and private road owned by the Charles Town Turf Club (formerly the Charles Town Jockey Club, Inc.), during the authorized racing season of the Charles Town Race Track, W. Va., serving no intermediate points. Linwood C. Major, Jr., 2001 Massachusetts Avenue NW., Washington, D.C., 20036, attorney for applicants.

No. MC-FC 67347. By order of November 17, 1964, the Transfer Board approved the transfer and substitution of Louis L. Grimm, Inc., as applicant in the pending "grandfather-proviso" proceeding, No. MC 54826 Sub 1, in lieu of Louis L. Grimm, seeking a Certificate of Registration under the provisions of section 206(a)(7) of the Act, covering the transportation of property between points in Pennsylvania. Edward M. Larkin, 2508 Grant Building, Pittsburgh, Pa., attorney for applicants.

[SEAL] HAROLD D. MCCOY,
Secretary.

[F.R. Doc. 64-11915; Filed, Nov. 20, 1964; 8:46 a.m.]

FOURTH SECTION APPLICATION FOR RELIEF

NOVEMBER 18, 1964.

Protests to the granting of an application must be prepared in accordance with Rule 1.40 of the general rules of practice (49 CFR 1.40) and filed within 15 days from the date of publication of this notice in the FEDERAL REGISTER.

AGGREGATE-OF-INTERMEDIATES

FSA No. 39407: *Liquid caustic soda from Port Neches, Tex.* Filed by Texas-Louisiana Freight Bureau, agent (No. 522), for interested rail carriers. Rates on liquid caustic soda, in tank carloads, from Port Neches, Tex., to Dallas, Fort Worth and Sherman, Tex.

Grounds for relief: Maintenance of depressed rates published to meet intrastate competition without use of such rates as factors in constructing combination rates.

Tariff: Supplement 21 to Texas-Louisiana Freight Bureau, agent, tariff I.C.C. 998.

By the Commission.

[SEAL] HAROLD D. MCCOY,
Secretary.

[F.R. Doc. 64-11914; Filed, Nov. 20, 1964; 8:46 a.m.]

CUMULATIVE CODIFICATION GUIDE—NOVEMBER

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PART II

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Department of Health, Education, and Welfare

Food and Drug Administration

Certification of Antibiotic and Antibiotic-Containing Drugs

Rules and Regulations

Title 21—FOOD AND DRUGS

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

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

PART 144—ANTIBIOTIC DRUGS; EXEMPTIONS FROM LABELING AND CERTIFICATION REQUIREMENTS

PART 145—ANTIBIOTIC DRUGS; DEFINITIONS AND INTERPRETATIVE STATEMENTS

PART 146—ANTIBIOTIC DRUGS; PROCEDURAL REGULATIONS

PART 148—ANTIBIOTIC DRUGS; LABELING AND PACKAGING REQUIREMENTS

Recodification and Reorganization of General Regulations for the Certification of Antibiotic and Antibiotic-Containing Drugs

Pursuant to section 507 of the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended; 21 U.S.C. 357) and under the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), Parts 146 and 148 are reorganized as indicated below for the following reasons:

1. Elimination of repetitious or duplicated material.

2. Separation and rearrangement of textual material into logical sequences and correlation of related material.

3. Broadening of scope of existing parts and providing for expansion and growth by establishment of new parts.

4. Updating of old material.

The changes effected are principally editorial in nature and the only substantive amendments are made for the purpose of correcting inconsistencies, deletion of obsolete material, or updating of material, where necessary.

The changes effected are as follows:

1. Section 3.29 is revoked since the provisions therein are duplicated by § 121.9.

2. All antibiotic regulations concerning exemptions, with the exception of those specifically cross-referenced and with the exception of §§ 146.9, 146.12, and 146.28 which are revoked, are transferred to new Part 144, in accordance with the following redesignation table:

REDESIGNATION TABLE—PART 144

Old section	*New section*
146.18	144.3
146.19	144.4
146.20	144.5
146.21	144.6
146.22	144.7
146.23	144.8

REDESIGNATION TABLE—PART 144—Continued

Old section	*New section*
146.30	144.9
146.29	144.10
146.27	144.11
146.24	144.14
146.11	144.15
3.15	144.16
146.1(j)	144.23
146.13	144.24
146.25	144.25
146.26	144.26

3. All defining and interpretative antibiotic regulations are removed to a new Part 145, in accordance with the following redesignation table:

REDESIGNATION TABLE—PART 145

Old section	*New section*
146.1, introduction to section	145.1(a)
146.1(e)(3)	145.1(b)
146.1(e)(4)	145.1(d)
146.1(e) (1), (2)	145.1 (e), (f)
146(e)(5)	145.1(g)
146.1(a)(1)–(31)	145.2(a)(1)–(31)
146.1(b)(1)–(33)	145.3(a)(1)–(33)
146.1(d)	145.3(b)
146.1(c) (1), (2)	145.4
146.31	145.31

4. All antibiotic regulations concerning procedural requirements now contained in Part 146 will remain in that part, and all other antibiotic regulations relating solely to procedure are transferred to the new Part 146, in accordance with the following redesignation table:

REDESIGNATION TABLE—PART 146

Old section	*New section*
148.4	146.2(c)
146.2 (c), (d), (e)	146.2 (d), (e), (f)
146.1(f)	146.3(c)
146.3(c)	146.3(d)
146.1(h)	146.3(e)
146.1(g)	146.3(f)
146.1(j)	146.7
148.5	146.8(e)
146.26(d)	146.8(f)
146.8 (e), (f), (g)	146.8 (g), (h), (i)
3.501	146.9
146.7	146.10
146.1(i)	146.11
3.30	146.12

5. All antibiotic regulations concerning labeling and packaging requirements now in Part 148 remain in that part, and the heading to the part is changed. Sections 148.1 and 148.5 are revoked. Section 148.4 is removed to Part 146 as § 146.2(c). Sections 3.504 and 146.10 are combined into one section and transferred to Part 148 as new § 148.4. Section 146.14 is transferred to Part 148 as new § 148.5.

The affected parts read as follows:

PART 144—ANTIBIOTIC DRUGS; EXEMPTIONS FROM LABELING AND CERTIFICATION REQUIREMENTS

Sec.

AUTHORITY: The provisions of this Part 144 issued under sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357.

CROSS REFERENCE: For other regulations in this chapter relating to antibiotic drugs exempted from certification, see also: §§ 146a.24(f), 146a.27(f), 146a.30(f), 146a.37(f), 146a.51(f), 146a.69(f), 146a.88(c), 146a.93(e), 146b.112(f), 146b.115(f), 146b.119(f), 146b.125(b), 146b.129(b), 146c.205(f), 146c.207(b), 146c.219(f), 146c.230(f), 146e.402(f), 146e.423(c), 146e.425(f), 146e.427(b), 146e.431(b).

§ 144.1 [Reserved]

§ 144.2 [Reserved]

§ 144.3 Exemption for labeling.

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a certifiable antibiotic drug which is to be labeled at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from the requirement of section 502(l) of the act if the labeling of each shipping container bears the batch mark of the drug, the number of units per package and the expiration date, and if the person who introduced such shipment or delivery into interstate commerce holds a permit (Antibiotic Form 3) from the Commissioner authorizing shipment for labeling in such establishment.

(b) (1) An application for such a permit shall be in a form specified by the Commissioner and shall give the name and location of the establishment in which such labeling is to be done.

(2) In case the applicant is the operator of such establishment, the application shall include a written agreement signed by him that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801(d) of the act or § 144.8; that he will not remove any of such antibiotic

drug from such establishment unless it complies with section 502(l) of the act or is so exempt, or if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition; and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

(3) In case the applicant is not the operator of such establishment such application shall include or be accompanied by:

(i) A written agreement signed by the applicant that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801(d) of the act or § 144.8; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery; and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such shipment or delivery; and

(ii) A written agreement signed by the operator of such establishment that he will submit a request, supplemental to that of the applicant, for the certification of each batch or portion thereof comprised in any such shipment or delivery received by him unless it is exempt under section 801(d) of the act or § 144.8; that he will specify in his request the number of packages of each size in such shipment or delivery, the date of delivery, the batch mark thereof, and the batch mark he will use therefor; that the batch marks to be used (if different from those of the applicant) will be only those of which the key is specified in this agreement that the expiration date used for the batch will be only that assigned to the manufacturer by certification; that the labeling to be used for such packages will be only that of which specimens are attached to this agreement (including specimens of all brochures and other printed matter, except readily available medical publications, referred to in such labeling); that when any change is made in such key or labeling he will promptly submit to the Commissioner a full statement of such change or, in the case of changed labeling, specimens showing all such changes; that he will not remove any of such antibiotic drug from such establishment unless it complies with section 502(l) of the act or is exempt under section 801(d) of the act or § 144.8 or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records of the disposition of each such shipment and delivery; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition; and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

(4) When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after labeling, from such establishment unless such batch complies with section 502(l) of the act or is exempt under section 801(d) of the act or § 144.8 or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after labeling, from such establishment unless such batch complies with section 502(l) of the act or is exempt under section 801(d) of the act or § 144.8 or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 144.4 Exemption for storage.

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be stored at a warehouse located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such warehouse, from the requirements of section 502(l) of the act if the labeling of each shipping container bears the batch mark of the drug, and if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for storage in such warehouse.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the warehouse in which such drug is to be stored. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will request certification of each batch thereof unless it is exempt under section 801(d) of the act or § 144.3, 144.6, or 144.7, that he will not remove any of such drug from such warehouse unless it complies with section 502(l) of the act or is so exempt or if certification is refused unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such warehouse, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such shipment or delivery; and

(2) A written statement signed by the operator of such warehouse showing that he has adequate facilities for such storage; such statement shall contain an agreement that he will hold each shipment or other delivery of such drug intact, under such conditions as will not cause failure of the drug to comply with the requirements for certification, that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

If the applicant keeps complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug from such warehouse and the name and post-office address of the person to whom such shipment or delivery was made, the agreement to keep records of such disposals, to make such records available, and to afford opportunity for checking their correctness may be included in the applicant's agreement and omitted from that of the operator. When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such warehouse, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such warehouse unless such batch complies with section 502(l) of the act or is exempt under section 801(d) of the act or § 144.3, 144.6, or 144.7, or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such

exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such warehouse, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such warehouse unless such batch complies with section 502(l) of the act or is exempt under section 801(d) of the act or § 144.3, 144.6, or 144.7, or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed, or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 144.5 Exemption for processing.

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of any certifiable antibiotic drug subject to the regulations in this chapter in concentrated aqueous solution which is to be processed at an establishment located elsewhere than at the place of manufacture shall be exempt during the time of introduction into and movement in interestate commerce and the time of holding in such establishment from the requirements of section 502(l) of the act, if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for processing in such establishment, and each package of such solution bears the batch mark of the drug.

(b) An application for such a permit shall be in a form specified by the Commissioner and shall give the name and location of the establishment in which such processing is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, potency, and batch mark of each shipment and other delivery of any such solution to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such shipment or delivery;

(2) A written agreement signed by the operator of such establishment showing that he has adequate facilities for such processing; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the processing is completed that he will request certification of each batch thereof unless it is exempt under section 801(d) of the act or § 144.3, 144.4, 144.6, 144.7, or 144.8, and that he will not remove any of such drug from such establishment unless it complies with section 502(l) of the act or is so exempt.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after processing, from such establishment unless the batch made from such shipment or delivery complies with section 502(l) of the act or is exempt under section 801(d) of the act or § 144.3, 144.4, 144.6, 144.7, or 144.8, or, if certification is refused, unless such shipment or delivery is reprocessed and certified or destroyed within a reasonable time.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after processing, from such establishment unless the batch made from such shipment or delivery complies with section 502(l) of the act or is exempt under section 801 (d) of the act or § 144.3, 144.4, 144.6, 144.7, or 144.8, or, if certification has been refused, unless such shipment or delivery is reprocessed and certified or destroyed within a reasonable time.

§ 144.6 Exemption for repacking.

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be repacked at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment from the requirements of section 502(l) of the act if the labeling of each container bears the batch mark of the drug and the number of units per package, and if the person who introduces such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for repacking in such establishment.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such repacking is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of each shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for such repacking; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the repacking is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or § 144.3, 144.4, 144.7, or 144.8, and that he will not remove any of such drug from such establishment unless it complies with section 502(l) of the act or is returned to him for labeling or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after repacking, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801(d) of the act or § 144.3, 144.4, 144.7, or 144.8, or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after repacking, from such establishment unless such batch complies with section

502(l) of the act or is exempt under section 801(d) of the act or § 144.3, 144.4, 144.7, or 144.8, or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 144.7 Exemption for manufacturing use.

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of any certifiable antibiotic drug subject to the regulations in this chapter that is packed in containers of not less than 10,000,000 units of penicillin or 10 grams each of one of the other antibiotic drugs shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in the establishment where it is so used, from the requirements of section 502(l) of the act, if it conforms to the standards prescribed therefor by the section of the regulations in this chapter which is specifically applicable to such other antibiotic drug, if the label of each container bears the batch mark of the drug, the number of units or grams per package, and the date on which the latest assay of the drug was completed, and if the person who introduced each shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for manufacturing use in such establishment.

(b) An application for such a permit shall be in a form specified by the Commissioner, shall give the name and location of the establishment in which such drug is to be used and shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for the manufacture of such other drug; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof and showing the quantity and batch mark of each batch of such other drug manufactured by him and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after its manufacture is completed that he will request certification of each batch thereof unless it is exempt under section 801(d) of the act or § 144.3, 144.4, 144.6, or 144.8, and that he will not remove any of such drug from such establishment unless it complies with section 502(l) of the act or is so exempt or is returned to him for labeling.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such establishment, prior to its use in the manufacture of another drug, unless it is exempt under section 801(d) of the act.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such establishment, prior to its use in the manufacture of another drug, unless it is exempt under section 801(d) of the act.

§ 144.8 Exemption for investigational use.

A shipment or other delivery of an antibiotic drug shall be exempt from section 502(l) of the act if all the procedures outlined in § 130.3 of this chapter are complied with. For the purposes of this section, the references in § 130.3 of this chapter to "new drug" and "approved new-drug application" shall be deemed to read "antibiotic drug" and "approval for certification or exemption from certification," respectively.

§ 144.9 Exemption of antibiotic drugs for use in teaching, law enforcement, research, and analysis.

Antibiotic drugs subject to section 507 of the act shall be exempt from the requirements of section 502(l) if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use; or in law enforcement; or in research not involving clinical use; or in chemical analysis or physical testing, provided they are to be used only for such instruction, law enforcement, research, analysis, or testing, and provided further that their labels bear the statement "Not for drug use."

§ 144.10 Biological drugs that contain antibiotics.

Biological drugs that contain any certifiable antibiotic drug subject to the regulations in this chapter, and the purpose of the antibiotic is for use only as a preservative and the biological drug is conspicuously so labeled, shall be exempt from the requirements of sections 502(l) and 507 of the act, if such drugs are licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682; 42 U.S.C. 201 et seq.) or under the Virus-Serum-Toxin Act of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.)

§ 144.11 Antibiotics for fish diseases.

Any antibiotic drug subject to the regulations in this chapter intended for use solely in the prevention or treatment of disease in fish and conspicuously so labeled shall be exempt from the requirements of sections 502(l) and 507 of the act if the fish so treated are not intended for human consumption.

§ 144.12 [Reserved]

§ 144.13 [Reserved]

§ 144.14 Antibiotic powders for diagnostic use.

Dry powders of antibiotic substances, with or without suitable buffer substances and diluents, packaged for dispensing and intended for use solely in laboratory procedures in connection with the diagnosis or treatment of disease and conspicuously so labeled shall be exempt from the certification requirements of sections 502(l) and 507 of the act if they comply with all the following conditions:

(a) The potency and moisture content of the antibiotic used in the manufacture of the powder and the moisture content of the powder comply with the standards prescribed for the antibiotic by the specific regulations issued in this chapter.

(b) It is packaged in immediate containers that are tight containers as defined by the U.S.P. Each such container shall contain not less than 10 milligrams.

(c) Each package bears on the label or labeling of its outside wrapper or container and the immediate container the following:

(1) The statement "Diagnostic reagent. For professional use only."

(2) The number of milligrams or grams contained in each immediate container and the potency per milligram.

(3) The batch mark.

(4) The statement "Expiration date _____," the blank being filled in with the date that does not exceed the expiration date authorized for the antibiotic salt by this chapter.

(d) The circular or other labeling within or attached to the package bears directions adequate for the use of such drug.

CROSS-REFERENCES: For tests and methods of assay and certification of antibiotic sensitivity discs for laboratory diagnosis of disease, see §§ 147.1 and 147.2 of this chapter.

§ 144.15 Assay requirements for antibiotic drugs exempted from certification.

(a) Certain antibiotic drugs are exempted by regulations in this chapter from the certification requirements of section 507 of the act if such drugs com-

ply with standards prescribed by such regulations and on condition that the label of each package bears an expiration date which is determined from the date during which the batch was last assayed and released by the manufacturer.

(b) It is the position of the Food and Drug Administration that if each batch of such exempted drugs is not tested by the manufacturer or his agent to determine whether it complies with the standards of identity, strength, quality, and purity prescribed for it, the batch is not exempt from certification and it may be deemed to be misbranded under section 502(l) of the act when in interstate commerce.

§ 144.16 Antibiotic drugs intended for export.

(a) Unless exempted pursuant to section 507(c) of the Federal Food, Drug, and Cosmetic Act, antibiotic drugs consigned to persons engaged in export shipment of the articles are fully subject to the certification requirements of sections 502(l) and 507 of the act. Further, unless exempted pursuant to section 507(d) or section 801(d) of the act, such shipments are required to be labeled in full comformance with the act and regulations promulgated thereunder. In order to qualify for exemption under section 801(d) of the act, the drugs, at the time of introduction into interstate commerce, must be marked for export, must accord to the specifications of the foreign purchaser, and must not be in conflict with the laws of the country to which they are intended for export. The initial shipper has a responsibility to meet all the conditions of section 801(d) if exemption is to be claimed.

(b) Section 144.3 provides exemption from labeling. If the original shipper has an effective exemption permit under the regulations in this Part 144, the exporting firm named in the exemption permit may be allowed to receive and to hold the unlabeled drugs under the exemption until the conditions of section 801(d) are satisfied.

§§ 144.17–144.22 [Reserved]

§ 144.23 Records retention.

At the option of the person having control of records required to be kept by any regulation in this Part 144, photostatic or other permanent reproductions may be substituted for such records after the first 2 years of the holding period.

§ 144.24 Manganese bacitracin medicated animal feed.

Animal feed containing manganese bacitracin powder oral veterinary, with or without added suitable vitamin substances, shall be exempt from the requirements of sections 502(l) and 507 of the act when used in the amounts and for the purposes indicated in § 121.225 of this chapter.

§ 144.25 Antibiotic drugs for use in medicated animal feed (antibiotic medicated feed premixes; antibiotic medicated feed concentrates that must be diluted with feed ingredients before they are fed).

Any certifiable antibiotic drug subject to the regulations in Parts 146a, 146b, 146c, 146d, and 146e of this chapter or any combination of two or more such drugs, with or without those ingredients specified in § 144.26, intended for use solely as an ingredient in the manufacture of animal feed and conspicuously so labeled shall be exempt from the requirements of sections 502(l) and 507 of the act if it complies with the following conditions:

(a) It contains one or more suitable denaturants that make it unfit for human use; and

(b) Its labeling is such that animal feed mixed according to the directions contained therein complies with the requirements of § 144.26.

(c) It contains no substance for which § 144.26 requires exemptions from certification of the medicated feeds in which it is used as an ingredient, unless prior to shipment in commerce:

(1) The manufacturer obtained a permit from the Commissioner issued under the provisions of § 144.7 authorizing shipment for manufacturing use to such establishment; or

(2) The operator of the establishment where such drug is to be mixed or diluted meets all the conditions for exemption from certification of the medicated feed established by the applicable provisions of § 144.26, including when required, the submission to, and acceptance by the Commissioner of adequate information of the kind required by § 146.10 of this chapter, to establish the safety and efficacy of the finished medicated feed and to guarantee its identity, strength, quality, and purity.

§ 144.26 Animal feed containing certifiable antibiotic drugs.

Animal feed containing penicillin, streptomycin, chlortetracycline, bacitracin, feed grade zinc bacitracin, or bacitracin methylene disalicylate or any permitted combination of two or more of these, with or without added suitable vitamin substances, shall be exempt from the requirements of sections 502(l) and 507 of the act when used in accordance with § 121.225 of this chapter, and under the conditions set forth in any one of the following paragraphs of this section:

(a) It is intended for use solely as an animal feeding supplement, it is conspicuously so labeled, and it is manufactured with or without one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(1) Arsanilic acid: Not less than 0.005 percent and not more than 0.01 percent.

(2) Sodium arsanilate: Not less than 0.005 percent and not more than 0.01 percent.

(3) 3-Nitro-4-hydroxyphenol arsonic acid: Not less than 0.0025 percent and not more than 0.0075 percent.

(4) Furazolidone: 0.00083 percent.

(5) Furazolidone 0.00083 percent with or without nitrofurazone 0.0056 percent and/or 3-nitro-4-hydroxyphenylarsonic acid not less than 0.0025 percent and not more than 0.0075 percent.

(b) It is intended for use in the conditions set forth in any one of the following subparagraphs of this paragraph:

(1) It is intended for use solely in the prevention of coccidiosis outbreaks in poultry flocks, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) Sulfaquinoxaline: Not less than 0.0125 percent (or if it is intended solely for the prevention of the intestinal coccidia *E. acervalina* in poultry laying flocks, not less than 0.005 percent) and not more than 0.025 percent.

(ii) Nitrophenide: Not less than 0.0125 percent and not more than 0.025 percent.

(iii) Nitrofurazone: 0.0056 percent.

(iv) N^4-acetyl-N^1-(4-nitrophenyl) sulfanilamide 0.03 percent and 3-nitro-4-hydroxyphenylarsonic acid 0.009 percent.

(v) Furazolidone 0.00083 percent, nitrofurazone 0.0056 percent, with or without 3-nitro-4-hydroxyphenylarsonic acid not less than 0.0025 percent and not more than 0.0075 percent.

(2) It is intended for use solely in the control of coccidiosis outbreaks in poultry flocks, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) Sulfaquinoxaline: Not less than 0.033 percent and not more than 0.10 percent.

(ii) Nitrophenide: 0.05 percent.

(iii) Nitrofurazone: 0.0112 percent.

(3) It is intended for use solely in the prevention of outbreaks of histomoniasis ("blackhead") in turkey flocks, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) 2-Amino-5-nitrothiazole: 0.05 percent.

(ii) 4-Nitrophenylarsonic acid: 0.025 percent.

(4) It is intended for use solely in the control of outbreaks of histomoniasis ("blackhead") in turkey flocks, its labeling bears adequate directions and warnings for such use, and it contains 2-amino-5-nitrothiazole in a quantity, by weight of feed, of 0.10 percent.

(5) It is intended for use solely as an anthelmintic for poultry or swine, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) Di-*N*-butyl tin dilaurate 0.07 percent, nicotine 0.03 percent, and phenothiazine 0.29 percent.

(ii) Nicotine 0.067 percent, phenothiazine 0.60 percent, and 2,2'-dihydroxy-5,5'-dichlorodiphenylmethane 0.28 percent.

(iii) Phenothiazine, not less than 0.3 percent and not more than 1.0 percent, and nicotine, not less than 0.03 percent and not more than 0.07 percent.

(iv) Phenothiazine, not less than 0.3 percent and not more than 1.0 percent.

(v) Nicotine, not less than 0.03 percent and not more than 0.07 percent.

(vi) Sodium fluoride 0.3 percent and sodium sulfate 2.0 percent.

(vii) Cadmium anthranilate, 0.044 percent.

(viii) Cadmium oxide, 0.015 percent.

(ix) Sodium fluoride, not less than 0.5 percent and not more than 1.0 percent.

(x) Piperazine dihydrochloride, not less than 0.18 percent and not more than 0.72 percent (piperazine base 0.1 percent to 0.4 percent).

(xi) Piperazine phosphate monohydrate, not less than 0.23 percent and not more than 0.92 percent (piperazine base 0.1 percent to 0.4 percent).

(xii) Piperazine sulfate, not less than 0.21 percent and not more than 0.85 percent (piperazine base 0.1 percent to 0.4 percent).

(xiii) Piperazine monohydrochloride, not less than 0.13 percent and not more than 0.52 percent (piperazine base 0.1 percent to 0.4 percent).

(xiv) Di-*N*-butyl tin dilaurate 0.07 percent, piperazine sulfate 0.12 percent and phenothiazine 0.29 percent.

(6) It is intended for use solely in the prevention of chronic respiratory disease (air-sac infection) and hexamitiasis in poultry, bacterial swine enteritis, and/or bacterial calf diarrhea; its labeling bears adequate directions and warnings for such use, and it contains, per ton of feed, not less than 50 grams of chlortetracycline or oxytetracycline or a combination of such drugs; or, if it is intended solely for use as an aid in the prevention of bacterial swine enteritis, it contains, per ton of feed, not less than 45 grams nor more than 90 grams of penicillin and streptomycin in a combination containing 16.7 percent penicillin. If it contains not less than 100 grams of chlortetracycline or oxytetracycline or a combination of such drugs per ton of feed, it may also be represented for use as an aid in the prevention of synovitis in poultry. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified one, but only one, of the ingredients prescribed by paragraph (a) of this section.

(7) (i) It is intended for use solely as a treatment for complicated, chronic respiratory disease (air-sac infection), infectious sinusitis, blue comb (nonspecific infectious enteritis, mud fever), and hexamitiasis in poultry, and/or bacterial swine enteritis; its labeling contains adequate directions and warnings for such use; and it contains, per ton of feed, not less than 100 grams of chlortetracycline or oxytetracycline or a combination of such drugs or not less than 90 grams nor more than 180 grams of penicillin and streptomycin in a combination containing 16.7 percent penicillin. If it contains not less than 200 grams of chlortetracycline or oxytetracycline or a combination of such drugs per ton of feed, it may also be represented for use as an aid in the control of synovitis in poultry. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it is intended for use solely in poultry, it may contain 0.1 percent of para-aminobenzoic acid or the sodium or potassium salt of para-aminobenzoic acid; or if it is intended for continuation of coccidiosis prevention it shall contain, in the amount specified, one of the ingredients prescribed by subparagraph (1) of this paragraph. If it is intended for use solely in the treatment of the diseases of chickens described in this subparagraph, it contains, per ton of feed, not less than 100 grams and not more than 200 grams of chlortetracycline and it contains not less than 0.4 percent and not more than 0.8 percent of dietary calcium, then representations may be made in its labeling to the effect that the reduced amount of calcium aids in increasing the concentrations of the antibiotic in the blood of treated birds; the labeling of such medicated feed shall include that required by § 121.208 of this chapter. If it is intended for use solely as a treatment for bacterial swine enteritis, it may contain, per ton of feed, not less than 90 grams nor more than 270 grams of penicillin and streptomycin in a combination containing 16.7 percent penicillin, provided that its labeling bears a warning that the feed is not be be used for more than 14 days.

(ii) It is also intended for use in the prevention and control of coccidiosis in chickens caused by *E. tenella* and *E. necatrix;* its labeling bears adequate directions and warnings for such use (including the directions and warnings required by subdivision (i) of this subparagraph), and it contains, per ton of feed, 200 grams of chlortetracycline and 0.8 percent of dietary calcium.

(iii) It is also intended for use in the treatment of coccidiosis in chickens caused by *E. tenella* and *E. necatrix;* its labeling bears adequate directions and warnings for such use (including the directions and warnings required by subdivision (i) of this subparagraph); and it contains, per ton of feed, 200 grams of chlortetracycline and 0.4 percent to 0.55 percent of dietary calcium.

(8) It is intended for use solely in the prevention of coccidiosis and hexamitiasis outbreaks in turkey flocks, its labeling bears adequate directions and warnings for such use, and it contains di-*N*-butyl tin dilaurate in a quantity, by weight of feed, of 0.0375 percent.

(9) It is intended for use solely in the prevention of chronic respiratory disease (air-sac infection), infectious sinusitis, and blue comb (nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use, and it contains, per ton of feed, the equivalent of not less than 50 grams and not more than 100 grams of bacitracin, or not less than 50 grams and not more than 100 grams of penicillin, or not less than 50 grams and not more than 100 grams of penicillin and bacitracin in a combination containing not less than 50 percent nor more than 75 percent of bacitracin. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section.

(10) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection), infections sinusitis, and blue comb (nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, the equivalent of either 100 grams of penicillin, or not less than 100 grams and not more than 500 grams of bacitracin (as bacitracin or zinc bacitracin), or not less than 100 grams and not more than 200 grams of bacitracin (as bacitracin methylene disalicylate), or not less than 100 grams and not more than 500 grams of penicillin and bacitracin (as bacitracin or zinc bacitracin) in a combination containing not less than 50 percent nor more than 75 percent of bacitracin but in no case containing more than 125 grams of penicillin, or not less than 100 grams and not more than 200 grams of penicillin and bacitracin (as bacitracin methylene disalicylate) in a combination containing not less than 25 percent of penicillin nor less than 50 percent of bacitracin; except that, if it is intended for the treatment of bacterial swine enteritis, it contains, per ton of feed, either 100 grams of bacitracin (as bacitracin, zinc bacitracin, or bacitracin methylene disalicylate), or 100 grams of a combination of penicillin and bacitracin (as bacitracin, zinc bacitracin, or bacitracin methylene disalicylate), containing not less than 50 percent nor more than 75 percent of bacitracin. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section; *Provided, however,* That the level of antibiotic or antibiotic combination present is not greater than the minimum amount specified therefor in this subparagraph.

(11) It is intended for use solely as a treatment for bacterial swine enteritis caused by *Salmonella choleraesuis,* its labeling bears adequate directions and warnings for such use, and it contains nitrofurazone in a quantity, by weight of feed, of 0.056 percent.

(12) It is intended for use solely in the prevention of coccidiosis, chronic respiratory disease (air-sac infection) and hexamitiasis in poultry; its labeling bears adequate directions and warnings for such use; and it contains, in the amount specified, one of the ingredients prescribed by subparagraph (1) of this paragraph and not less than 50 grams of chlortetracycline per ton of feed. When intended for such uses it may also contain oxytetracycline in a quantity not less than 50 grams per ton of feed.

(13) It is intended for use solely in the prevention or treatment of chronic respiratory disease (air-sac infection) and infectious sinusitis in poultry; its labeling bears adequate directions and warnings for such use; and it contains

not less than 0.1 percent para-aminobenzoic acid or the sodium or potassium salt of para-aminobenzoic acid.

(14) It is intended solely as an aid in the prevention and control of losses due to low-grade bacterial enteritis in mink; its labeling bears adequate directions and warnings for such use; and it contains not less than 5.7 grams of chlortetracycline, 1.0 gram of bacitracin, and 0.75 gram of penicillin (with or without oxytetracycline) per ton of feed.

(15) It is intended for use solely as an aid in the prevention or treatment or to lessen the morbidity in poultry in outbreaks of fowl typhoid, pullorum, the paratyphoids, infectious arthritis due to a filterable agent, histomoniasis (blackhead), hexamitiasis, quail disease (ulcerated enteritis), paracolon infection, avian infectious hepatitis, and coccidiosis, its labeling bears adequate directions and warnings for such use; and it contains the following quantities of furazolidone, by weight of feed, for the conditions indicated:

(i) For the prevention of fowl typhoid, pullorum, and the paratyphoids in birds older than 2 weeks: 0.0055 percent.

(ii) For the prevention of the diseases listed in subdivision (i) of this subparagraph in birds younger than 2 weeks, and for the treatment of these same conditions in birds regardless of age: 0.011 percent.

(iii) For the prevention of histomoniasis (blackhead), paracolon infection, and infectious arthritis due to a filterable agent, and for the prevention and treatment of hexamitiasis and quail disease (ulcerative enteritis): 0.011 percent.

(iv) For the treatment of histomoniasis (blackhead), paracolon infection, and avian infectious hepatitis of chickens, and to lessen the morbidity in outbreaks of infectious arthritis due to a filterable agent: 0.022 percent.

(v) For the prevention of coccidiosis in chickens: 0.0055 percent.

(vi) For the control of coccidiosis in chickens: 0.011 percent.

(16) (i) It is intended for use solely in the prevention of chronic respiratory disease (air-sac infection); its labeling bears adequate directions and warnings for such use; and it contains not less than 50 grams of chlortetracycline or oxytetracycline or a combination of these two drugs per ton of feed. When intended for such use, it may also contain the equivalent of not less than 50 grams of bacitracin per ton of feed.

(ii) It is also intended for the prevention or treatment of the diseases of poultry specified in subparagraph (15) of this paragraph; it contains one of the ingredients in the amount and under the conditions set forth in subdivision (i) of this subparagraph; and it contains furazolidone in the amount specified in subparagraph (15) of this paragraph.

(17) (i) It is intended for use solely as an aid in the treatment of chronic respiratory disease (air-sac infection), infectious sinusitis, blue comb (nonspecific infectious enteritis, mud fever) in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 100 grams of chlortetracycline or oxytetracycline or a combination of these two drugs per ton of feed. When intended for such use, it may also contain the equivalent of not less than 100 grams of bacitracin per ton of feed.

(ii) It is also intended for the prevention or treatment of the diseases of poultry specified in subparagraph (15) of this paragraph; it contains one of the ingredients in the amount and under the conditions set forth in subdivision (i) of this subparagraph; and it contains furazolidone in the amount specified in subparagraph (15) of this paragraph.

(18) (i) It is intended for use solely in the prevention of outbreaks of coccidiosis in poultry flocks, and it contains nicarbazin (4,4'-dinitrocarbanilide complex with 2-hydroxy-4-6-dimethylpyrimidine) in a quantity, by weight of feed, of not less than 0.01 percent and not more than 0.02 percent, or arsenosobenzene in a quantity, by weight of feed, of 0.002 percent, or 2,4-diamino-5-(*p*-chlorophenyl)-6-ethylpyrimidine in a quantity, by weight of feed, of 0.00075 percent and sulfaquinoxaline in a quantity, by weight of feed, of 0.0075 percent, or 2,2'-dihydroxy-3,3',5,5'-tetrachlorodiphenyl sulfide (bithionol) 0.05 percent and 4,6-diamino-1-(4-methylmercaptophenyl)-1,2-dihydro-2,2-dimethyl-1,3,5-triazine hydrochloride (methiotriazamine) 0.01 percent; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug or the methods used in its manufacturing, processing, or packaging or the facilities and controls used for such manufacturing, processing, or packaging, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information describing such proposed changes, and such amendment has been accepted by the Commissioner.

(ii) It is also intended for the prevention or treatment of the diseases of poultry specified in subparagraphs (6) and (7) and/or (9) and (10) or (16) and (17) of this paragraph, it contains one of the ingredients in the amount and under the conditions set forth in subdivision (i) of this subparagraph, and it contains the ingredients in the amounts specified in subparagraphs (6) and (7) and/or (9) and (10) or (16) and (17) of this paragraph, except that the coccidiostat shall be only one of those specified in subdivision (i) of this subparagraph.

(iii) It is intended for use in the diseases specified in subdivisions (i), (ii) and (iv) of this subparagraph, it contains ingredients in the amounts and under the conditions specified in those subdivisions, and it contains one, but only one, of the ingredients prescribed by paragraph (a) of this section and in the amounts specified in that paragraph.

(iv) It is also intended for use as an adjunct in reducing the tapeworm and large roundworm burden of chickens so treated, it contains 2,2'-dihydroxy-3,3',5,5'-tetrachlorodiphenyl sulfide (bithionol), and 4,6-diamino-1-(4-methylmercaptophenyl)-1,2-dihydro-2,2-dimethyl-1,3,5-triazine hydrochloride (methiotriazamine), in the amounts and under the conditions set forth in subdivision (i) of this subparagraph.

(19) (i) It is intended for use solely in the prevention or control of outbreaks of histomoniasis (blackhead) in turkey flocks, and it contains 2-acetylamino-5-nitrothiazole in a quantity, by weight of feed, of 0.015 percent if intended for the prevention of the disease, or 0.05 percent if intended for the control of the disease, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition of such drug, or the methods used in, and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

(ii) It is intended for use in the disease specified in subdivision (i) of this subparagraph; it contains the ingredient in the amount and under the conditions specified in that subdivision; and it contains one, but only one, of the ingredients prescribed by paragraph (a) of this section and in the amounts specified in that paragraph.

(20) It is intended as an aid in stimulating growth, the prevention of coccidiosis, large roundworms and tapeworms in chickens and turkeys and the prevention of hexamitiasis in turkeys, and it contains in a quantity, by weight of feed, acetyl (*p*-nitrophenyl) sulfanilamide 0.03 percent, dibutyl tin dilaurate 0.02 percent, dinitrodiphenylsulfonylethylenediamine 0.02 percent, and 3-nitro-4-hydroxyphenylarsonic acid 0.0075 percent.

(21) (i) It is intended for promoting distribution of fat in chickens and turkeys; its labeling bears adequate directions and warnings for such use, including a warning against its use in laying hens and a warning that its use must be discontinued 24 hours before the treated chickens or turkeys are slaughtered for human consumption; and it contains dienestrol diacetate in a quantity, by weight of feed, of not less than 0.0023 percent and not more than 0.007 percent; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug or the methods used in and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the

Commissioner, in triplicate, amended information describing such proposed changes, and such amendment has been accepted by the Commissioner.

(ii) It is also intended for the prevention or treatment of the diseases of poultry specified in subparagraphs (6) and (7) of this paragraph, it contains dienestrol diacetate in the amounts and under the conditions set forth in subdivision (i) of this subparagraph, and it contains the antibiotics in the amounts specified in subparagraphs (6) and (7) of this paragraph.

(iii) It is also intended for continuation of coccidiosis prevention in poultry, it contains dienestrol diacetate in the amounts and under the conditions set forth in subdivision (i) of this subparagraph, and it contains one, but only one, of the ingredients prescribed by subparagraph (1) of this paragraph and in the amounts specified in that subparagraph, or it contains one, but only one, of the coccidiostats prescribed by subparagraph (18) of this paragraph, and in the amounts specified in that subparagraph.

(iv) It is also intended for use in the prevention of outbreaks of histomoniasis (blackhead) in turkey flocks, it contains dienestrol diacetate in the amounts and under the conditions set forth in subdivision (i) of this paragraph, and it contains one, but only one, of the ingredients prescribed by subparagraph (3) of this paragraph and in the amounts specified in that subparagraph.

(v) It is also intended for the prevention or treatment of the diseases of poultry specified in subparagraph (15) of this paragraph, it contains dienestrol diacetate in the amounts and under the conditions set forth in subdivision (i) of this subparagraph, and it contains furazolidone in the amounts specified in subparagraph (15) of this paragraph.

(vi) It is intended for use in the diseases specified in subdivisions (i), (ii), (iii), (iv) and (v), of this subparagraph, it contains ingredients in the amounts and under the conditions specified in those subdivisions, and it contains one, but only one, of the ingredients prescribed by paragraph (a) of this section, and in the amounts specified in that paragraph. If it contains one of the arsenic compounds prescribed in paragraph (a) of this section, its labeling must bear a warning that it must be discontinued 5 days (instead of 24 hours as required in this subparagraph) before the treated chickens or turkeys are slaughtered for human consumption.

(22) (i) It is intended for use solely in the control of outbreaks of coccidiosis in poultry flocks and it contains in a quantity, by weight of feed, not less than 0.003 percent and not more than 0.006 percent of 2,4-diamino-5-(*p*-chlorophenyl)-6-ethylpyrimidine and not less than 0.01 percent and not more than 0.02 percent of sulfaquinoxaline, and there has been submitted to the Commissioner, in triplicate, the information referred to in § 146.10 of this chapter, as well as any additional information necessary to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug or the methods used in its manufacturing, processing, or repackaging, or the facilities and controls used for such manufacturing, processing, or repackaging, unless the person who obtains the exemption has submitted to the Commissioner, in triplicate, amended information describing such proposed changes and such amendment has been accepted by the Commissioner.

(ii) It is intended for use in the disease specified in subdivision (i) of this subparagraph, it contains the ingredients in the amounts and under the conditions specified in that subdivision, and it contains one, but only one, of the ingredients prescribed by paragraph (a) of this section and in the amounts specified in that paragraph.

(23) It is intended for use solely as an aid in the reduction of losses due to enterotoxemia in sheep; its labeling bears adequate directions and warnings for such use; and it contains not less than 20 grams of chlortetracycline per ton of feed.

(24) It is intended for use in the maintenance of weight gains of swine in the presence of atrophic rhinitis or as an aid in reducing the incidence of cervical abscesses in swine; its labeling bears adequate directions and warnings for such use; and it contains not less than 50 grams of chlortetracycline per ton of feed.

(25) It is a medicated cattle feed containing chlortetracycline in the amounts and for the purposes indicated in §121.-208 of this chapter, and its labeling bears adequate directions and warnings for such use.

(26) (i) It is intended for use solely for accelerating weight gains in beef cattle, and it contains a quantity of diethylstilbestrol adequate to provide not more than 10 milligrams per head per day when fed in accordance with the directions for use that accompany the feed, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in §146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug or the methods used in its manufacturing, processing, packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information describing such proposed changes, and such amendment has been accepted by the Commissioner.

(ii) It is also intended for the prevention or treatment of the diseases specified in subparagraph (25) of this paragraph, it contains diethylstilbestrol in the amount and under the conditions set forth in subdivision (i) of this subparagraph, and it contains the antibiotic in the amount specified in subparagraph (25) of this paragraph.

(27) It is intended for use as an aid in maintaining or increasing egg production, hatchability of eggs, prevention of early mortality of chicks when due to organisms that are sensitive to chlortetracycline, and for improving feed efficiency as related to egg production; its labeling bears adequate directions and warnings for such use; and it contains not less than 50 grams of chlortetracycline per ton of feed, except that if it is intended for use in the presence of disease outbreaks it shall contain not less than 100 grams of chlortetracycline per ton of feed.

(28) It is intended for use solely as an aid in the prevention or control of outbreaks of histomoniasis (blackhead) in poultry flocks, and it contains carbasone in a quantity, by weight of feed, of not less than 0.05 percent and not more than 0.1 percent (except that if it is intended for prevention of histomoniasis in turkey flocks it contains not less than 0.0375 percent) and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition of such drug, or the methods used in and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

(29) It is intended for use solely as an an aid in reducing the incidence of bacterial diarrhea in laboratory mice; its labeling bears adequate directions and warnings for such use; and it contains not less than 100 grams of chlortetracycline per ton of feed.

(30) It is intended for use as an aid in maintaining or increasing egg production of chickens, hatchability of eggs, prevention of early mortality of chicks when due to organisms that are sensitive to streptomycin and penicillin, and for improving feed efficiency of chickens or turkeys; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, not less than 22.5 grams and not more than 50 grams of penicillin and streptomycin in a combination containing 16.7 percent penicillin, except that if it is intended for use in the presence of disease as an aid in maintaining or increasing hatchability of eggs or for the prevention of early mortality of chicks, it contains 90 grams per ton of fed of penicillin and streptomycin in a combination containing 16.7 percent penicillin.

(31) It is intended for use in nursing sows to stimulate milk flow; it contains 100 milligrams of iodinated casein per pound; and its labeling bears information that it is to be administered as the complete ration for 3 days before farrowing and until pigs are weaned. It may also be intended for use in the prevention or treatment of bacterial swine enteritis if it contains the antibiotics in the amounts prescribed by this section for that disease.

(32) (i) It is intended for use as an aid in the control of infestation of large roundworms (*Ascaris suis*), nodular worm (*Oesophagostemum dentatum*), and whipworm (*Trichuris suis*) in swine; its labeling bears adequate directions and warnings for such use, including a warning that its use must be discontinued 48 hours before the treated swine are slaughtered for human consumption. If it is a complete feed it contains 6,000 units (6 milligrams) of hygromycin B (produced by the growth of *Streptomyces hygroscopicus*) per pound, or if it is a hygromycin B feed supplement or premix it contains not more than 8,000,000 units (8 grams) of hygromycin B per pound. It contains less than 50 grams of antibiotics per ton of finished feed. If it is a hygromycin B feed supplement or premix and it contains more than 8,000,000 units of hygromycin B per pound, it shall be exempt from certification only if there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. Such exemption shall expire at the beginning of any act changing the composition or labeling of such drug or the methods used in its manufacturing, processing, or packaging, or the facilities and controls used for such manufacturing, processing, or packaging unless the person who obtained the exemption has submitted to the Commissioner (in triplicate) amended information describing such proposed changes, and such amendment has been accepted by the Commissioner. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it contains one of the arsenic compounds prescribed in such paragraph, its labeling must bear a warning that it must be discontinued 5 days (in lieu of 48 hours as required in this subparagraph) before the treated swine are slaughtered for human consumption.

(ii) It is also intended for the prevention or treatment of bacterial swine enteritis as specified in subparagraphs (9) and (10) of this paragraph; it contains hygromycin B in the amounts and under the conditions set forth in subdivision (i) of this subparagraph; and it contains the drugs in the amount specified in subparagraphs (9) and (10) of this paragraph. If it contains one of the arsenic compounds prescribed in paragraph (a) of this section, its labeling must bear the warning specified in subdivision (i) of this subparagraph.

(iii) It is also intended for the prevention and treatment of bacterial swine enteritis, it contains hygromycin B in the amounts and under the conditions set forth in subdivision (i) of this subparagraph, and it contains penicillin and streptomycin in the amounts specified in subparagraphs (6) and (7) of this paragraph. If it contains one of the arsenic compounds prescribed in paragraph (a) of this section, its labeling must bear the warning specified in subdivision (i) of this subparagraph.

(iv) It is also intended for the prevention and treatment of bacterial swine enteritis, for the maintenance of weight gains of swine in the presence of atrophic rhinitis and for reducing the incidence of cervical abscesses in swine, it contains hygromycin B in the amounts and under the conditions set forth in subdivision (i) of this subparagraph, and it contains, per pound of feed, 0.025 gram (50 grams per ton), of the chlortetracycline; except that if it is intended for use in the treatment of bacterial swine enteritis it shall contain, per pound of feed, 0.05 gram (100 grams per ton) of chlortetracycline.

(33) It is intended for use as an aid in reducing the incidence and severity of bloat in cattle on legume pastures; it contains a quantity of procaine penicillin that, when used as directed in the labeling, is sufficient to furnish each treated bovine animal not less than 75,000 units as a single daily dose; and, if the drug supplement used to prepare the medicated feed contains more than 2 percent moisture, its manufacturer has submitted to the Commissioner information adequate to prove its stability for 6 months under customary conditions of purchase and use.

(34) It is intended for use as an aid in the reduction of bacterial diarrhea in dairy cattle or as an aid in reduction of losses due to respiratory infection (infectious rhinotracheitis—shipping fever complex) or as an aid in the prevention of foot rot in cattle; its labeling bears adequate directions and warnings for such uses; and it contains the following quantities of chlortetracycline, by weight of feed, for the conditions indicated:

(i) For the prevention of foot rot and as an aid in the reduction of bacterial diarrhea in dairy cattle: 0.1 milligram per pound of body weight per day.

(ii) As an aid in reduction of losses due to respiratory infection (infectious rhinotracheitis—shipping fever complex) in dairy cattle: 0.1 milligram per pound of body weight per day, except that if it is intended for use for more than 30 days it may contain chlortetracycline, in a quantity by weight of feed to provide 70 milligrams per head per day.

(35) It is intended for use solely as an aid in the prevention of coccidiosis and as an aid in stimulating growth in chicken flocks; its labeling bears adequate directions and warnings for such use, including a warning against its use in laying hens and a warning that its use must be discontinued 5 days before the treated chickens are slaughtered for human consumption; and it contains in a quantity, by weight of feed, 0.03 percent acetyl (paranitrophenyl) sulfanilamide, 0.025 percent 3,5-dinitrobenzamide, and 0.005 percent 3-nitro-4-hydroxyphenylarsonic acid; it contains less than 50 grams of antibiotics per ton of feed; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition of such drug, or the methods used in, and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

(36) It is intended for use solely as an aid in stimulating growth in chickens and turkeys and as an aid in the prevention of outbreaks of histomoniasis (blackhead) in chickens and turkeys and hexamitiasis in turkeys; its labeling bears adequate directions and warnings for such use, including a warning against its use in laying hens and a warning that its use must be discontinued 24 hours before the treated chickens or turkeys are slaughtered for human consumption; and it contains nithiazide (1-ethyl-3-(5-nitro-2-thiazolyl) urea) in a quantity, by weight of feed, of not less than 0.0125 percent and not more than 0.04 percent; it contains less than 50 grams of antibiotics per ton of feed; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug or the methods used in and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information describing such proposed changes, and such amendment has been accepted by the Commissioner. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it contains one of the arsenic compounds prescribed in paragraph (a) of this section, its labeling must bear a warning that it must be discontinued 5 days (instead of 24 hours as required in this subparagraph) before the treated chickens or turkeys are slaughtered for human consumption.

(37) It is intended for use solely in the prevention of outbreaks of coccidiosis and as an aid in stimulating growth in chicken flocks; its labeling bears adequate directions and warnings for such use, including a warning against its use in laying hens and a warning that its use must be discontinued 4 days before the treated chickens are slaughtered for human consumption; and it contains glycarbylamide (4,5-imidazole-dicarboxamide) in a quantity, by weight of feed, of not less than 0.002 percent and not more than 0.006 percent; it contains less than 50 grams of antibiotics per ton of feed; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the

safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition of such drug, or the methods used in, and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it contains one of the arsenic compounds prescribed in such paragraph, its labeling shall bear a warning that it must be discontinued 5 days (in lieu of 4 days as required in this subparagraph) before the treated chickens are slaughtered for human consumption.

(38) It is intended for use solely for accelerating weight gains in sheep; its labeling bears adequate directions and warnings for such use, including a warning that its use must be discontinued 48 hours before the treated animals are slaughtered for human consumption; it contains a quantity of diethylstilbestrol adequate to provide not more than 2 milligrams per head per day when fed in accordance with the directions for use that accompany the feed; it contains less than 50 grams of antibiotics per ton of feed; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug, or the methods used in its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information describing such proposed changes, and such amendment has been accepted by the Commissioner.

(39) It is intended for use solely as an aid in the prevention or treatment of fowl typhoid, paratyphoid, and pullorum disease and as an aid in stimulating growth in poultry flocks; its labeling bears adequate directions and warnings for such use, including a warning against its use in laying hens and a warning that its use must be discontinued 48 hours before the treated animals are slaughtered for human consumption; and it contains 3,5-dinitrobenzamide in a quantity, by weight of feed, of not less than 0.075 percent and not more than 0.15 percent; it contains less than 50 grams of antibiotics per ton of feed; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug, or the methods used in and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it contains one of the arsenic compounds prescribed in paragraph (a) of this section, its labeling must bear a warning that it must be discontinued 5 days (in lieu of 48 hours as required in this subparagraph) before the treated chickens or turkeys are slaughtered for human consumption.

(40) It is intended as an aid in maintaining or increasing egg production, hatchability of eggs, reduction of the effects of stress, prevention of early mortality of chicks, and reduction of the effects of diseases when due to organisms that are sensitive to bacitracin or to a mixture of bacitracin and penicillin, for maintaining appetite and for improving feed efficiency as related to egg production; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, the equivalent of 50 grams of bacitracin or a mixture of 37.5 grams of bacitracin and 12.5 grams of penicillin when fed during the first 4 to 6 weeks of egg production, and not less than the equivalent of 10 grams of bacitracin or a mixture of 7.5 grams of bacitracin and 2.5 grams of penicillin when fed during the remainder of the laying period; except that if it is intended for use to increase egg hatchability or prevention of early mortality of chicks or for use in the presence of disease outbreaks or during periods of stress, it shall contain, per ton of feed, the equivalent of 100 grams of bacitracin or a mixture of 75 grams of bacitracin and 25 grams of penicillin, and except that if it is a starter ration for chicks for the purpose of preventing early mortality of chicks due to susceptible organisms, it may contain, per ton of feed, 100 grams to 500 grams of a combination of penicillin and bacitracin (as bacitracin or zinc bacitracin) containing not less than 50 percent and not more than 75 percent of bacitracin, but in no case more than 125 grams of penicillin.

(41) (i) It is intended for use as an aid in reducing the spread of leptospirosis in swine; it contains 200 grams of chlortetracycline per ton of feed; and its labeling bears information that it is to be administered continuously.

(ii) It is intended for use solely as an aid in reducing the shedding of leptospirae in swine and as an aid in reducing abortion rate and mortality of newborn pigs in the presence of leptospirosis; it contains 400 grams of chlortetracycline per ton of feed; and its labeling bears information that it is to be administered to the animals for 14 days.

(42) It is a medicated chicken, turkey, and swine feed containing certifiable antibiotics and nystatin in the amounts and for the purposes indicated in § 121.220 of this chapter; its labeling bears adequate directions and warnings for such use; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition of such drug, or the methods used in, and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

(43) It is intended for use solely as an aid in reducing the incidence of vibrionic abortion in breeding sheep; its labeling bears adequate directions and warnings for such use, including information that it is to be administered continuously during pregnancy; and it contains chlortetracycline in a quantity that, when administered as directed in its labeling, will provide a total daily dose of 80 milligrams per animal.

(44) It is a medicated chicken or turkey feed containing antibiotics and amprolium, with or without arsanilic acid, in the amounts and for the purposes indicated in § 121.210 of this chapter, and its labeling bears adequate directions and warnings for such use; *Provided, however,* That such medicated complete feed has been prepared from a concentrated amprolium-antibiotic medicated feed that contained not more than 0.05 percent amprolium. If the complete medicated feed is prepared from a product of amprolium that contains more than 0.05 percent of the drug, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug, or the methods used in and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtains the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner. Both concentrates and finished poultry feed containing amprolium must comply with all the requirements of § 121.210 of this chapter, including labeling.

(45) It is a medicated chicken or turkey feed containing antibiotics and zoalene, with or without arsanilic acid, in the amounts and for the purposes indicated in § 121.207 of this chapter; *Provided, however,* That such medicated complete feed has been prepared from a concentrated zoalene-antibiotic medicated feed that contained not more than

0.0375 percent zoalene. If the complete medicated feed is prepared from a product of zoalene that contains more than 0.0375 percent zoalene, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug, or the methods used in and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtains the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner. Both concentrates and complete poultry feed containing zoalene must comply with all the requirements of § 121.207 of this chapter, including labeling.

(46) It is a mink feed containing chlortetracycline, in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

(47) It is a pheasant feed containing bacitracin, zinc bacitracin, or bacitracin methylene disalicylate and penicillin, in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

(48) It is a quail feed containing bacitracin and penicillin, in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

(49) It is a medicated chicken or turkey feed containing antibiotics and reserpine in the amounts and for the purposes indicated in § 121.205 of this chapter; its labeling bears adequate directions and warnings for such use; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition of such drug, or the methods used in, and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

(50) It is a medicated chicken feed containing antibiotics and hygromycin B in the amounts and for the purposes indicated in § 121.213 of this chapter, and its labeling bears adequate directions and warnings for such use: *Provided, however,* That such medicated complete feed has been prepared from a feed additive concentrate that contains not more than 32 grams of hygromycin B per ton. If the medicated feed is prepared from a feed additive concentrate containing more than 32 grams of hygromycin B per ton, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug, or the materials used in, and the facilities and controls used for, its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

(51) It is a medicated chicken or turkey feed containing bacitracin, bacitracin methylene disalicylate, or zinc bacitracin or a combination of one of these with penicillin, in the amounts and for the purposes indicated in §§ 121.232, 121.233, and 121.252 of this chapter, and its labeling bears adequate directions and warnings for such use.

(52) It is a cattle feed containing zinc bacitracin, with or without diethylstilbestrol, in the amounts and for the purposes indicated in § 121.225 or § 121.241 of this chapter, and its labeling bears adequate directions and warnings for such use; *Provided, however,* That if such feed contains diethylstilbestrol it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug or the methods used in its manufacturing, processing, packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

(53) It is a medicated feed for turkeys and contains chlortetracycline hydrochloride and dietary calcium in the amounts and for the purposes indicated in § 121.208(d), Table 1, Item 12, of this chapter; and its labeling bears adequate directions and warnings for such use.

(54) It is a medicated feed for growing broiler and replacement chickens; it contains amprolium, ethopabate (methyl-4-acetamido-2-ethoxy benzoate), and antibiotics, with or without arsanilic acid, in the amounts and for the purposes indicated in § 121.210 of this chapter; and its labeling bears adequate directions and warnings for such use; *Provided, however,* That such medicated complete feed has been prepared from a concentrated medicated feed that contained not more than 0.05 percent amprolium and not more than 0.0016 percent ethopabate If the medicated feed is prepared from a product that contains more than 0.05 percent amprolium and more than 0.0016 percent ethopabate, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug, or the methods used in and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtains the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner. Both concentrates and finished poultry feed containing amprolium and ethopabate must comply with all the requirements of § 121.210 of this chapter, including labeling.

(55) It is a medicated swine feed containing a combination of chlortetracycline, sulfamethazine, and penicillin in the amounts and for the purposes indicated in § 121.208 of this chapter, and its labeling bears adequate directions and warnings for such use.

(56) It is a medicated feed for chickens containing a combination of procaine penicillin and tylosin phosphate in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use; *Provided, however,* That such medicated complete feed has been prepared from a concentrated medicated feed that contained not more than 200 grams of tylosin phosphate per ton. If the medicated feed is prepared from a concentrated medicated feed containing more than 200 grams of tylosin phosphate per ton, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug, or the methods used in and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtains the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

(57) It is a horse feed containing chlortetracycline in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

(58) It is medicated feed for swine containing a combination of streptomycin and tylosin phosphate in the amounts and for the purposes indicated in § 121.217 of this chapter, and its labeling bears adequate directions and warnings for such use; *Provided, however,* That such

medicated complete feed has been prepared from a feed additive premix or feed additive concentrate that contains streptomycin and not more than 500 grams of tylosin phosphate per ton. If the medicated feed is prepared from a feed additive premix or feed additive concentrate containing streptomycin and more than 500 grams of tylosin phosphate per ton, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug, or the methods used in and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtains the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

(59) It is a medicated feed for chickens containing penicillin, tylosin phosphate, and either amprolium or zoalene, or hygromycin B and zoalene, in the amounts and for the purposes indicated in § 121.207, 121.210, or 121.213 of this chapter, and its labeling bears adequate directions and warnings for such use; *Provided, however,* That such medicated complete feed has been prepared from a concentrated penicillin-tylosin phosphate-amprolium, or penicillin-tylosin phosphate-zoalene, or penicillin-tylosin phosphate-zoalene-hygromycin B medicated feed containing, per ton of feed, not more than 200 grams of tylosin and either not more than 0.05 percent amprolium or not more than 0.0375 percent zoalene, or not more than 0.0375 percent zoalene and not more than 32 grams per ton of hygromycin B. If the medicated feed is prepared from a product that contains more than any of the specified quantities, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.10 of this chapter to establish the safety and efficacy of the article and to guarantee its identity, strength, quality and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug, or the methods used in and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtains the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

PART 145—ANTIBIOTIC DRUGS; DEFINITIONS AND INTERPRETATIVE REGULATIONS

Subpart A—Definitions

Subpart B—Statements of Policy and Interpretation

AUTHORITY: The provisions of this Part 145 issued under sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357.

Subpart A—Definitions

§ 145.1 Definitions applicable to all certifiable antibiotic drugs.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in the regulations in this chapter covering the certification of antibiotic and antibiotic-containing drugs.

(b) The term "Commissioner" means the Commissioner of Food and Drugs and any other officer of the Food and Drug Administration whom he may designate to act in his behalf for the purpose of the regulations for the certification of antibiotic and antibiotic-containing drugs.

(c) The term "act" means the Federal Food, Drug, and Cosmetic Act and amendments thereto. (52 Stat. 1040 et seq.; 21 U.S.C. 301–392).

(d) The term "U.S.P." means the official Pharmacopeia of the United States, including supplements thereto. The term "N.F." means the official National Formulary, including supplements thereto.

(e) The term "batch" means a specific homogeneous quantity of a drug.

(f) The term "batch mark" means an identifying mark or other identifying device assigned to a batch by the manufacturer or packer thereof.

(g) The term "manufacture" does not include the use of a drug as an ingredient in compounding any prescription issued by a practitioner licensed by law to administer such drug.

§ 145.2 Definitions of antibiotic substances.

(a) The following are definitions of antibiotic substances:

(1) *Penicillin.* Each of the several antibiotic substances (e.g., penicillin F, penicillin G, penicillin X) produced by the growth of *Penicillium notatum* or *Penicillium chrysogenum,* and each of the same substances produced by any other means, is a kind of penicillin.

(2) *Streptomycin.* Each of the several antibiotic substances produced by the growth of *Streptomyces griseus,* and each of the same substances produced by any other means, is a kind of streptomycin.

(3) *Dihydrostreptomycin.* Each of the antibiotic substances produced by hydrogenation of streptomycin, and each of the same substances produced by any other means, is a kind of dihydrostreptomycin.

(4) *Chlortetracycline.* Each of the several antibiotic substances produced by the growth of *Streptomyces aureofaciens,* and each of the same substances produced by any other means is a kind of chlortetracycline.

(5) *Tetracycline.* Each of the several antibiotic substances produced by the hydrogenation of chlortetracycline, and each of the same substances produced by any other means, is a kind of tetracycline.

(6) *Chloramphenicol.* Each of the several antibiotic substances produced by the growth of *Streptomyces venezuelae,* and each of the same substances produced by any other means, is a kind of chloramphenicol.

(7) *Bacitracin.* Each of the several antibiotic substances produced by the growth of *Bacillus subtilis* var. Tracy, and each of the same substances produced by any other means, is a kind of bacitracin.

(8) *Amphomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces canus,* and each of the same substances produced by any other means, is a kind of amphomycin.

(9) *Amphotericin.* Each of the antibiotic substances produced by the growth of *Streptomyces nodosus,* and each of the same substances produced by any other means, is a kind of amphotericin.

(10) *Colistin.* Each of the antibiotic substances produced by the growth of *Bacillus polymyxa* var. *colistinus,* and each of the same substances produced by any other means, is a kind of colistin.

(11) *Cycloserine.* Each of the antibiotic substances produced by the growth of *Streptomyces orchidaceus,* and each of the same substances produced by any other means, is a kind of cycloserine.

(12) *Erythromycin.* Each of the antibiotic substances produced by the growth of *Streptomyces erythreus,* and each of the same substances produced by any other means, is a kind of erythromycin.

(13) *Gramicidin.* Each of the antibiotic substances produced by the growth of *Bacillus brevis,* and each of the same substances produced by any other means, is a kind of gramicidin.

(14) *Griseofulvin.* Each of the antibiotic substances produced by the growth of *Penicillium patulum* or *Penicillium griseofulvum,* and each of the same substances produced by any other means, is a kind of griseofulvin.

(15) *Kanamycin.* Each of the antibiotic substances produced by the growth of *Streptomyces kanamyceticus,* and each of the same substances produced by any other means, is a kind of kanamycin.

(16) *Neomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces fradiae,* and each of the same substances produced by any other means, is a kind of neomycin.

(17) *Novobiocin.* Each of the antibiotic substances produced by the growth of *Streptomyces niveus* (known also as *Streptomyces spheroides*), and each of the same substances produced by any other means, is a kind of novobiocin.

(18) *Nystatin.* Each of the antibiotic substances produced by the growth of *Streptomyces noursei*, and each of the same substances produced by any other means, is a kind of nystatin.

(19) *Oleandomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces antibioticus*, and each of the same substances produced by any other means, is a kind of oleandomycin.

(20) [Reserved]

(21) *Oxytetracycline.* Each of the antibiotic substances produced by the growth of *Streptomyces rimosus*, and each of the same substances produced by any other means, is a kind of oxytetracycline.

(22) *Paromomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces rimosus* var. *paromomycinus*, and each of the same substances produced by any other means, is a kind of paromomycin.

(23) *Polymyxin.* Each of the antibiotic substances produced by the growth of *Bacillus polymyxa*, and each of the same substances produced by any other means, is a kind of polymyxin.

(24) *Ristocetin.* Each of the antibiotic substances produced by the growth of *Nocardia lurida*, and each of the same substances produced by any other means, is a kind of ristocetin.

(25) *Tyrothricin.* Each of the mixtures of antibiotic substances produced by the growth of *Bacillus brevis*, and each of the same mixtures of substances produced by any other means, is a kind of of tyrothricin.

(26) *Vancomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces orientalis*, and each of the same substances produced by any other means, is a kind of vancomycin.

(27) *Viomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces puniceus* or *Streptomyces floridae* or *Actinomyces vinaceus*, and each of the same substances produced by any other means, is a kind of viomycin.

(28)–(30) [Reserved]

(31) *Cephalosporin.* Each of the antibiotic substances produced by the growth of *Cephalosporium acremonium*, and each of the same substances produced by any other means, is a kind of cephalosporin.

§ 145.3 Definitions of master and working standards.

(a) *Master standards*—(1) *Penicillin and salts of penicillin*—(i) *Penicillin G.* The term "penicillin G master standard" means a specific lot of crystalline sodium penicillin G (sodium penicillin II) that is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin G working standard.

(ii) *Penicillin O.* The term "penicillin O master standard" means a specific lot of crystalline potassium penicillin O standardized by the penicillin G master standard and which is designated by the Commissioner as the standard of comparison in determining the penicillin O content of the penicillin O working standard.

(iii) *Penicillin V.* The term "penicillin V master standard" means a specific lot of crystalline penicillin V that is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin V working standard.

(iv) *Potassium-L-phenethicillin.* The term "potassium-L-phenethicillin master standard" means a specific lot of potassium-L-phenethicillin that is designated by the Commissioner as the standard of comparison in determining the potency of the potassium-L-phenethicillin working standard.

(v) *Potassium-D-phenethicillin.* The term "potassium-D-phenethicillin master standard" means a specific lot of potassium-D-phenethicillin that is designated by the Commissioner as the standard of comparison in determining the potency of the potassium-D-phenethicillin working standard.

(vi) *Methicillin sodium.* The term "methicillin sodium master standard" means a specific lot of methicillin sodium that is designated by the Commissioner as the standard of comparison in determining the potency of the methicillin sodium working standard.

(vii) *Sodium oxacillin.* The term "sodium oxacillin master standard" means a specific lot of sodium oxacillin that is designated by the Commissioner as the standard of comparison in determining the potency of the sodium oxacillin working standard.

(viii) *Ampicillin.* The term "ampicillin master standard" means a specific lot of ampicillin that is designated by the Commissioner as the standard of comparison in determining the potency of the ampicillin working standard.

(ix) *Nafcillin.* The term "nafcillin master standard" means a specific lot of sodium nafcillin that is designated by the Commissioner as the standard of comparison in determining the potency of the nafcillin working standard.

(2) *Streptomycin.* The term "streptomycin master standard" means a specific lot of crystalline trihydrochloride calcium chloride salt of streptomycin that is designated by the Commissioner as the standard of comparison in determining the potency of the streptomycin working standard.

(3) *Dihydrostreptomycin.* The term "dihydrostreptomycin master standard" means a specific lot of crystalline dihydrostreptomycin sulfate that is designated by the Commissioner as the standard of comparison in determining the potency of the dihydrostreptomycin working standard.

(4) *Chlortetracycline.* The term "chlortetracycline master standard" means a specific lot of crystalline chlortetracycline hydrochloride that is designated by the Commissioner as the standard of comparison in determining the potency of the chlortetracycline working standard.

(5) *Demethylchlortetracycline.* The term "demethylchlortetracycline master standard" means a specific lot of crystalline 6-demethylchlortetracycline hydrochloride that is designated by the Commissioner as the standard of comparison in determining the potency of the 6-demethylchlortetracycline working standard.

(6) *Tetracycline.* The term "tetracycline master standard" means a specific lot of crystalline tetracycline hydrochloride that is designated by the Commissioner as the standard of comparison in determining the potency of the tetracycline working standard.

(7) *Rolitetracycline.* The term "rolitetracycline master standard" means a specific lot of crystalline rolitetracycline that is designated by the Commissioner as the standard of comparison in determining the potency of the rolitetracycline working standard.

(8) *Chloramphenicol.* The term "chloramphenicol master standard" means a specific lot of crystalline chloramphenicol that is designated by the Commissioner as the standard of comparison in determining the potency of the chloramphenicol working standard.

(9) *Bacitracin.* The term "bacitracin master standard" means a specific lot of bacitracin that is designated by the Commissioner as the standard of comparison in determining the potency of the bacitracin working standard.

(10) *Amphomycin.* The term "amphomycin master standard" means a specific lot of amphomycin designated by the Commissioner as the standard of comparison in determining the potency of the amphomycin working standard.

(11) *Amphotericin.* The term "amphotericin A master standard" means a specific lot of amphotericin A designated by the Commissioner as the standard of comparison in determining the potency of the amphotericin A working standard. The term "amphotericin B master standard" means a specific lot of amphotericin B designated by the Commissioner as the standard of comparison in determining the potency of the amphotericin B working standard.

(12) *Colistin.* The term "colistin master standard" means a specific lot of colistin designated by the Commissioner as the standard of comparison in determining the potency of the colistin working standard.

(13) *Colistimethate.* The term "colistimethate master standard" means a specific lot of colistimethate designated by the Commissioner as the standard of comparison in determining the potency of the colistimethate working standard.

(14) *Cycloserine.* The term "cycloserine master standard" means a specific lot of cycloserine designated by the Commissioner as the standard of comparison in determining the potency of the cycloserine working standard.

(15) *Erythromycin.* The term "erythromycin master standard" means a specific lot of erythromycin designated by the Commissioner as the standard of comparison in determining the potency of the erythromycin working standard.

(16) *Gramicidin.* The term "gramicidin master standard" means a specific lot of gramicidin designated by the Commissioner as the standard of comparison

in determining the potency of the gramicidin working standard.

(17) *Griseofulvin.* The term "griseofulvin master standard" means a specific lot of griseofulvin designated by the Commissioner as the standard of comparison in determining the potency of the griseofulvin working standard.

(18) *Kanamycin.* The term "kanamycin master standard" means a specific lot of kanamycin designated by the Commissioner as the standard of comparison in determining the potency of the kanamycin working standard.

(19) *Neomycin.* The term "neomycin master standard" means a specific lot of neomycin designated by the Commissioner as the standard of comparison in determining the potency of the neomycin working standard.

(20) *Novobiocin.* The term "novobiocin master standard" means a specific lot of novobiocin designated by the Commissioner as the standard of comparison in determining the potency of the novobiocin working standard.

(21) *Nystatin.* The term "nystatin master standard" means a specific lot of nystatin designated by the Commissioner as the standard of comparison in determining the potency of the nystatin working standard.

(22) *Oleandomycin.* The term "oleandomycin master standard" means a specific lot of oleandomycin designated by the Commissioner as the standard of comparison in determining the potency of the oleandomycin working standard.

(23) *Oxytetracycline.* The term "oxytetracycline master standard" means a specific lot of oxytetracycline designated by the Commissioner as the standard of comparison in determining the potency of the oxytetracycline working standard.

(24) *Paromomycin.* The term "paromomycin master standard" means a specific lot of paromomycin designated by the Commissioner as the standard of comparison in determining the potency of the paromomycin working standard.

(25) *Polymyxin B.* The term "polymyxin B master standard" means a specific lot of polymyxin B designated by the Commissioner as the standard of comparison in determining the potency of the polymyxin B working standard.

(26) *Ristocetin.* The term "ristocetin A master standard" means a specific lot of ristocetin A designated by the Commissioner as the standard of comparison in determining the potency of the ristocetin A working standard. The term "ristocetin B master standard" means a specific lot of ristocetin B designated by the Commissioner as the standard of comparison in determining the potency of the ristocetin B working standard.

(27) *Vancomycin.* The term "vancomycin master standard" means a specific lot of vancomycin designated by the Commissioner as the standard of comparison in determining the potency of the vancomycin working standard.

(28) *Viomycin.* The term "viomycin master standard" means a specific lot of viomycin designated by the Commissioner as the standard of comparison in determining the potency of the viomycin working standard.

(29)–(32) [Reserved]

(33) *Cephalothin.* The term "cephalothin master standard" means a specific lot of cephalothin designated by the Commissioner as the standard of comparison in determining the potency of the cephalothin working standard.

(b) *Working standards.* The potency or purity of each preparation has been determined by comparison with its master standard, and each has been designated by the Commissioner as working standards for use in determining the potency or purity of antibiotic substances subject to the regulations in this chapter.

(1) *Penicillin.* (i) The term "penicillin G working standard" means a specific lot of a homogeneous preparation of one or more salts of penicillin.

(ii) The term "penicillin O working standard" means a specific lot of a homogeneous preparation of potassium penicillin O.

(iii) The term "penicillin V working standard" means a specific lot of a homogeneous preparation of penicillin.

(iv) The term "potassium-L-phenethicillin working standard" means a specific lot of a homogeneous preparation of potassium-L-phenethicillin. The term "potassium-D-phenethicillin working standard" means a specific lot of a homogeneous preparation of potassium-D-phenethicillin.

(v) The term "methicillin working standard" means a specific lot of a homogeneous preparation of methicillin.

(vi) The term "sodium oxacillin working standard" means a specific lot of a homogeneous preparation of sodium oxacillin.

(vii) The term "ampicillin working standard" means a specific lot of a homogeneous preparation of ampicillin.

(viii) The term "nafcillin working standard" means a specific lot of a homogeneous preparation of sodium nafcillin.

(2) *Amphotericin A.* The term "amphotericin A working standard" means a specific lot of a homogeneous preparation of amphotericin A.

(3) *Amphotericin B.* The term "amphotericin B working standard" means a specific lot of a homogeneous preparation of amphotericin B.

(4) *Streptomycin.* The term "streptomycin working standard" means a specific lot of a homogeneous preparation of one or more streptomycin salts.

(5) *Dihydrostreptomycin.* The term "dihydrostreptomycin working standard" means a specific lot of a homogeneous preparation of one or more dihydrostreptomycin salts.

(6) *Chlortetracycline.* The term "chlortetracycline working standard" means a specific lot of a homogeneous preparation of one or more chlortetracycline salts.

(7) *Demethylchlortetracycline.* The term "demethylchlortetracycline working standard" means a specific lot of a homogeneous preparation of one or more 6-demethylchlortetracycline salts.

(8) *Tetracycline.* The term "tetracycline working standard" means a specific lot of a homogeneous preparation of one or more tetracycline salts.

(9) *Rolitetracycline.* The term "rolitetracycline working standard" means a specific lot of a homogeneous preparation of one or more rolitetracycline salts.

(10) *Chloramphenicol.* The term "chloramphenicol working standard" means a specific lot of a homogeneous preparation of one or more chloramphenicols.

(11) *Bacitracin.* The term "bacitracin working standard" means a specific lot of a homogeneous preparation of one or more bacitracins.

(12) *Amphomycin.* The term "amphomycin working standard" means a specific lot of a homogeneous preparation of amphomycin.

(13) *Colistin.* The term "colistin working standard" means a specific lot of a homogeneous preparation of colistin.

(14) *Colistimethate.* The term "colistimethate working standard" means a specific lot of a homogeneous preparation of colistimethate.

(15) *Cycloserine.* The term "cycloserine working standard" means a specific lot of a homogeneous preparation of cycloserine.

(16) *Erythromycin.* The term "erythromycin working standard" means a specific lot of a homogeneous preparation of erythromycin.

(17) *Gramicidin.* The term "gramicidin working standard" means a specific lot of a homogeneous preparation of gramicidin.

(18) *Griseofulvin.* The term "griseofulvin working standard" means a specific lot of a homogeneous preparation of griseofulvin.

(19) *Kanamycin.* The term "kanamycin working standard" means a specific lot of a homogeneous preparation of kanamycin.

(20) *Neomycin.* The term "neomycin working standard" means a specific lot of a homogeneous preparation of neomycin.

(21) *Novobiocin.* The term "novobiocin working standard" means a specific lot of a homogeneous preparation of novobiocin.

(22) *Nystatin.* The term "nystatin working standard" means a specific lot of a homogeneous preparation of nystatin.

(23) *Oleandomycin.* The term "oleandomycin working standard" means a specific lot of a homogeneous preparation of oleandomycin.

(24) [Reserved]

(25) *Oxytetracycline.* The term "oxytetracycline working standard" means a specific lot of a homogeneous preparation of oxytetracycline.

(26) *Paromomycin.* The term "paromomycin working standard" means a specific lot of a homogeneous preparation of paromomycin.

(27) *Polymyxin B.* The term "polymyxin B working standard" means a specific lot of a homogeneous preparation of polymyxin B.

(28) *Vancomycin.* The term "vancomycin working standard" means a specific lot of a homogeneous preparation of vancomycin.

(29) *Viomycin.* The term "viomycin working standard" means a specific lot of a homogeneous preparation of viomycin.

(30)–(32) [Reserved]

(33) *Cephalothin.* The term "cephalothin working standard" means a specific lot of a homogeneous preparation of cephalothin.

§ 145.4 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

(a) *"Unit"*—(1) *Penicillin.* The term "unit" applied to penicillin means a penicillin activity contained in 0.6 microgram of the penicillin G master standard, except that the term "unit" applied to penicillin V means a penicillin activity contained in 0.59 microgram of the penicillin V master standard. The term "unit" applied to phenethicillin potassium means a penicillin activity contained in 0.68 microgram of the potassium-D-phenethicillin or potassium-L-phenethicillin master standard, or in 0.61 microgram of the free acid, the latter value being used as a basis of conversion from units to the metric system. The term "penicillin potency" means the number of such units in a specified quantity of a substance.

(2) *Bacitracin.* The term "unit" applied to bacitracin means a bacitracin activity contained in 23.8 micrograms of the bacitracin master standard after it is dried for 3 hours at 60° C. and a pressure of 5 millimeters or less; the term "bacitracin potency" means the number of such units in a specified quantity of a substance.

(3) *Nystatin.* The term "unit" applied to nystatin means the nystatin activity (potency) contained in 0.2817 microgram of the nystatin master standard when dried for 2 hours at 40° C. and a pressure of 5 millimeters or less.

(4) *Polymyxin B.* The term "unit" applied to polymyxin B means the polymyxin activity (potency) contained in 1.2739 micrograms of the polymyxin B master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(b) *"Microgram"*—(1) *Streptomycin.* The term "microgram" applied to streptomycin means the streptomycin activity (potency) contained in 1.38 micrograms of the streptomycin master standard after it is dried for 4 hours at 56° C. and a pressure of 50 microns or less.

(2) *Dihydrostreptomycin.* The term "microgram" applied to dihydrostreptomycin means the dihydrostreptomycin activity (potency) contained in 1.25 micrograms of the dihydrostreptomycin master standard after it is dried for 4 hours at 100° C. and a pressure of 50 microns or less.

(3) *Chlortetracycline.* The term "microgram" applied to chlortetracycline means the chlortetracycline activity (potency) contained in 1.0 microgram of the chlortetracycline master standard.

(4) *6-Demethylchlortetracycline.* The term "microgram" applied to 6-demethylchlortetracycline means the 6-demethylchlortetracycline activity (potency) contained in 1.0 microgram of 6-demethylchlortetracycline master standard.

(5) *Tetracycline.* The term "microgram" applied to tetracycline means the tetracycline activity (potency) contained in 1.0 microgram of tetracycline master standard.

(6) *Rolitetracycline.* The term "microgram" applied to rolitetracycline means the rolitetracycline activity (potency) contained in 1.0 microgram of the rolitetracycline master standard.

(7) *Chloramphenicol.* The term "microgram" applied to chloramphenicol means the chloramphenicol activity (potency) contained in 1.0 microgram of the chloramphenicol master standard.

(8) *Methicillin.* The term "microgram" applied to methicillin means the methicillin activity (potency) contained in 1.105 micrograms of the methicillin master standard.

(9) *Oxacillin.* The term "microgram" applied to oxacillin means the oxacillin activity (potency) contained in 1.0996 micrograms of the sodium oxacillin master standard.

(10) *Amphomycin.* The term "microgram" applied to amphomycin means the amphomycin activity (potency) contained in 0.9355 microgram of the amphomycin master standard when dried for 4 hours at 60° C. and a pressure of 5 millimeters or less.

(11) *Amphotericin A.* The term "microgram" applied to amphotericin A means the amphotericin A activity (potency) contained in 1.0 microgram of the amphotericin A master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(12) *Amphotericin B.* The term "microgram" applied to amphotericin B means the amphotericin B activity (potency) contained in 1.124 micrograms of the amphotericin B master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(13) *Colistin.* The term "microgram" applied to colistin means the colistin base activity (potency) contained in 1.495 micrograms of the colistin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(14) *Colistimethate.* The term "microgram" applied to colistimethate means the activity (potency) calculated as colistin base that is contained in 1.938 micrograms of the colistimethate master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(15) *Cycloserine.* The term "microgram" applied to cycloserine means the cycloserine activity (potency) contained in 1.0 microgram of the cycloserine master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(16) *Erythromycin.* The term "microgram" applied to erythromycin means the erythromycin base activity (potency) contained in 1.02 micrograms of the erythromycin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(17) *Gramicidin.* The term "microgram" applied to gramicidin means the gramicidin activity (potency) contained in 1.0 microgram of the gramicidin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(18) *Griseofulvin.* The term "microgram" applied to griseofulvin means the griseofulvin activity (potency) contained in 1.0 microgram of the griseofulvin master standard.

(19) *Kanamycin.* The term "microgram" applied to kanamycin means the kanamycin base activity (potency) contained in 1.299 micrograms of the kanamycin master standard.

(20) *Neomycin.* The term "microgram" applied to neomycin means the neomycin base activity (potency) contained in 1.429 micrograms of the neomycin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(21) *Novobiocin.* The term "microgram" applied to novobiocin means the novobiocin acid activity (potency) contained in 1.033 micrograms of the novobiocin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(22) *Oleandomycin.* The term "microgram" applied to oleandomycin means the oleandomycin base activity (potency) contained in 1.176 micrograms of the oleandomycin master standard.

(23) [Reserved]

(24) *Oxytetracycline.* The term "micogram" applied to oxytetracycline means the oxytetracycline base activity (potency) contained in 1.13 micrograms of the oxytetracyline master standard.

(25) *Paromomycin.* The term "microgram" applied to paromomycin means the paromomycin base activity (potency) contained in 1.333 micrograms of paromomycin master standard.

(26) *Tyrothricin.* The term "microgram" applied to tyrothricin means the activity (potency) contained in 0.2 microgram of the gramicidin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(27) *Vancomycin.* The term "microgram" applied to vancomycin means the vancomycin base activity (potency) contained in 1.25 micrograms of the vancomycin master standard.

(28) *Viomycin.* The term "microgram" applied to viomycin means the viomycin base activity (potency) contained in 1.355 micrograms of the viomycin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(29) *Ampicillin.* The term "microgram" applied to ampicillin means the ampicillin activity (potency) contained in 1.1547 micrograms of the ampicillin master standard.

(30) *Nafcillin.* The term "microgram" applied to nafcillin means the nafcillin activity (potency) contained in 1.052 micrograms of the nafcillin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(31)–(33) [Reserved]

(34) *Cephalothin.* The term "microgram" applied to cephalothin means the cephalothin activity (potency) contained in 1.055 micrograms of the cephalothin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

Subpart B—Statements of Policy and Interpretation

§ 145.31 Antibiotic drugs not subject to certification prior to May 1, 1963; statement of policy.

(a) Prior to the enactment of the 1962 amendments to the Federal Food, Drug, and Cosmetic Act, the only antibiotic drugs required to be submitted to the Food and Drug Administration for certification were those containing penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative of one of these antibiotics. Scientific proof of safety and efficacy was required. In the case of a drug containing any other antibiotic, it was necessary, unless the drug was then considered to be generally recognized as safe, that the applicant submit proof of safety under the new-drug provisions of the act. Furthermore, prior to enactment of the 1962 amendments, a number of these drugs had been declared no longer new drugs, since they had become generally recognized as being safe for their intended uses. As a result, there are now on the market antibiotic-containing drugs with labeling claims that, in the opinion of the Administration, are not supported by available medical data. This is particularly true for drugs such as troches, nose drops, mouth washes, and deodorants intended for use by the laity.

(b) Antibiotic drugs not subject to certification prior to May 1, 1963, therefore fall into two categories:

(1) Drugs for which, prior to their being marketed, the manufacturers applied for and obtained effective new-drug applications under the provisions of section 505 of the act.

(2) Drugs not cleared through the new-drug procedures prior to their being marketed.

(c) Under the provisions of the 1962 amendments, drugs described in paragraph (b)(1) of this section are exempt from an affirmative finding of efficacy for the conditions covered by the prior approval of the new-drug application, and the initial regulations listing them for certification for such conditions may not be withdrawn for lack of proof of efficacy until October 9, 1964. The deferred effective date as to efficacy does not apply to the drugs described in paragraph (b)(2) of this section.

(1) The Food and Drug Administration is now drafting regulations to provide for the certification of the drugs in paragraph (b)(1) of this section. Samples will be accepted from any manufacturer or repacker of a drug described in such regulations with a view to certification if the drug meets the requirements of the regulations or, pending the effective date of such regulations, with a view to release as provided in section 507(a) of the act. Thus, each manufacturer or repacker of a drug described in paragraph (b)(1) of this section need not hold an effective new-drug application for the drug in order to qualify for certification, but all such drugs will be certified only with the claims for those conditions for which the drugs were found to be safe under the new-drug procedures. If a regulation providing for the certification of a drug in paragraph (b)(1) has not been revoked before October 9, 1964, it will be revoked after that date unless the Commissioner of Food and Drugs has received substantial evidence to support the claims of effectiveness.

(2) The Commissioner does not intend to issue regulations to provide for the certification of any drug covered by paragraph (b)(2) of this section until he has received substantial evidence to support such regulations. A drug in this group, even though marketed before October 10, 1962, may not now be marketed until an appropriate regulation has issued and the drug has been certified or the drug has been released as provided in section 507(a) of the act. To permit orderly transition to the certification requirements, the Commissioner will continue to accept samples of a drug in this group with a view to release of batches as provided in section 507(a) of the act, provided the manufacturer submits to the Food and Drug Administration by September 6, 1963, evidence to support the claims for such drugs.

PART 146—ANTIBIOTIC DRUGS; PROCEDURAL REGULATIONS

Sec.

AUTHORITY: The provisions of this Part 146 issued under sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357.

CROSS REFERENCE: For other regulations in this chapter concerning antibiotic and antibiotic-containing drugs, see also §§ 8.3, 120.117, 120.148, and Parts 121 and 130.

§ 146.1 Procedure for the establishment of regulations. [Reserved]

§ 146.2 Requests for certification, check tests and assays, and working standards; information and samples required.

(a) A request for certification of a batch shall be addressed to the Commissioner and shall be in a form specified by him. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(b) The initial request for certification of a batch of any drug submitted by any person shall be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and purity of each batch, including a description of (1) the methods and processes used in the manufacture of the drug; (2) the tests and assays of the drug made during the manufacture of the batch and after it is packaged; and (3) the laboratory facilities used in such controls. Such initial request shall also be preceded or accompanied by the key of the batch marks used by such person and by specimens of all labeling (including specimens of all brochures and other printed matter except readily available medical publications referred to in such labeling) to be used for such drug. When any change is made in any such facility or control, or in any such key or labeling, such person shall promptly submit to the Commissioner a full statement of such change or, in the case of changed labeling, specimens showing all such changes.

(c) A person who requests certification or check tests and assays of a batch shall submit with his request the following information and samples:

(1) The batch mark of the drug.

(2) The quantity of each ingredient used in making the batch.

(3) The size of the batch, including the number of containers of each size in the batch.

(4) The date of the latest assay of the batch.

(5) The results of tests and assays made by or for him on the batch as required for the drug by specific regulations.

(6) The batch mark(s) of the antibiotic(s) used in making the batch.

(7) Unless previously submitted, the results of tests and assays made by or for him on the antibiotic(s) used in making the batch as required by specific regulations.

(8) The number of accurately representative samples that are required for the batch by specific regulations: In the case of drugs such as dry powders, solutions, ointments, and suspensions, the sample shall be collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal. In no case, however, shall more than 5,000 immediate containers have been packaged during each such interval of sampling, except for a sample collected for sterility testing. In the case of drugs such as tablets or other such unit dosage forms, the sample shall be collected by taking single tablets at such intervals throughout the entire time of tableting the batch that the quantities tableted during the intervals are approximately equal. In no case, however, shall more than 5,000 tablets have been tableted during each interval of sampling, except for a sample collected for time of disintegration. If the person who packages the tablets into dispensing-size containers is not the manufacturer, such sample shall be collected throughout the entire time of packaging the batch into such containers.

(d) Each sample submitted pursuant to the regulations in this chapter shall be addressed to the Commissioner. Its package shall be clearly identified as to its contents and shall bear the name and

post-office address of the person submitting it.

(e) In addition to the information and samples specifically required to be submitted to the Commissioner by the regulations in this chapter, the person who requests certification of a batch shall submit such further information and samples as the Commissioner may require for the purpose of investigations to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate.

(f) Upon the request of any person, stating reasonable grounds therefor, the Commissioner shall furnish such person with a portion of the working standards.

§ 146.3 Certification.

(a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and samples required by or pursuant to the regulations in this chapter have been submitted, and the request for certification contains no untrue statement of a material fact; and

(2) The batch complies with the regulations in this chapter and conforms to the applicable standards of identity, strength, quality, and purity prescribed by the regulations in this chapter;

the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of certificates as are prescribed by § 146.4, and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that the information submitted pursuant to the regulations in this chapter, or the batch covered by such request, does not comply with the requirements set forth in paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) All statements, samples, and other information and materials submitted in connection with a request for certification shall be considered to be part of such request.

(d) Compliance of a drug with the standards of identity, strength, quality, and purity prescribed by regulations in this chapter shall be determined by the tests and methods of assay prescribed for such drug by regulations issued under this chapter.

(e) The regulations in this chapter, prescribing tests and methods of assay for antibiotic and antibiotic-containing drugs, shall not be construed as preventing the Commissioner from using any other test or method of assay in his investigations to determine whether or not:

(1) A request for certification contains any untrue statement of a material fact; or

(2) A certification has been obtained through fraud, or through misrepresentation or concealment of a material fact.

(f) Except as specifically provided by the regulations in this chapter, no provision of any regulation shall be construed as exempting any certifiable antibiotic drug from any applicable provision of the act or any regulation thereunder.

§ 146.4 Conditions on the effectiveness of certificates.

(a) A certificate shall not become effective:

(1) If it is obtained through fraud or through misrepresentation or concealment of a material fact;

(2) With respect to any package unless it complies with the packaging requirements, if any, prescribed by the regulations in this chapter which were in effect on the date of the certificate;

(3) With respect to any package unless its label and labeling bear all words, statements, and other information required by the regulations in this chapter; or

(4) With respect to any package of a certifiable antibiotic drug subject to the regulations in this chapter, when it is included in a packaged combination with another drug, unless such other drug complies with the requirements of the regulations in this chapter.

(b) A certificate shall cease to be effective:

(1) With respect to any immediate container after the expiration date, if any, prescribed by the regulations in this chapter;

(2) With respect to any immediate container when it or its seal (if the regulations in this chapter require it to be sealed) is broken, or when its label or labeling is altered, mutilated, destroyed, obliterated, or removed in whole or in part, or ceases to conform to any labeling requirement prescribed by the regulations in this chapter, except that:

(i) If the drug in such container is repacked or used as an ingredient in the manufacture of another drug, and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch;

(ii) If the drug is in a container packaged for dispensing and is used in compounding a prescription issued by a practitioner licensed by law to administer such drug, such certificate shall continue to be effective for a reasonable time to permit the delivery of the drug compounded on such prescription; or

(iii) If its label or labeling is removed in whole or in part for the purpose of relabeling and supplemental certification of the relabeled drug is requested, as provided by § 144.3 of this chapter.

(3) With respect to any immediate container of penicillin when it is included in the packaged combination penicillin with aluminum hydroxide gel or penicillin with a vasoconstrictor, or to any immediate container of bacitracin when it is included in the packaged combination bacitracin with a vasoconstrictor, except that when certification of the batch so included is requested, such certificate shall continue to be effective for a reasonable time to permit certification of such batch which is part of such combination;

(4) With respect to any package when the drug therein fails to meet the standards of identity, strength, quality, and purity which were in effect on the date of the certificate; except that those minor changes which occur before the expiration date and which are normal and unavoidable in good storage and distribution practice shall be disregarded.

(5) With respect to any package of a certifiable antibiotic drug subject to the regulations in this chapter, included in a packaged combination with another drug, when such other drug fails to meet the requirements of the regulations in this chapter; or

(6) With respect to any immediate container, if such regulations require its labeling to bear a caution against dispensing otherwise than on prescription, at the beginning of the act of dispensing or offering to dispense it otherwise than:

(i) By a practitioner licensed by law to administer such drug; or

(ii) On his prescription issued in his professional practice.

§ 146.5 Records of distribution.

(a) The person who requested certification shall keep complete records showing each shipment and other delivery (including exports) of each certified batch or part thereof by such person or by any person subject to his control. Such records shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than 3 years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§ 146.6 Refusal of certification service.

When the Secretary finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;

(b) Falsified the records required to be kept by § 146.5; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of stocks on hand or otherwise to check the correctness of such records, as required by § 146.5, and such failure may materially impair the certification service;

the Secretary will immediately suspend service to such person under the regulations in this chapter and will continue such suspension unless and until such person shows adequate cause why such service should be resumed.

§ 146.7 Records retention.

At the option of the person having control of records required to be kept by any regulation in this Part 146, photostatic or other permanent reproductions may be substituted for such records after the first 2 years of the holding period.

§ 146.8 Fees.

(a) Fees for the services rendered under the regulations in this chapter shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(b) The fee for such services with respect to each batch of a drug, certification of which is provided by the regulations in this chapter, including those published hereafter, is the fee prescribed in the section relating specifically to such drug plus an additional 30 percent of whatever that fee may be, except that in the case of a supplemental request submitted pursuant to the provisions of § 144.3 of this chapter, the fee shall be $3.00.

(c) When the Commissioner considers it necessary to make investigations of a new product containing a certifiable antibiotic drug on which a request has been submitted in accordance with § 146.10, the fee for such service shall be the cost thereof. In such case the request shall be followed by an advance deposit in such amount as the Commissioner specifies, and thereafter such additional advance deposits shall be made as the Commissioner estimates may be necessary to prevent arrears in the payment of such fee.

(d) A person requiring continuing certification services may maintain an advance deposit of the estimated cost of such services for a two-month period. Such deposit shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in the regulations in this chapter unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(e) The fees for the services rendered with respect to each batch certified under the regulations in this chapter shall accompany the request for certification, or the request for check tests and assays, unless such fee is covered by an advance deposit maintained in accordance with paragraph (d) of this section. Also, if the Commissioner considers that investigations other than examination of such samples are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the fee shall include the cost of such investigations.

(f) The fees for the services rendered with respect to each application for an exemption from certification under the regulations in § 144.26(b) of this chapter, and for each amendment thereto, shall be:

(1) $5.00 for each medicated feed formula containing one or more new-drug substances described in an initial application.

(2) $5.00 for changes in one or more new-drug substances contained in a medicated feed formula described in an amendment to such application.

The fee prescribed by this paragraph shall accompany each application and each amendment to such application unless such fee is covered by an advance deposit maintained in accordance with paragraph (d) of this section.

(g) The unearned portion of any advance deposit shall be refunded to the depositor upon his application.

(h) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under §§ 144.3 and 144.26 of this chapter.

(i) All deposits and fees required by the regulations in this chapter shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, D.C. All such deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C., 20204, whereupon after making appropriate records thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasurer of the United States, for deposit to the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

§ 146.9 Disposition of outdated drugs.

When certification becomes invalid because the expiration date is passed, such articles should not be disposed of for drug use either through commercial or charitable channels unless the articles have been assayed to establish potency and recertified.

§ 146.10 New antibiotic and antibiotic-containing products.

Any request that the Secretary provide for the certification of batches of a drug for which no provision for certification is made in the existing regulations in this chapter shall be in a form specified by the Commissioner and shall be accompanied by:

(a) A statement of the conditions for which the person who makes such request intends such drug to be used, and adequate directions for use in each such condition;

(b) Full reports of investigations which have been made to show whether or not such drug is safe and efficacious for use in such conditions;

(c) A full list of the articles used as components of such drug;

(d) A full statement of the composition of such drug;

(e) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of such drug;

(f) A full description of, or references to publications containing practical and accurate tests and methods of assay to determine the identity, strength, quality, and purity of such drug;

(g) Such samples of such drug and of the articles used as components thereof as the Commissioner may require; and

(h) Specimens of all labeling (including all brochures and other printed matter, except readily available medical publications, referred to in such labeling) proposed to be used for such drug.

§ 146.11 Declaration of potency.

Wherever the potency of an antibiotic drug included in the regulations in this chapter is expressed in terms of weight, such potency shall be equivalent to that contained in the same weight of the master standard of the drug.

§ 146.12 Shipment of antibiotic drugs packaged in bulk containers.

(a) The Food and Drug Administration has received inquiries from certain interested manufacturers concerning their shipment of certified antibiotics, packaged in bulk containers, to hospitals and pharmacies for repacking or for use in the manufacture of another drug on the order or prescription of a physician. The regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) do not prohibit the shipment of certified bulk containers of antibiotics to such persons. However, under the provisions of § 146.4 (b)(2)(i) of this chapter, certification should be requested of each repacked batch and of each batch of another drug manufactured from such bulk drug, unless the repackaged drug or other drug has been made exempt from the certification requirements by regulation. The fact that the drug is to be repacked or manufactured on the order or prescription of a physician does not exempt it from the certification requirements of the act. Under the provisions of § 146.4 (b)(2)(ii) of this chapter, it is only when the drug used to compound a prescription is in a container packaged for dispensing that certification of the drug so compounded is not required.

(b) In the light of these provisions, unless the manufacturer and shipper of bulk containers of antibiotics has, with the consignee, an effective permit issued under § 144.6 of this chapter, if the drug is to be repacked, or under § 144.7 of this chapter if it is to be used in the manufacture of another drug, the shipper has the responsibility of seeing that certification is requested of each repacked batch and of each batch of another drug manufactured from such drug.

§ 146.13 Forms for certification or exemption of antibiotic drugs.

The following forms which must be supplied in connection with certain certification or exemption procedures for antibiotic drugs may be obtained from the Division of Antibiotics and Insulin Certification, Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C., 20204:

Form
1 Application for exemption for storage.
2 Application for exemption for processing.
3 Application for exemption for labeling.
4 Application for exemption for manufacturing use.
5 Request to provide for certification of a new antibiotic product.
6 Data to accompany or precede every initial request for certification of a batch of an antibiotic drug.
7 Request for check tests and assays or certification of a batch of _____ (the blank to be filled in with the name of the antibiotic drug).
8 Application for exemption for repacking.
9 Request for supplemental certification of a batch of an antibiotic drug.
10 Application for exemption for antibiotics mixed in animal feeds.

PART 148—ANTIBIOTIC DRUGS; PACKAGING AND LABELING REQUIREMENTS

Sec.
148.1 [Reserved]
148.2 Packaging requirements.
148.3 Labeling requirements.
148.4 Labeling of antibiotic drugs intended for export.
148.5 Antibiotic and antibiotic-containing drugs intended for use in milk-producing animals; labeling.

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

CROSS REFERENCE: For other regulations in this chapter concerning antibiotic drugs exempted from certain labeling requirements, see also § 1.107 of this chapter.

§ 148.1 [Reserved]

§ 148.2 Packaging requirements.

Each drug described in Parts 148a to 148z, inclusive, of this chapter shall be packaged in immediate containers that comply with the requirements described in Parts 146a to 146e, inclusive, of this chapter for the immediate containers used to package the same dosage form unless otherwise required for the drug by specific regulations.

§ 148.3 Labeling requirements.

(a) If an antibiotic drug is packaged for dispensing:

(1) It shall be labeled in accordance with the requirements prescribed by § 1.106(b) of this chapter, issued under section 502(f) of the act, unless the regulations pertaining to such drug specifically exempt it from such requirements.

(2) Its labeling shall bear any additional information required for the drug by specific regulations.

(3) Each package shall bear on its outside wrapper or container and the immediate container an expiration date prescribed for the drug by specific regulations, except that the date may be used that is 18, 24, 30, 36, 42, 48, 54, or 60 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time. If the manufacturer or repacker of the drug has been exempted from the certification requirements, such date shall be the number of months after the month during which the batch was last assayed and released by the manufacturer or repacker. If an expiration date is used that is longer than the minimum date provided for the drug by specific regulations, it may be used only if the manufacturer has submitted information to the Commissioner adequate to prove that the drug is stable for such time.

(b) If it is packaged solely for manufacturing use or for repacking, each package shall bear on its outside wrapper or container and the immediate container, the following:

(1) The number of units or micrograms of activity per milligram or per gram, and the number of grams or kilograms in the immediate container.

(2) The batch mark.

(3) The statement "Caution: Federal law prohibits dispensing without prescription."

(4) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," and, if it is not sterile, the statement "nonsterile."

(5) The required expiration date.

(c) The expiration date prescribed for a drug by the regulations in this chapter may be omitted from the label of the immediate container if such container contains a single dose and it is packaged in an individual wrapper or container that bears the date prescribed.

§ 148.4 Labeling of antibiotic drugs intended for export.

(a) Antibiotic drugs subject to certification under section 507 of the act and intended for export will be certified notwithstanding failure to meet the labeling requirements of the applicable sections if the labeling used for such drugs meets the following conditions:

(1) It has been approved before use by the government authorities of the country to which the drugs are intended for export; and

(2) Such labeling represents that such drugs are for use only in those conditions for which they are certified for domestic distribution.

(b) The legend "Caution: Federal law prohibits dispensing without prescription" might be inappropriate on antibiotic drugs exported from the United States, since their sale may or may not be so restricted under the laws of the country of destination. The Food and Drug Administration would not object to a slight modification of the wording to read, "Caution: Federal (U.S.A.) law prohibits dispensing without prescription," by a manufacturer who wishes to market a drug under the same label both in domestic and foreign commerce.

§ 148.5 Antibiotic and antibiotic-containing drugs intended for use in milk-producing animals; labeling.

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement "Warning: Not for use in animals producing milk, since this use will result in contamination of the milk" or the statement "Warning: Milk taken from treated animals within—hours after the latest treatment must not be used for food", and the blank has been filled in with the figure, which shall not be greater than 96, that the Commissioner has authorized the manufacturer of the drug to use. The Commissioner shall determine what such figure shall be from information submitted by the manufacturer and which the Commissioner considers is adequate to prove that period of time after the latest treatment that the milk from treated animals will contain no residues from use of the preparation. If the use of the antibiotic drug as recommended does not result in its appearance in the milk neither of the above warning statements is required.

5. All citations to § 148.4 in Parts 148a–148w are changed to read "§ 146.2".

This revision and recodification of the antibiotic regulations involved in this order supersedes all prior amendments.

Although this document includes certain substantive amendments to existing regulations, such amendments are made solely for the purpose of interpretation or clarification of existing material and are not restrictive in nature. Therefore, I find that notice and public procedure and delayed effective date are not necessary prerequisites to the promulgation of this order.

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

(Sec. 507, 59 Stat. 463 as amended; 21 U.S.C. 357)

Dated: November 18, 1964.

JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

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