STATUTORY INSTRUMENTS

1968 No. 908

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Manufacture of Preparations of Human Blood) Amendment Regulations 1968

Made - - -	10*th June* 1968
Laid before Parliament	17*th June* 1968
Coming into Operation	1*st July* 1968

The Joint Committee constituted by section 4(1) of the Therapeutic Substances Act 1956(**a**), in exercise of the powers conferred on them by sections 1 and 5 of the said Act, after consultation with the Advisory Committee constituted under section 4(2) of the said Act, hereby make the following regulations :—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Therapeutic Substances (Manufacture of Preparations of Human Blood) Amendment Regulations 1968 and shall come into operation on 1st July 1968.

(2) The Therapeutic Substances (Manufacture of Preparations of Human Blood) Regulations 1963 and 1966(**b**) and these regulations may be cited together as the Therapeutic Substances (Manufacture of Preparations of Human Blood) Regulations 1963 to 1968.

(3) The Interpretation Act 1889(**c**) shall apply to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament.

Amendment of the Therapeutic Substances (Manufacture of Preparations of Human Blood) Regulations 1963

2. The Therapeutic Substances (Manufacture of Preparations of Human Blood) Regulations 1963, as amended by the Therapeutic Substances (Manufacture of Preparations of Human Blood) Amendment Regulations 1966, shall be further amended as follows :—

(*a*) in regulation 6 (which relates to the method of preparation) there shall be added the following paragraph—

"(3) Any establishment in which preparations of human blood are prepared shall be under the complete direction and control of an expert approved by the licensing authority." ;

(*b*) in regulation 37(*b*) (which relates to the quality of plasma protein fraction) after the word "albumin ;" there shall be added the words "and the remaining protein shall have the mobility characteristics of globulins of which not more than 1 per cent is gamma G globulin ;";

(**a**) 1956 c. 25. (**b**) S.I. 1963/1456, 1966/503 (1963 II, p. 2539; 1966 I, p. 1040).
(**c**) 1889 c. 63.

(*c*) in the title to Part X and in regulations 40 to 44 wherever the words "human gamma G-immunoglobulin" appear, there shall be substituted therefor the words "human normal immunoglobulin";

(*d*) in regulation 42(*d*)(ii) (which relates to the solubility of human normal immunoglobulin in solid form) for the words "10 minutes" there shall be substituted the words "15 minutes";

(*e*) regulation 48 (which relates to the storage and labelling of human serum albumin and preparations thereof) shall be renumbered regulation 49, and after regulation 47 there shall be inserted the following regulation—

"*Tests for freedom from pyrogenic substances*

48.—(1) Human serum albumin shall, if the licensing authority so require, be tested for freedom from pyrogenic substances in accordance with the general regulations, and shall in any event be free from such substances to such an extent that, if so tested, it would pass the test.

(2) The quantity of human serum albumin for the purpose of the test for freedom from pyrogenic substances shall be not greater than 1,000 milligrams and not less than 500 milligrams per kilogram of the weight of each rabbit used in the test, or such lesser quantity as may be approved by the licensing authority";

(*f*) where by any provisions of regulations 9(1), 34(1), 44(1) and 49(2) (as renumbered by these regulations) any particulars are required to be borne by the container of any substance to which those regulations relate, and such container is of a capacity of less than 2.5 millilitres, such particulars may, with the consent of the licensing authority, be borne instead by the package in which the container is offered for sale;

(*g*) part XII (which relates to 131-radioiodinated human serum albumin) shall be deleted, and after regulation 49 (as renumbered by these regulations) there shall be inserted the following regulations—

"PART XII

GENERAL PROVISIONS RELATING TO ISOTOPE-LABELLED HUMAN SERUM ALBUMIN

Definition and proper name

50. Isotope-labelled human serum albumin is a preparation of the organic compound formed by the union of the radioactive isotope with human serum albumin. The proper name of any such substance shall be such as may be approved by the licensing authority, so, however, that such name shall be required to include the words "human serum albumin" together with an indication of the nature of the isotope and, where such is the case, a further indication that the human serum albumin is denatured.

Quality

51. Isotope-labelled human serum albumin shall be prepared from human serum albumin complying with part XI of these regulations. Human serum albumin added as a diluent shall also comply with part XI of these regulations.

Test for absence of denatured protein

52. Except where isotope-labelled human serum albumin has been prepared so as to contain denatured protein, and this is indicated on the container of the albumin, it shall be free from denatured protein and shall be tested for such freedom by a test which is approved by the licensing authority.

Tests for sterility and for freedom from pyrogenic substances

53. Isotope-labelled human serum albumin shall, if, having regard to any limitations imposed by the presence of radioactivity therein, the licensing authority so require, be tested for sterility and for freedom from pyrogenic substances in accordance with the general regulations, and it shall in any event be free from pyrogenic substances to such an extent that, if tested therefor, it would pass the test.

Storage and labelling

54.—(1) Isotope-labelled human serum albumin shall be stored in a manner approved by the licensing authority, and at a temperature of not less than 2°C and not more than 10°C.

(2) In addition to the particulars required by regulation 9(1) and (2) of these regulations, the following further particulars shall be borne by the container of isotope-labelled human serum albumin:—

(*a*) the nature and volume of the contents and words certifying that such contents are radioactive;

(*b*) the total radioactivity in microcuries or millicuries of the contents, and the date and, if the licensing authority so require, the time to which the measurement refers;

(*c*) the total weight of human serum albumin in the container;

(*d*) the nature and concentration of the added substances present; and

(*e*) the date after which the contents should not be used:

Provided that, when isotope-labelled human serum albumin is issued in containers of less than 2.5 millilitres capacity and in packages of not more than ten such containers the particulars mentioned in sub-paragraph (*d*) of this paragraph may, with the consent of the licensing authority, be borne instead by the package.

PART XIII

SPECIAL PROVISIONS RELATING TO IODINATED (^{125}I) HUMAN SERUM ALBUMIN

Definition and proper name

55. Iodinated (^{125}I) human serum albumin is the isotope-labelled human serum albumin formed by the union of radioactive iodine (^{125}I) with human serum albumin. Its proper name is "iodinated (^{125}I) human serum albumin".

Quality

56.—(1) The calculated average number of iodine atoms bound to each molecule of human serum albumin in iodinated (^{125}I) human serum albumin shall be not greater than one.

(2) The pH value of iodinated (^{125}I) human serum albumin shall lie between 6.5 and 8.5.

Test for protein-bound iodine

57. Iodinated (^{125}I) human serum albumin shall contain not less than 95 per cent of its total iodine as protein-bound iodine, as determined by a method approved by the licensing authority.

Quantity for purpose of the test for freedom from pyrogenic substances

58. The quantity of iodinated (^{125}I) human serum albumin for the purpose of the test for freedom from pyrogenic substances shall be such as the licensing authority may approve.

PART XIV

SPECIAL PROVISIONS RELATING TO IODINATED (^{131}I) HUMAN SERUM ALBUMIN

Definition and proper name

59. Iodinated (^{131}I) human serum albumin is the isotope-labelled human serum albumin formed by the union of radioactive iodine (^{131}I) with human serum albumin. Its proper name is "iodinated (^{131}I) human serum albumin".

Quality

60.—(1) The calculated average number of iodine atoms bound to each molecule of human serum albumin in iodinated (^{131}I) human serum albumin shall be not greater than one.

(2) The pH value of iodinated (^{131}I) human serum albumin shall lie between 6.5 and 8.5.

Test for protein-bound iodine

61. Iodinated (^{131}I) human serum albumin shall contain not less than 95 per cent of its total iodine as protein-bound iodine, as determined by a method approved by the licensing authority.

Quantity for purpose of the test for freedom from pyrogenic substances

62. The quantity of iodinated (^{131}I) human serum albumin for the purpose of the test for freedom from pyrogenic substances shall be such as the licensing authority may approve.".

These regulations were made by the aforesaid Joint Committee on 10th June 1968.

Kenneth Robinson,
William Ross,
Wm. J. Morgan,
Members of the Joint Committee.

W. F. Farrant,
Clerk to the Joint Committee.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations, made under Part I of the Therapeutic Substances Act 1956, amend the Therapeutic Substances (Manufacture of Preparations of Human Blood) Regulations 1963 and 1966 by adding general provisions relating to isotope-labelled human serum albumin and special provisions relating to iodinated (^{125}I) human serum albumin and to iodinated (^{131}I) human serum albumin, including provisions as to quality, freedom from pyrogenic substances, and labelling.

They also amend requirements as to the method of preparation of human blood products, and the special provisions relating to the quality of plasma protein fraction, substitute the name human normal immunoglobulin for that of human gamma G-immunoglobulin, amend the regulations relating to the solubility of human normal immunoglobulin in solid form, introduce a test for freedom from pyrogenic substances for human serum albumin, and amend certain provisions relating to labelling of containers of less than 2.5 millilitres capacity.