U.S. PUBLIC HEALTH SERVICE

REGULATIONS FOR THE SALE OF VIRUSES, SERUMS, TOXINS AND ANALOGOUS PRODUCTS IN THE DISTRICT OF COLUMBIA AND IN INTERSTATE TRAFFIC

U.S. Public Health Service

Regulations for the Sale of Viruses, Serums, Toxins and Analogous Products

In the District of Columbia and in Interstate Traffic

Approved October 12, 1940

To supersede Regulations issued February 25, 1935
and amendments thereto

✦

MISCELLANEOUS PUBLICATION No. 10

FEDERAL SECURITY AGENCY

UNITED STATES PUBLIC HEALTH SERVICE

THOMAS PARRAN, *Surgeon General*

DIVISION OF SANITARY REPORTS AND STATISTICS

CHARLES V. AKIN, *Assistant Surgeon General, Chief of Division*

✦

UNITED STATES GOVERNMENT PRINTING OFFICE, WASHINGTON: 1941

For sale by the Superintendent of Documents, Washington, D. C.

Price 5 cents

UNITED STATES PUBLIC HEALTH SERVICE DECISION NO. 8, UNDER SECTION 63 OF THE REGULATIONS FOR THE SALE OF VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS (REVISED)

FEDERAL SECURITY AGENCY,
UNITED STATES PUBLIC HEALTH SERVICE,
Washington, November 1, 1940.

(Superseding all earlier dating decisions)

To Manufacturers of Viruses, Serums, Toxins, and Analogous Products, and Others Concerned:

In accordance with the provisions of paragraph 63 of the Regulations for the Sale of Viruses, Serums, Toxins, and Analogous Products, approved October 12, 1940, the following decision prescribing the datings for all licensed biologic products is hereby promulgated.

Any lot of any product shall be subject to recall, regardless of dating, upon the discovery of lack of purity or potency, or if it is found to be subject to undue deterioration.

For the purpose of fixing the expiration date (the date beyond which the contents of the package cannot be expected beyond reasonable doubt to yield their specific results), the date of manufacture shall be as follows:

1. For products for which an official standard of potency exists, or which are subject to official potency tests, the last date of passing satisfactory potency tests.

For products submitted to the National Institute of Health for release the last date of passing satisfactory potency tests shall be the date of release.

2. For products for which no official standard of potency exists and which are not subject to official potency tests, the date of removal from the animal in the case of animal products, or the date of cessation of growth in the case of other products, except products used for specific desensitization, in which case the date of extraction shall be used, and except venoms, in which case the date of solution shall be used.

The date of issue shall, unless otherwise specifically provided, be not more than 3 months after date of manufacture if the product is kept constantly at a temperature not exceeding 15° C., or not more than 6 months after the date of manufacture if the product is kept constantly at a temperature not exceeding 10° C., or not more than 1 year after the date of manufacture if the product is kept constantly at a temperature not exceeding 5° C., or not more than 2 years after date of manufacture if the product is kept constantly at a temperature not exceeding 0° C.

The period of storage before issue may be extended provided the total period from date of manufacture to expiration date is not exceeded.

297019—41

Dried products referred to herein shall contain not more than 1 percent of moisture.

The dates beyond which the different products cannot be expected, beyond reasonable doubt, to yield their specific results (expiration dates) shall be not later than the following:

Liquid antitoxins with official standards, or subject to official potency tests.—One year after date of manufacture or date of issue, with a 20 percent excess of potency; 2 years with a 30 percent excess; 3 years with a 40 percent excess; or 4 years with a 50 percent excess.

Dried antitoxins with official standards, or subject to official potency tests.—Five years after date of manufacture or date of issue, with a 10 percent excess of potency.

Liquid antitoxins without official standards and not subject to official potency tests.—One year after date of manufacture or date of issue.

Dried antitoxins without official standards and not subject to official potency tests.—Five years after the date of manufacture or date of issue.

Liquid antidysenteric serum.—Eighteen months after date of manufacture or date of issue.

Dried antidysenteric serum.—Five years after the date of manufacture or date of issue.

Liquid antimeningococcic serum and liquid meningococcus antitoxin.—One year after the date of manufacture or date of issue.

Dried antimeningococcic serum and dried meningococcus antitoxin.—Five years after the date of manufacture or date of issue.

Liquid antipneumococcic serum and liquid pneumococcus typing serum.—One year after the date of manufacture or date of issue.

Dried antipneumococcic serum and dried pneumococcus typing serum.—Five years after the date of manufacture or date of issue.

All other liquid immune serums.—One year after the date of manufacture or date of issue provided that the date of issue shall be not more than 2 years after the date of manufacture if the product is kept constantly at a temperature not exceeding 5° C.

All other dried immune serums.—Five years after the date of manufacture or date of issue.

Liquid nonimmune serums and liquid plasmas.—One year after the date of manufacture.

Dried nonimmune serums and dried plasmas.—Five years after the date of manufacture or date of issue.

Smallpox vaccine.—Smallpox vaccine, which has been kept constantly below 0° C., may be issued more than 2 years after date of manufacture, provided that the filled and completed product, tested for potency within 9 months of the date of issue by the technique described in Hygienic Laboratory Bulletin No. 149, pages 12–16, meets the minimum requirements for smallpox vaccine stored less than 2 years, and provided further that it shows a potency not materially less than that of a lot of freshly prepared highly potent vaccine used on each rabbit for a control test.

The date of issue may be used instead of the date of manufacture only if the product is kept constantly below 0° C. between the date of manufacture and the date of issue. The expiration date shall be stated on the package as 1 week from the date of manufacture or date of issue, if not accompanied by the following quoted provision as to temperature of storage. If immediately followed by the words "if kept below 5° C. (41° F.)", the expiration date shall be stated on the package as not more than 3 months from the date of manufacture or

date of issue. Dried smallpox vaccine, preserved in a vacuum, may be given a date not to exceed 6 months from date of manufacture or date of issue.

Rabies vaccine.—Twenty-one days after emulsification in the case of an emulsion of living virus containing less than 50 percent glycerin; 1 month after emulsification in the case of an emulsion of living virus containing at least 50 percent glycerin; 6 months after date of issue in the case of frozen, desiccated living virus *in vacuo*, or from date of emulsification thereof; 6 months after date of issue in the case of dead virus; the first 7 doses of any form of treatment being considered, for the purpose of dating, as dead virus. Virus known to be living may be kept in cold storage before final preparation as follows: 6 months below 0° C., 3 months below 5° C., 6 weeks below 10° C., or 3 weeks below 15° C. The date of issue shall be not more than 6 months after the date of emulsification, provided the product is kept constantly at a temperature not exceeding 5° C.

Equine encephalomyelitis vaccine.—Six months from the date of manufacture or date of issue.

Liquid tuberculins.—Five years after date of manufacture or date of issue in the case of concentrated tuberculins containing at least 50 percent glycerin; 1 year after date of manufacture or date of issue in the case of other tuberculins, not dried.

Dried tuberculins.—Five years after the date of manufacture or date of issue.

Liquid bacterial vaccines.—Eighteen months after date of manufacture or date of issue.

Dried bacterial vaccines.—Five years after the date of manufacture or date of issue.

Liquid sensitized bacterial vaccines.—Eighteen months after date of manufacture or date of issue.

Dried sensitized bacterial vaccines.—Five years after the date of manufacture or date of issue.

Liquid modified bacterial derivatives.—Eighteen months after date of manufacture or date of issue.

Dried modified bacterial derivatives.—Five years after the date of manufacture or date of issue.

Liquid bacterial antigens.—Eighteen months after date of manufacture or date of issue.

Dried bacterial antigens.—Five years after the date of manufacture or date of issue.

Toxoids.—Two years after date of manufacture or date of issue.

Diphtheria toxin-antitoxin mixture.—Six months after date of manufacture or date of issue.

Diphtheria toxin for the Schick test.—Six months after date of manufacture or date of issue for undiluted toxin; 1 year after date of manufacture or date of issue of diluted toxin; the label for each product to bear the provision following the expiration date "if kept between 0° and 8° C. (32° and 46.4° F.)".

Scarlet fever streptococcus toxin for the Dick test.—Six months after date of dilution for diluted toxin; 5 years after date of manufacture for undiluted toxin if the product is kept constantly at a temperature not exceeding 5° C.

Scarlet fever streptococcus toxin for immunization.—Six months after date of dilution for diluted toxin; 5 years after date of manufacture for undiluted toxin if the product is kept constantly at a temperature not exceeding 5° C.

Leucocyte extract.—One year after date of manufacture or date of issue.

Pollen extracts, animal epidermal extracts, animal food extracts, vegetable food extracts, and miscellaneous allergenic extracts.—Eighteen months after date

of manufacture or date of issue. For extracts containing at least 50 percent glycerin, the date of issue shall be not more than 4 years after the date of manufacture if the product is kept constantly at a temperature not exceeding 10° C.

Animal oil extracts and vegetable oil extracts.—Five years after date of manufacture or date of issue.

Fungus extracts and fungus antigens.—Three years after date of manufacture or date of issue, provided the date of issue shall be not more than 2 years after the date of manufacture if the product is kept constantly at a temperature not exceeding 5° C.

Liquid venoms.—Eighteen months after date of manufacture or date of issue.

Dried venoms.—Five years after date of manufacture or date of issue.

Trichinella extract.—Eighteen months after date of manufacture or date of issue.

THOMAS PARRAN,
Surgeon General.

U. S. GOVERNMENT PRINTING OFFICE: 1941

For sale by the Superintendent of Documents, Washington, D. C. - - - - - - Price 5 cents

FEDERAL SECURITY AGENCY,
Washington, D. C., September 30, 1940.

These regulations have been prepared by the undersigned board of officers pursuant to the authority contained in section 4 of the act of July 1, 1902, 32 Stat. 729 (U. S. C., title 42, sec. 145), entitled "An act to regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in said articles, and for other purposes." They are hereby promulgated and will supersede the regulations issued February 25, 1935.

JAS. C. MAGEE,
Surgeon General, U. S. Army.
ROSS T. MCINTIRE,
Surgeon General, U. S. Navy.
THOMAS PARRAN,
Surgeon General, U. S. Public Health Service.

Approved October 12, 1940.

WAYNE COY,
Acting Administrator,
Federal Security Agency.

REGULATIONS FOR THE SALE OF VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS

Pursuant to the authority contained in section 4 of the act of July 1, 1902, 32 Stat. 729 (U.S.C., title 42, sec. 145), the following regulations for the sale of viruses, serums, toxins, and analogous products in the District of Columbia and in interstate traffic are hereby promulgated:

LICENSES

1. Licenses shall be issued, suspended, and revoked by the Administrator of the Federal Security Agency, hereafter designated as "the Administrator," upon the recommendation of the Surgeon General of the United States Public Health Service.

2. Licenses shall be issued only after inspection of establishments and examination of the products for which license is desired. In the case of establishments already licensed, licenses for new products may, at the discretion of the Administrator, be granted without reinspection of the establishment. License for new products shall not be granted without satisfactory evidence of therapeutic or prophylactic efficiency.

3. Whenever deemed necessary by the Surgeon General of the United States Public Health Service, the reports of inspection and laboratory examination shall be passed upon by the Sanitary Board of the United States Public Health Service. The board shall report its findings to the Surgeon General who shall forward the report, together with his recommendations, to the Administrator for action.

4. Licenses shall be valid until suspended or revoked. The following form of license is prescribed:

This is to certify that _____ of _____ is hereby authorized under the provisions of "An act to regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in such articles, and for other purposes", to engage in the manufacture, barter, and sale of such of these viruses, serums, toxins, and analogous products as are specified from time to time by the Administrator or Assistant Administrator of the Federal Security Agency, and of only such as have been so specified and for which license has not been suspended or revoked, in accordance with the above-mentioned act and regulations thereunder.

_____

Administrator.

5. Licenses shall not be reissued without inspection of the establishments and laboratory examination of the products. The inspection

and laboratory reports shall be passed upon by the Surgeon General of the United States Public Health Service in accordance with the provisions of paragraph 3.

6. An establishment shall be subject to license when one or more of its products is held by the Administrator to be a virus, serum, toxin, or antitoxin, or a product analogous thereto and applicable to the prevention or cure of diseases of man.

7. For the purpose of these regulations, viruses, serums, toxins, antitoxins, and analogous products applicable to the prevention or cure of diseases of man are referred to as biologic products and defined as follows: I. A virus is a product containing the minute living cause of an infectious disease. II. A serum is the product obtained from the blood of an animal by removing the clot or clot components and the blood cells. III. A toxin is a product containing a soluble substance poisonous to laboratory animals or to man in doses of 1 milliliter or less of the product, and having the property, following the injection of nonfatal doses into an animal, of causing to be produced therein another soluble substance which specifically neutralizes the poisonous substance and which is demonstrable in the serum of the animal thus immunized. IV. An antitoxin is a product containing the soluble substance in the serum or other body fluid of an immunized animal which specifically neutralizes the toxin against which the animal is immune. V. A product is analogous (*a*) to a virus if prepared from a virus, including micro-organisms actually or potentially virulent; (*b*) to a serum, if prepared from some protein constituent of the blood and intended for parenteral administration; (*c*) to a toxin or antitoxin, if intended, by parenteral administration, for the prevention or treatment of disease through specific immunization.

8. Instances of manufacture, importation, or sale of unlicensed products contrary to law, or of labeling unlicensed products as licensed or as if subject to license, shall be reported by officers of the Public Health Service, by State and local health authorities, by physicians, and by others to the Surgeon General of the United States Public Health Service for investigation or reference to the Department of Justice.

9. In order to obtain a license for any biologic product, manufacturers shall make application therefor to the Surgeon General of the United States Public Health Service on forms prescribed for the purpose. Inspectors shall be furnished with the original forms and shall certify thereon as to the condition of the establishment, with recommendations.

10. Should important changes in personnel, method, equipment, or location be made by an establishment holding license, the manufac-

turer shall immediately notify the Surgeon General of the United States Public Health Service and make notation on the form required by paragraph 9 to be kept on file in the establishment.

11. Biologic products imported from foreign countries will be refused entry by collectors of customs unless produced in an establishment holding an unsuspended and unrevoked license, or intended for examination prior to obtaining a license. Each foreign establishment holding license and importing biologic products into the United States shall be required to file the name and address of one or more representatives in the United States authorized by the establishment to distribute their products, and such representatives shall keep records of such distribution.

12. The importation of smallpox vaccine from any foreign country into the United States is prohibited, except smallpox vaccine sent to the National Institute of Health of the United States Public Health Service, where tests shall be applied to demonstrate the absence of any other pathogenic virus.

13. Each foreign importation of biologic products shall be accompanied by two sample packages of each lot number contained in the shipment, and said samples shall be forwarded by the collector of customs at the port of entry to the National Institute of Health of the United States Public Health Service for examination. If separate samples are not found accompanying the shipment, samples shall be obtained from the shipment by the collector of customs and forwarded to the National Institute of Health of the United States Public Health Service.

INSPECTION

14. The inspections shall be made by an inspector or a board of inspectors detailed by the Administrator upon the recommendation of the Surgeon General of the United States Public Health Service.

15. The inspectors shall be officers of the United States Public Health Service.

16. Inspections shall be unannounced, unless special circumstances render this undesirable.

17. It shall be the duty of the inspector to call upon the acting head of the establishment, stating the object of his visit.

18. The inspectors shall examine all portions of the premises, appliances, stables, barns, warehouses, records, and the methods employed in actual operation.

19. Inspectors are authorized to interrogate the proprietors and personnel of the establishment under oath.

20. The inspectors shall investigate fully the methods of preparation, storing, dispensing, and other details in the manufacture and sale of serums, viruses, toxins, and analogous products.

21. The inspector shall carefully examine into location, construction, or administration of establishments which would tend to endanger the potency or purity of the products.

22. Inspections for original licenses of an establishment need not be made until assurances are received that the establishment is in running order and manufacturing the complete product for which license is desired.

23. In case license is refused following an inspection, reinspection shall not be ordered until assurances have been received that the establishment affected has corrected all the faulty conditions which were made the basis for the previous refusal of a license.

24. In case faulty methods of preparation, faulty location, faulty construction, or faulty administration of establishments are observed during inspection, the inspector shall bring the same to the attention of the manufacturer, and shall forward a report of the conditions found, together with his recommendations, to the Surgeon General of the United States Public Health Service.

25. Should the faulty conditions discovered during inspection or upon laboratory tests be found upon review by the Surgeon General of the United States Public Health Service to be of sufficient importance, the Surgeon General shall recommend to the Administrator that the license of the establishment be canceled or suspended. In case of suspension, if the said faulty conditions are not corrected within 60 days he shall recommend that the said license be revoked.

26. The fact of suspension or revocation of license, with causes therefor, may be published by the Administrator.

MANUFACTURING ESTABLISHMENTS

27. The organization of a licensed establishment shall be such that the responsible head is actually in permanent control of the buildings, grounds, equipment, and personnel; and good discipline shall prevail.

28. In considering the license of an establishment, regard shall be had to the training and competence of the technical workers concerned.

29. Permanent records shall be kept, with dates, of the various steps in the manufacture, testing, disposition, and distribution of each lot, so that at any time these steps may be traced by an inspector as regards any lot number.

30. Laboratory cultures and other materials used in the production of biologic products shall be labeled and preserved in a safe and orderly manner.

31. All work with spore-bearing pathogenic micro-organisms shall be so separated from other work, and the containers permanently so marked, as to avoid the possibility of contamination of products.

32. Laboratory procedures of a diagnostic nature shall, if conducted in an establishment, be entirely separate from those for the production of biologic products.

33. Laboratories for the production of biologic products shall be efficiently screened during the fly season.

34. Sterilization and subsequent handling of containers, filling apparatus, and other materials which may come in contact with biologic products during manufacture shall be such as to insure the absence of living bacterial spores; except that the concentration of antitoxins may be conducted with scrupulous cleanliness rather than with absolute sterility.

35. Records of the date, duration, and temperature of each sterilization shall be kept. Such records shall be made by means of automatic registering devices or by the personnel of the sterilizing room.

36. Details of sanitary standards, methods of manufacturing and of testing, and methods of keeping records, may be communicated to manufacturers by inspectors.

37. All containers used in the preparation of biologic products shall be of such construction as will readily permit inspection for cleanliness.

38. The construction of bleeding rooms and rooms for vaccine animals shall be such as to permit thorough hosing down and cleaning.

39. Hot water shall be provided in bleeding rooms and vaccine stables.

40. Stable floors shall be so constructed and cared for as to insure cleanliness, and stables shall be well lighted and well ventilated.

41. No manure shall be so stored as to permit the breeding of flies on the premises of any establishment.

42. All personnel, animals, and equipment used in the production of hog-cholera serum shall be kept entirely separate from personnel, animals, and materials used in the production of biologic products for human use.

43. Animals used in the production of biologic products shall be kept under competent daily inspection and preliminary quarantine by the establishment for a period of at least 7 days before use. Only healthy animals free from communicable disease shall be used; during the quarantine period those of the equine genus must be shown to be free from glanders, and those of the bovine genus must be shown to be free from tuberculosis.

44. All horses used in the production of biologic products, except those horses which are actively immune to tetanus, shall be given not less than 500 units of tetanus antitoxin semimonthly, or 2,000 units monthly.

45. Necropsy records shall be kept of all animals which die or are killed after having been used in the production of biologic products.

46. In case of actual or suspected infection with foot-and-mouth disease, glanders, tetanus, anthrax, gas gangrene, equine infectious anemia, or equine encephalomyelitis among animals used for the production of biologic products, the manufacturer shall immediately notify the Surgeon General of the United States Public Health Service.

47. Animals used for propagation of smallpox vaccine shall be thoroughly cleansed with soap and water at the beginning of the quarantine and at its conclusion. No part of the animal shall be vaccinated which is liable to be contaminated by feces.

48. Preliminary to taking vaccine material from vaccinated animals, said animals shall be killed or rendered insensible to pain.

49. Each year at least two of the animals used in propagating smallpox vaccine of any one strain shall be kept for a period of 2 weeks subsequent to the removal of the virus and observed sufficiently to demonstrate the absence of foot-and-mouth disease. At the termination of the period of observation in the case of these two animals, and within 48 hours after taking the smallpox vaccine in the case of all other animals, a necropsy shall be made upon each animal, and permanent records kept of each necropsy, in which particular note shall be made of pathologic changes.

50. All vaccine material from any animal having, or suspected of having, a communicable disease, other than vaccinia, shall be destroyed.

51. No animals used for the purpose of propagating smallpox vaccine shall be removed from the establishment prior to necropsy.

52. The personnel who care for the vaccine animals shall be excluded from horse stables and paddocks and from contact with horses while vaccine is being propagated.

53. Extraneous materials shall not be stored or permitted in or about vaccine stables or operating rooms.

54. Smallpox vaccine shall be furnished only in glass capillary tubes or in other glass containers. This shall not prohibit the inclosure in the same package, but separate from the virus, of a metal or glass instrument for inserting the virus.

55. Capillary tubes for smallpox vaccine shall be filled mechanically in vacuum jars, and prior to filling shall be sterilized in the same containers which are used for filling.

LABELING

56. For purposes of labeling, the proper name of each product shall be that specified in the license.

57. The proper name of each product must appear upon the outside label in legible type and shall be given precedence in position and prominence over any other descriptive or trade name.

58. In the case of products prepared by methods other than the usual or standard methods, the proper name used to designate the product in the license and on the labels shall be sufficiently descriptive to indicate such deviation. Should the species of animal used differ from that usually or originally employed, the name of the species shall be included as part of the proper name on the label.

59. In case of products for which an official standard of potency has been adopted, the potency shall be expressed on the label in terms of the official standard. In case no official standard of potency has been adopted and no official test is made prior to the release of the product for sale, the label shall bear the following statement: "No U. S. standard of potency." This provision shall not be held to apply to smallpox vaccine, nor to rabies vaccine.

60. The requirement that each package shall be marked with the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results shall be held to be complied with if the label bears the date of manufacture or date of issue as defined in paragraphs 61 and 62 of these regulations, and a statement of the period in months or days from this date of manufacture or date of issue during which they may be expected to yield their specific results.

61. Unless otherwise specifically provided as indicated in paragraph 63, the date of manufacture shall be: (1) For products for which an official standard of potency exists, the last date of satisfactorily passing a potency test; (2) for products for which no official standard of potency exists, the date of removal from the animal in case of animal products, or the date of cessation of growth in the case of other products or (3) in the case of products used for specific desensitization, the date of extraction.

62. Unless otherwise specifically provided as indicated in paragraph 63, the date of issue from cold storage may be accepted in lieu of the date of manufacture, provided the date of issue is not more than 3 months after date of manufacture if the product is kept constantly at a temperature not exceeding 15° C., or not more than 6 months after the date of manufacture if the product is kept constantly at a temperature not exceeding 10° C., or not more than 1 year after the date of manufacture if the product is kept constantly at a temperature not exceeding 5° C., or not more than 2 years after date of manufacture if the product is kept constantly at a temperature not exceeding 0° C.

63. Decisions shall be issued from time to time by the Surgeon General of the United States Public Health Service, regarding the dating of special products in accordance with tests made thereon.

64. All labels affixed to containers shall bear the number of the lot of the product contained therein.

65. The following items shall appear on the outside label:

(1) Name of manufacturer.
(2) Address of manufacturer.
(3) License number.
(4) Proper name of product.
(5) Minimum potency of product.
(6) "No U. S. standard of potency" if no such standard is established.
(7) Lot number.
(8) Date of manufacture or issue with period of potency; or the expiration date.

66. In case a product manufactured by one establishment is sold by another, the name, address, license number, and lot number of the original manufacturer shall appear plainly on the label, provided the name of the second establishment may appear on the label as the selling agent. In case any part of the process, such as bottling, is performed by the second establishment, this establishment also must hold a license for the manufacture of the product; the names, addresses, and license numbers of both establishments must appear on the label, and the records of both establishments shall show plainly the degree of responsibility of each in the process of manufacture. Labels bearing a license number shall appear only on packages of products for the manufacture of which a license is in force.

EXAMINATION OF PRODUCTS

67. Establishments shall furnish to the inspector and, on request, shall send to the National Institute of Health of the United States Public Health Service, adequate samples of products for examination.

68. Samples of special lots of products, or of all lots of particular products, may be required to be sent to the National Institute of Health of the United States Public Health Service for examination prior to being placed in interstate commerce or on sale in the District of Columbia.

69. It shall be the duty of the Director of the National Institute of Health of the United States Public Health Service to test samples sent him by inspectors, and the result of this examination shall be given to the inspectors, who shall give this report due weight in making their recommendations.

70. Biologic products offered for sale in the District of Columbia, or in interstate traffic, shall be obtained from time to time and examined at the National Institute of Health of the United States Public Health Service as to purity and potency and as to whether said products were properly labeled.

71. In examining biologic products consideration shall be given to the character and safety of containers and to those materials accompanying them which are intended to facilitate administration of their contents.

72. Official methods of testing, standards, and standard units shall be employed upon authorization of the Surgeon General of the United States Public Health Service. The official standards of potency for all forms of diphtheria antitoxin, tetanus antitoxin, botulinus antitoxin type A, botulinus antitoxin type B, perfringens antitoxin, scarlet fever streptococcus antitoxin, vibrion septique antitoxin, antipneumococcic serum (types I, II, V, VII, and VIII), antidysenteric serum (Shiga), staphylococcus antitoxin, histolyticus antitoxin, oedematiens antitoxin, and sordellii antitoxin shall be those distributed by the United States Public Health Service.

73. Diphtheria antitoxin shall have a potency of not less than 500 units per cubic centimeter if in liquid form, and not less than 4,000 units per gram if in solid form. Tetanus antitoxin shall have a potency of not less than 400 units per cubic centimeter if in liquid form, and not less than 2,400 units per gram if in solid form. Scarlet fever streptococcus antitoxin shall have a potency of not less than 400 units per cubic centimeter.

74. Standard samples for comparison of products other than those mentioned in paragraph 72 may be distributed by the National Institute of Health, and the Director of the National Institute of Health is authorized to request manufacturers to forward such samples of their products for testing as may be required to insure safety and potency of products.

75. Tests for potency, if applicable, shall be made after the completion of all the processes of manufacture except filling the final containers.

76. A sample of each lot of all products shall be tested for identity if such test is applicable, and for safety, after the labels have been affixed to the final containers.

77. No liquid serum shall contain more than 20 percent total solids, nor more than 0.5 percent of preservative.

78. Products intended to be used intraspinally or intravenously shall be clear, free from excessive coloration, or excessive viscosity, and those to be used intraspinally shall contain not more than 0.35 percent of preservative.

79. Containers of products intended to be used intraspinally or intravenously shall be of such material that the presence of objectionable color or of sediment in the contents may be detected.

80. Any lot of any product shall be subject to withdrawal and recall from the market, regardless of dating, upon the discovery of lack of purity, potency, or safety, or if the product is found to be subject to undue deterioration. Upon the discovery of such information the same shall be communicated to the manufacturer of the product in question and the identification of said product may be made public by the Administrator.

[PUBLIC—No. 244]

AN ACT To regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in said articles, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That from and after six months after the promulgation of the regulations authorized by section 4 of this act no person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State, Territory, or the District of Columbia into any State, Territory, or the District of Columbia, or from any foreign country into the United States, or from the United States into any foreign country, any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention and cure of diseases of man, unless (a) such virus, serum, toxin, antitoxin, or product has been propagated and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary of the Treasury as hereinafter authorized, to propagate and prepare such virus, serum, toxin, antitoxin, or product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; nor (b) unless each package of such virus, serum, toxin, antitoxin, or product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results: *Provided*, That the suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, or product aforesaid which has been sold and delivered by the licentiate prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, or product aforesaid has been notified by the Secretary of the Treasury not to sell, barter, or exchange the same.

SEC. 2. That no person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, or product aforesaid, nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, or product aforesaid so as to falsify such label or mark.

SEC. 3. That any officer, agent, or employee of the Treasury Department duly detailed by the Secretary of the Treasury for that purpose, may, during all reasonable hours, enter and inspect any establishment for the propagation and preparation of any virus, serum, toxin, antitoxin, or product aforesaid for sale, barter, or ex-

change in the District of Columbia, or to be sent, carried, or brought from any State, Territory, or the District of Columbia into any other State or Territory or the District of Columbia, or from the United States into any foreign country, or from any foreign country into the United States.

SEC. 4. That the Surgeon General of the Army, the Surgeon General of the Navy, and the supervising Surgeon General of the Marine Hospital Service be, and they are hereby, constituted a board with authority, subject to the approval of the Secretary of the Treasury, to promulgate from time to time such rules as may be necessary in the judgment of said board to govern the issue, suspension, and revocation of licenses for the maintenance of establishments for the propagation and preparation of viruses, serums, toxins, antitoxins, and analogous products, applicable to the prevention and cure of diseases of man, intended for sale in the District of Columbia, or to be sent, carried, or brought for sale from any State, Territory, or the District of Columbia into any other State, Territory, or the District of Columbia, or from the United States into any foreign country, or from any foreign country into the United States: *Provided*, That all licenses issued for the maintenance of establishments for the propagation and preparation in any foreign country of any virus, serum, toxin, antitoxin, or product aforesaid for sale, barter, or exchange in the United States, shall be issued upon condition that the licentiates will permit the inspection of the establishments where said articles are propagated and prepared, in accordance with section 3 of this act.

SEC. 5. That the Secretary of the Treasury be, and he is hereby, authorized and directed to enforce the provisions of this act and of such rules and regulations as may be made by authority thereof; to issue, suspend, and revoke licenses for the maintenance of establishments aforesaid, and to detail for the discharge of such duties such officers, agents, and employees of the Treasury Department as may in his judgment be necessary.

SEC. 6. That no person shall interfere with any officer, agent, or employee of the Treasury Department in the performance of any duty imposed upon him by this act or by regulations made by authority thereof.

SEC. 7. That any person who shall violate, or aid or abet in violating, any of the provisions of this act shall be punished by a fine not exceeding five hundred dollars or by imprisonment not exceeding one year, or by both such fine and imprisonment in the discretion of the court.

SEC. 8. That all acts and parts of acts inconsistent with the provisions of this act be, and the same are hereby, repealed.

Approved, July 1, 1902.

O