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Changes in Proper Names of Certain Biological Products; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 606, 610, 620, 630, 640, and 660

[Docket No. 80N-0053]

Changes in Proper Names of Certain Biological Products

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by changing the proper names of certain biological products; updating all applicable regulations to reflect these new names; and updating, clarifying, and reorganizing certain regulations. The "proper name" of a product is the name that FDA requires that manufacturers use on the label of the product. FDA is taking these actions to reduce the length of a name, more accurately identify a product, or make the name more consistent with the name of the same product in the United States Pharmacopeia (U.S.P.) or in the United States Adopted Names (USAN).

EFFECTIVE DATE: January 29, 1986 for all affected products initially introduced or initially delivered for introduction into interstate commerce. See Supplementary Information for full discussion of proposed effective date.

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SUPPLEMENTARY INFORMATION: In the Federal Register of October 31, 1980 (45 FR 72404), FDA proposed to change the proper names of more than 50 biological products, including various blood, viral, and bacterial products, antivenins, and one category of allergenic extracts, and update applicable regulations in 21 CFR Parts 600 through 660 to reflect these new proposed proper names. (The term "proper name" is defined in 21 CFR 600.3(k).) Further, FDA proposed to reorganize and clarify 21 CFR 610.53(a) concerning the prescribed dating periods for licensed biological products. FDA also proposed to delete the names of 30 biological products in 21 CFR 610.53(a) that are no longer licensed and add the names of 11 biological products that are licensed now but are not listed in the regulations. FDA developed and issued these regulations in collaboration with the United States Adopted Names Council (USAN) to designate meaningful and distinctive nonproprietary names for these biological products. USAN is sponsored by the American Medical Association, the United States Pharmacopeial Convention, and the American Pharmaceutical Association.

FDA provided a public comment period of 60 days on the proposal. However, in response to a request from a manufacturer, FDA extended the comment period an additional 60 days (Federal Register of December 9, 1980; 45 FR 81065).

FDA received 37 letters in response to the proposal and several of these letters contained more than one comment. Eight letters expressed approval of the amendments as proposed, eight other letters expressed approval of the amendments with some reservations, and the remaining letters contained general comments or suggestions of alternative names. Because certain comments objected to the proposed changes in proper names of one or more products or upon reconsideration, FDA advises that in the final rule about 30 percent of the proper names that FDA proposed to change were not changed. For more detailed information, see table I at the end of the preamble to this final rule. Summaries of all of the comments and FDA's responses follow:

1. One comment noted a discrepancy concerning the modifier to be used with the proposed proper name of each of several blood and blood products.

FDA agrees with the comment. In several instances in the proposal, FDA identified incorrectly a proposed proper name with a modifier as the proper name. Accordingly, in the final rule FDA is excluding any modifier from the proper name of a product. Examples follow:

Proper name	Proper name with modifier
Red blood cells	Red blood cells deglycerolized.
Red blood cells	Red blood cells frozen.
Whole blood	Whole blood cryoprecipitate removed.

2. Two comments suggested new names for five products but gave no reasons why these names should be used instead of the names that FDA proposed.

Name suggested by comments	Name proposed by FDA
Albumin 96 pct. pure	Albumin.
Albumin 83 pct. pure	Plasma protein fraction.
AHF lyophilized	Antihemophilic factor.
AHF cryoprecipitated	Cryoprecipitated AHF.
Factor VIII	Antihemophilic factor and cryoprecipitated AHF.

FDA disagrees with the comments. FDA believes that the names that were suggested offer no advantages over the names that FDA proposed. Accordingly, FDA is rejecting the suggested name changes above for these products. (See also FDA's response in paragraph 29.)

3. One comment stated that proposed § 600.13 concerning retention sample requirements is not accurate because § 600.13 lists some but not all of the products in proposed § 600.15. Section 600.15 specifies temperatures of products to be maintained during shipment.

FDA disagrees with the comment. Section 600.13 lists certain products and categories of products that are exempt from the retention sample requirements. Section 600.15 is unrelated to § 600.13. Section 600.15 specifies temperatures of products to be maintained during shipment. All products shown in § 600.15 should not be listed in § 600.13, because all of the products in § 600.15 are not exempt from the retention sample requirements.

4. One comment stated that proposed § 600.15(a) does not state whether freshly collected whole blood may be shipped before the blood has cooled to 10 °C or colder, as described in proposed § 640.6(b) in FDA's proposal of October 31, 1980 (45 FR 72422).

FDA agrees that proposed § 600.15(a) should be clarified. Accordingly, in the final rule FDA is amending § 600.15(a) to incorporate transit storage temperature requirements.

5. One comment on proposed § 600.15 stated that the name Red Blood Cells should not be identified with the phrase "(liquid product)", because the phrase could easily be mistaken for a proper name, a modifier, or a qualifier.

FDA disagrees with the comment. FDA believes that the phrase "(liquid product)" that is not capitalized and is placed in parentheses helps to clarify the form of the product that is affected by the requirement and the phrase is not part of the proper name of the product. Accordingly, FDA rejects this comment.

6. Two comments on proposed § 610.53(c) stated that the dating periods are incorrect for some products. One comment stated that the dating periods for antisera are unrealistic and wasteful.

FDA disagrees with the comments. The dating periods listed in proposed § 610.53 are minimum dating periods for the products. FDA notes, however, that there could be instances where even shorter dating periods may be necessary to maintain product safety or potency. Therefore, FDA considers the "minimum dating period" to be the dating period based on usage, clinical experience, or laboratory testing which initially may be assigned to a product before the

manufacturer completes extended shelf life stability studies. As an amendment to its product license, a manufacturer may submit stability data to the Director, Center for Drugs and Biologics, to support a dating period longer than the minimum dating period shown in § 610.53. Accordingly, in the final rule FDA is changing § 610.53(a) by inserting the word "minimum" in the first sentence.

7. FDA proposed in § 610.53 to delete the 10-year dating period for Albumin (Human) packaged in hermetically sealed metal containers. Two comments suggested that the 10-year dating period for Albumin (Human) packaged in hermetically sealed metal containers be retained, because the Department of Defense still uses the product packaged in this manner.

FDA agrees with the comments. Accordingly, in the final rule FDA is retaining the 10-year dating period for Albumin (Human) packaged in hermetically sealed metal containers.

8. One comment on proposed § 610.53(c) objected to the proposal to change the name of Allergenic Extracts, Alum Precipitated, to Allergenic Extracts Adsorbed, because the manufacturers' administrative and financial costs from revising all labels and labeling of alum precipitated allergenic extracts would well exceed any expected benefit from consistency in names with other adsorbed products.

FDA now believes that only minimal benefits would result from the proposed change in the name. Accordingly, in the final rule FDA is retaining the current proper names of these products.

9. Four comments on proposed § 610.53(c) concerned the proposed proper names of the antivenins and the proposed word change of "antivenin" to "antivenom." One comment suggested the name Antivenom Black Widow Spider as an alternative to the proposed name Antivenom Widow Spider, because the proposed name suggests that this antivenom may have a broader specificity than has been demonstrated. For a similar reason, another comment objected to the proposed name Antivenom Coral Snake and suggested retaining the name Antivenin (*Micrurus fulvius*) for this product. One comment suggested adding a comma after "Copperhead" in the proposed name Antivenom Rattlesnake, Copperhead and Moccasin. One comment suggested that the current name of all antivenins be retained and that the proposed name Antivenom Rattlesnake, Copperhead and Moccasin is incorrect, because no copperhead or moccasin venom is used in the manufacture of this product. Instead, the venom of a tropical American pit viper is used in the manufacture of this antiserum.

FDA recognizes that confusion may result from changing the names of antivenins to the common names that were proposed, particularly if the products were to be exported to another country where the common name may represent a different genus or species. Thus, FDA agrees with the comments that suggested that the current proper names be retained without change. Accordingly, upon reconsideration, FDA is retaining the current names listed in the biologics regulations for these products. In addition, FDA is retaining the word "antivenin" rather than the proposed word "antivenom."

10. One comment on proposed § 610.53(c) noted that four products (Granulocytes, Pheresis; Granulocytes, Pooled; Granulocytes Platelets Pheresis; and Recovered Plasma, Pooled) that were listed in the Guideline for the Uniform Labeling of Blood and Blood Components that FDA made available in the **Federal Register** of October 31, 1980 (45 FR 72416) were not included in proposed § 610.53. Another comment suggested changing the proper name Recovered Plasma to Source Plasma, Recovered.

FDA advises that the four products identified by the comment were not licensed at the time of the proposal and thus were not included in proposed § 610.53. The three granulocyte preparations and Recovered Plasma still are unlicensed. FDA believes that the proper name Recovered Plasma is widely accepted and understood by the blood banking community and, therefore, FDA rejects the suggested name change for that product.

11. One comment on proposed § 610.53(c) suggested reversing the order of the words in the names of all immune globulins so that they could be listed together.

FDA agrees in part and disagrees in part with the comment. FDA does not believe that it is necessary to change the names of all immune globulins to list them together in the regulations. However, FDA agrees that listing the immune globulins together will aid in locating these products in the dating period listings. Accordingly, in the final rule FDA is reorganizing § 610.53 so that all immune globulin products are listed together. Likewise, FDA is reorganizing § 610.53 so that all plasma products are listed together.

12. Two comments on proposed § 610.53(c) concerned the proposed proper name Rh_o(D) Immune Globulin. One comment suggested substituting the name Rh Immune Globulin, because the product is almost universally known as Rh Immune Globulin or RhoGam. One comment stated that the proposed proper name of this product should be D(Rh_o) Immune Globulin, for consistency with the nomenclature of Blood Grouping Sera.

FDA disagrees with the comments. FDA believes that the most important part of the product name, i.e., Rh_o(D), should appear first. FDA rejects the suggested name D(Rh_o) Immune Globulin because the product is used therapeutically to prevent Rh hemolytic disease. Accordingly, in the final rule FDA is continuing to use the § 610.53(c) the current proper name Rh_o(D) Immune Globulin (Human). (See also FDA's response in paragraph 29.)

13. One comment on proposed § 610.53(c) suggested that the name "Measles and Mumps Virus Vaccine, Live" be changed by deleting the comma, to be consistent with similar products and the nomenclature in the U.S.P.

FDA agrees with the comment. FDA proposed this change in the codified text of § 610.53(c) in the proposal of October 31, 1980, but FDA mistakenly omitted it from the name change amendments listed in the preamble to the proposal. Accordingly, in the final rule FDA is identifying the product as Measles and Mumps Virus Vaccine Live.

14. One comment recommended deleting Mumps Immune Globulin from proposed § 610.53(c), because action has been taken taken by FDA to revoke product licenses for this product.

FDA agrees with the comment. After FDA published the proposal in the **Federal Register**, FDA revoked the licenses of 12 products in addition to the 30 products FDA proposed be deleted. In a final rule published in the **Federal Register** of June 8, 1982 (47 FR 24696), FDA deleted the following six products from § 610.53: Adenovirus and Influenza Virus Vaccines Combined Aluminum Hydroxide Adsorbed, Adenovirus and Influenza Virus Vaccines Combined Aluminum Phosphate Adsorbed, Adenovirus Vaccine, Mumps Immune Globulin (Human), Rocky Mountain Spotted Fever Vaccine, and Typhus Vaccine. Accordingly, in this final rule FDA is deleting the following 35 products from § 610.53: Aggregated Radio-Iodinated (I^{131}) Albumin (Human), Anti-Human Chorionic Gonadotropic Serum, Cobra Venom Solution, Cobra Venom Solution with Silicic and Formic Acids, Diphtheria and Tetanus Toxoids, Diphtheria and Tetanus Toxoids and Pertussis and Poliomyelitis Vaccine Adsorbed, Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Diphtheria and Tetanus Toxoids and

Pertussis Vaccine Adsorbed and Poliomyelitis Vaccine, Diphtheria and Tetanus Toxoids and Poliomyelitis Vaccine, Diphtheria Toxoid and Pertussis Vaccine, Diphtheria Toxoid and Pertussis Vaccine Adsorbed, Fibrinogen (Human), Fibrinogen with Antihemophilic Factor (Human), Gas Gangrene Polyvalent Antitoxin, Haemophilus Influenzae Typing Serum, Histamine Azoprotein, Leukocyte Typing Serum, Lymphogranuloma Venereum Antigen, Measles Immune Globulin (Human), Modified Plasma (Bovine), Mumps Vaccine, Poliomyelitis Vaccine Adsorbed, Polyvalent modified bacterial antigens with "No U.S. Standard of Potency," Pseudomonas Polysaccharide, Radio-Chromated (Cr^{51}) Serum Albumin (Human), Radio-Iodinated (I^{125}) Serum Albumin (Human), Radio-Iodinated (I^{131}) Serum Albumin (Human), Reagent Blood Group Specific Substances A and B, Russell Viper Venom, Schick Test Control, Staphylococcus Antitoxin, Staphylococcus Toxoid, Streptokinase-Streptodornase, Tetanus and Gas Gangrene Polyvalent Antitoxin, Trichinella Extract. Also, FDA proposed to codify existing dating periods for 11 licensed products which previously had not been listed in § 610.53. After publication of the proposed rule, FDA revoked the product license for 1 of the 11 products, Anticarcinoembryonic Antigen Serum, and has issued product licenses for 14 additional products. Accordingly, in the final rule FDA is identifying in § 610.53 dating periods for the following new products: Adenovirus Vaccine Live Oral Type 4; Adenovirus Vaccine Live Oral Type 7; Anti-Inhibitor Coagulant Complex; Asparaginase; Hepatitis B Immune Globulin (Human); Hepatitis B Vaccine; Immune Globulin Intravenous (Human); Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine); Meningococcal Polysaccharide Vaccine Group A; Meningococcal Polysaccharide Vaccine Group C; Meningococcal Polysaccharide Vaccine Groups A and C Combined; Meningococcal Polysaccharide Vaccine Groups A, C, Y, and W135 Combined; Pertussis Vaccine Adsorbed; Pneumococcal Vaccine Polyvalent; Rabies Immune Globulin (Human); Red Blood Cells Deglycerolized; Skin Test Antigens for Cellular Hypersensitivity; Source Leukocytes; Therapeutic Exchange Plasma; Thrombin Impregnated Pad; Varicella-Zoster Immune Globulin (Human).

15. One comment on proposed § 610.53(c) suggested that the storage temperature for Liquid Plasma be included in column D under both (a) and (b).

FDA agrees that this suggested change will clarify the regulations. Accordingly, in the final rule FDA is presenting the storage temperature for Liquid Plasma in column D under both (a) and (b).

16. One comment on proposed § 610.53(c) suggested that reversing the order of the words in the proposed names of some plasma and red blood cell products would allow the proper name and common name to be the same.

FDA agrees that reversing the order of the words in the proposed proper names of some plasma products will clarify the regulations. Accordingly, in the final rule FDA is changing the following proposed proper names to read as follows:

Proposed proper name	Proper name in final rule
Plasma fresh frozen	Fresh frozen plasma.
Plasma liquid	Liquid plasma.
Plasma platelet rich	Platelet rich plasma.

17. One comment on proposed § 610.53(c) stated that the information regarding dating periods for Plasma Protein Fraction in column D were confusing and suggested that the dating period regulations for this product be consistent with the dating period for Albumin.

FDA accepts the comment. In the final rule FDA is revising the information in the dating period regulations so that the requirements regarding manufacturer's storage temperature are consistent for Plasma Protein Fraction (Human) and Albumin (Human).

18. One comment on proposed § 610.53(c) suggested reversing the order of the names of anticoagulated products, e.g., ACD Red Blood Cells and CPD Whole Blood, because the name of the product is more important than the name of the anticoagulant.

FDA disagrees with the comment. FDA sees no advantage in having the name of the anticoagulant following the name of the product. In addition, for consistency with the terminology in the U.S.P., FDA believes that the name of the anticoagulant should precede the name of the product.

19. One comment on proposed § 610.53(c) stated that the hematocrit should be less than 80 percent for 35-day dating of CPDA–1 Red Blood Cells and questioned whether this information should be added to § 610.53.

FDA disagrees with the comment. FDA believes that it is inappropriate for hematocrit levels to be included in the dating period listing in § 610.53. Rather, a blood establishment should include this information in the blood establishment's standard operating procedures and in its product license application. FDA also advises that it currently is reviewing all blood regulations and evaluating hematocrit levels.

20. Two comments noted that no provision was made in proposed § 610.53(c) for Tuberculin, Old, on a multiple puncture device and also questioned why Tuberculin, Old, containing at least 50 percent glycerin was no longer identified.

FDA agrees that Tuberculin, Old, on a multiple puncture device should have been listed in § 610.53(c) and in the final rule FDA is including this product. FDA advises that Tuberculin, Old, containing at least 50 percent glycerin was excluded from proposed § 610.53(c) because the product is no longer manufactured under license.

21. One comment on proposed § 630.10 suggested deleting the comma in the proposed name Poliovirus Vaccine Live Oral, Trivalent, as well as the comma in each of the proposed names of the three monovalent vaccines.

FDA agrees with the comment. In the final rule FDA is deleting each of the commas. FDA notes, however, that only Poliovirus Vaccine Live Oral Trivalent is licensed for distribution. FDA has licensed and is releasing the three monovalent vaccines only for use in manufacturing the trivalent product.

22. One comment on proposed § 630.80 objected to the proposed name Measles-Smallpox Vaccine Live and suggested the name "Measles Live and Smallpox Vaccine" for two reasons: (1) the hyphen is unnecessary and should be replaced by the customary word "and"; and (2) the word "Live" should be placed after "Measles," not at the end of the proper name, to distinguish it from the inactivated form.

FDA agrees with the comment. Accordingly, in the final rule FDA is changing the proper name of the product to Measles Live and Smallpox Vaccine.

23. One comment on proposed § 640.(c) and (h) stated that the term "Heparinized" in the product name "Heparinized Whole Blood" should be changed to "Heparin," to be consistent with the practice of preceding the proper name with the name of the specific anticoagulant used.

FDA agrees with the comment. Accordingly, in the final rule FDA is changing the name of the product to Heparin Whole Blood.

24. One comment on proposed § 640.5(c) stated that Rh "typing" serum should not be changed to "grouping" serum because group refers to ABO and type refers to Rh and other factors.

FDA disagrees with this comment. FDA believes that Rh now is considered a group like ABO. FDA is not changing the regulation as suggested.

25. FDA received five comments on proposed §§ 640.6 and 640.7 concerning the proposed name Whole Blood Platelets and/or Cryoprecipitate Removed. One comment stated that Whole Blood, Modified, Platelets Removed, and Whole Blood, Modified, Cryoprecipitate Removed, should not be combined into one proposed name, because many physicians would not use the product for hemophiliacs if the label stated "Platelets and/or Cryoprecipitate Removed," when in fact only the Platelets had been removed. One comment stated that the name Whole Blood Platelets and/or Cryoprecipitate Removed is more cumbersome than Whole Blood (Human) Modified and suggested the names Blood, Platelets and/or Cryoprecipitate Poor; Whole Blood, Modified; Blood, Whole Blood, Modified; or Blood, Modified, as alternatives. One comment suggested inserting a comma or dash between Whole Blood and the component removed for clarification. One comment proposed two separate names—Platelets and Platelets Cryoprecipitate Removed—while another comment suggested two other separate names—Whole Blood Platelets Removed and Whole Blood Cryoprecipitated AHF Removed.

FDA agrees that the name Whole Blood Platelets and/or Cryoprecipitate Removed is cumbersome. FDA believes that it is important for physicians treating hemophiliacs to know if the Cryoprecipitate has been removed from the product. Further, FDA believes that it is unnecessary to indicate whether platelets have been removed because the blood would have to be very fresh for the platelets to be of value. Further, FDA does not believe that a comma or dash is necessary between the proper name and the modifier because the proper name and modifier appear on a different line on the label. FDA does not believe that the comment suggesting the names Platelets and Platelet Cryoprecipitate Removed should be adopted. The suggested names do not indicate that the product is whole blood that lacks platelets and cryoprecipitate. FDA has evaluated all alternative proper names and concludes that the proper name of the product should be Whole Blood Cryoprecipitate Removed. Accordingly, in the final rule FDA is changing the proper name in §§ 640.6 and 640.7 to Whole Blood Cryoprecipitate Removed.

26. One comment on proposed § 640.20 urged retention of the name Platelet Concentrate, because it is essential to differentiate this product from Whole Blood, Platelets and/or Cryoprecipitate Removed.

FDA disagrees with this comment. FDA believes that the name Platelet Concentrate does not identify the product more clearly than the proposed name Platelets and the comment misunderstood that the second product as Whole Blood from which Platelets or Cryoprecipitate or both have been removed. Accordingly, in the final rule FDA is adopting the name Platelets as proposed.

27. One comment on proposed § 640.34(d) stated that the term cubic milliliter should be cubic millimeter and that the phrase "250,000 platelets per cubic milliliter" should be "400,000 platelets per microliter."

FDA agrees in part and disagrees in part with the comment. FDA agrees that the term "cubic milliliter" is incorrect. Indeed, in the editorial revisions FDA published in the **Federal Register** of March 29, 1983 (48 FR 13052), the term "cubic milliliter" was corrected to read "microliter." FDA disagrees that the number of platelets should be increased from 250,000 to 400,000, because this action would result in wasting otherwise useful platelet preparations that could be used for treating pediatric patients.

28. Two comments on proposed § 640.50 objected to the proposed proper name Cryoprecipitated AHF. One comment stated that the abbreviation AHF is too subjective and uninformative and urged that the name Cryoprecipitated Antihemophilic Factor be retained. Another comment stated that it is misleading to call the product Cryoprecipitated AHF because it contains fibrinogen and von Willebrand factor in addition to Antihemophilic Factor. The comment suggested the name Cryoprecipitate be used, because the term is well recognized and widely used.

FDA disagrees with the comments. FDA believes that the proposed name Cryoprecipitated AHF is clear, informative, and in keeping with the principle of reducing the length of proper names wherever possible. FDA notes that the suggested proper name Cryoprecipitate is indeed uninformative and ambiguous. The term Cryoprecipitate can be used to identify any number of biological products and is, therefore, unacceptable. Accordingly, in the final rule FDA is retaining the proposed proper name Cryoprecipitated AHF in §§ 600.13, 600.15, 606.120, 610.11, 610.12, 610.53, 640.34, 640.50, 640.52, 640.53, 640.54, 640.55, and 640.56.

29. Five comments on proposed § 640.80 noted that the proposed proper name "Albumin" was inconsistent with the name "Albumin Human" in the current U.S.P. Two comments recommended retaining the word "Human" in the proper names of fractionation products, such as albumin, because blood products of animal origin are still available.

FDA agrees with these comments. Accordingly, in the final rule FDA is retaining the word "Human" in the proper names of the following products because similar blood products of animal origin are still available: Albumin (Human), Antihemophilic Factor (Human), Fibrinolysin (Human), Hepatitis B Immune Globulin (Human), Immune Globulin (Human), Pertussis Immune Globulin (Human), Plasma Protein Fraction (Human), Rabies Immune Globulin (Human), Rh_o(D) Immune Globulin (Human), Tetanus Immune Globulin (Human), Vaccinia Immune Globulin (Human).

30. Three comments on proposed § 660.28 concerned Blood Grouping Serum products. One comment stated that Anti-Colton^b is the synonym for Anti-Co^b. One comment noted that the synonym for Anti-CDE is Anti-Rh_o' ", not Anti-Rh_o' ". One comment noted the omission of the bars over the letters in Anti-c, Anti-e, Anti-k, and Anti-s and stated that the bar could be eliminated over the letter e but should be retained for each of the letters c, s, and k to differentiate the lower case letters from the upper case letters.

FDA agrees in part and disagrees in part with the comments. FDA has considered adding Anti-Colton^b to the table in § 660.28(d) as a synonym for Anti-Co^b, but now believes that confusion and typographical errors can be avoided by not listing each Blood Grouping Serum specificity in § 610.53. Instead, FDA is amending § 610.53 to state that all liquid Blood Grouping Serum products have a minimum dating period of 2 years, whereas all dried Blood Grouping Serum products have a minimum dating period of 5 years. The second and third comments deal with typographical errors that are corrected in this final rule. FDA notes that it has already eliminated the bar over the letter e in the biologics regulations (48 FR 13025; March 29, 1983).

31. Six comments concerned the proposed effective date of the final regulation (180 days after publication of the final regulation). The comments suggested changing the effective date to: 18 months (one comment); 1 year (one

comment); 1 year or varying effective dates for different products (one comment); 1 year or when supply of labels run out (one comment); and 2 years (two comments). One comment also suggested that FDA allow the use of "mixed" labeling (both new names and former names) before the effective date.

FDA essentially agrees with the suggestions of the comments regarding the need for a later effective date for the final rule. Accordingly, FDA is changing the effective date to January 29, 1986, which is 1 year after publication of this regulation. Also, FDA is allowing manufacturers to voluntarily begin use of labeling including the new proper name of a product along with labeling including the former proper name of the product, provided that such manufacturers alert their consignees or customers of any significant inconsistencies in the proper name of their products. Any product subject to this final rule that is initially introduced or initially delivered for introduction into interstate commerce on or after January 29, 1986 shall bear labeling including the new proper name of the product established herein.

Table I

For each product subject of a proposed change in proper name that was included in the proposal of October 31, 1980; FDA is listing below the current codified name, the proposed name, and the new proper name, if any, established herein.

Current codified name	Proposed name	Revised proper name (if any) and modifier (if applicable) under final rule
Blood Products		
Normal serum albumin (human)	Albumin	Albumin (human).
Antihemophilic factor (human)	Antihemophilic factor	No change in current codified name (see preamble paragraph 29)
Cryoprecipitated antihemophilic factor (human)	Cryoprecipitated AHF	Cryoprecipitated AHF.
Factor IX complex (human)	Factor IX complex	Factor IX complex.
Fibrinolysin (human)	Fibrinolysin	No change in current codified name (see preamble paragraph 29)
Immune serum globulin (human)	Immune globulin	Immune globulin (human).
Mumps immune globulin (human)	Mumps immune globulin	Product no longer licensed (see preamble paragraph 14).
Measles immune globulin (human)	Measles immune globulin	Do.
Pertussis immune globulin (human)	Pertussis immune globulin	No change in current codified name (see preamble paragraph 29)
Single donor plasma (human)	Plasma	Plasma.
Single donor plasma (human), fresh frozen	Plasma fresh frozen	Fresh frozen plasma.
Single donor plasma (human), liquid	Plasma liquid	Liquid plasma.
Single donor plasma (human), platelet rich	Plasma platelet rich	Platelet rich plasma.
Plasma protein fraction (human)	Plasma protein fraction	No change in current codified name (see preamble paragraph 29)
Platelet concentrate (human)	Platelets	Platelets.
Rabies immune globulin (human)	Rabies immune globulin	No change in current codified name (see preamble paragraph 29)
Reagent red blood cells (human)	Reagent red blood cells	Reagent red blood cells.
Red blood cells (human)	Red blood cells	Red blood cells.
Red blood cells (human), deglycerolized	Red blood cells deglycerolized	Red blood cells deglycerolized.
Red blood cells (human), frozen	Red blood cells frozen	Red blood cells frozen.
$Rh_o1(D)$ immune globulin (human)	$Rh_o(D)$ immune globulin	No change in current codfiad name (see preamble paragraph 29)
Source plasma (human)	Source plasma	Source plasma.
Source plasma (human), liquid	Source plasma liquid	Source plasma liquid.
Source plasma (human), pooled	Source plasma pooled	Source plasma pooled.
Source plasma (human), salvaged	Source plasma salvaged	Source plasma salvaged.
Tetanus immune globulin (human)	Tetanus immune globulin	No change in current codified name (see preamble paragraph 29)
Vaccinia immune globulin (human)	Vaccinia immune globulin	Do.
Whole blood (human)	Whole blood	Whole blood.
Whole blood (human), modified	Whole blood platelets and/or cryoprecipitate removed	Whole blood cryoprecipitate removed.
Viral Products		
Measles and mumps virus vaccine, live	Measles and mumps virus vaccine live	Measles and mumps virus vaccine live.
Measles virus vaccine, live attenuated	Measles virus vaccine live	Measles virus vaccine live.
Measles, mumps, and rubella virus vaccine, live	Measles, mumps and rubella virus vaccine live	Measles, mumps, and rubella virus vaccine live.
Measles and rubella virus vaccine, live	Measles and rubella virus vaccine live	Measles and rubella virus vaccine live.
Measles-smallpox vaccine, live	Measles-smallpox vaccine live	Measles live and smallpox vaccine.
Mumps virus vaccine live	Mumps virus vaccine live	Mumps virus vaccine live.
Poliovirus vaccine live, oral, trivalent	Poliovirus vaccine live oral, trivalent	Poliovirus vaccine live oral trivalent.
Poliovirus vaccine live, oral, type I	Poliovirus vaccine live oral, type I	Poliovirus vaccine live oral type I.
Poliovirus vaccine live, oral, type II	Poliovirus vaccine live oral, type II	Poliovirus vaccine live oral type II.
Poliovirus vaccine live, oral, type III	Poliovirus vaccine live oral, type III	Poliovirus vaccine live oral type III.
Poliomyelitis vaccine	Poliovirus vaccine inactivated	Poliovirus vaccine inactivated.
Rubella and mumps virus vaccine live	Rubella and mumps virus vaccine live	Rubella and mumps virus vaccine live.
Rubella virus vaccine, live	Rubella virus vaccine live	Rubella virus vaccine live.
Adenovirus and influenza virus vaccines combined aluminum phosphate adsorbed.	Adenovirus and influenza virus vaccines combined adsorbed.	Product no longer licensed (see preamble paragraph 14)
Bacterial Products		
Anthrax vaccine, adsorbed	Anthrax vaccine adsorbed	Anthrax vaccine adsorbed.
Diphtheria and tetanus toxoids and pertussis and poliomyelitis vaccines adsorbed.	Diphtheria and tetanus toxoids and pertussis and poliovirus vaccines inactivated, adsorbed.	Product no longer licensed (see preamble paragraph 14).
Diphtheria and tetanus toxoids and pertussis vaccine adsorbed and poliomyelitis vaccine.	Diphtheria and tetanus toxoids and pertussis vaccine adsorbed and poliovirus vaccine inactivated.	Product no longer licensed (see preamble paragraph 14).
Tetanus and diphtheria toxoids adsorbed (for adult use)	Tetanus and diphtheria toxoids adsorbed for adult use	Tetanus and diphtheria toxoids adsorbed for adult use.
Antivenins		
Antivenin (crotolidae) polyvalent	Antivenom rattlesnake, copper head and moccasin	No change in current codified name (see preamble paragraph 9)
Antivenin (lactrodectus mactans)	Antivenom widow spider	Do.
Antivenin (micrurus fulvius)	Antivenom coral snake	Do.
Allergenic Extracts		
Allergenic extracts, alum precipitated	Allergenic extracts adsorbed	No change in current codified name (see preamble paragraph 8)

Accordingly, FDA is updating any applicable regulations in Parts 600 through 660 to reflect the new proper names and is updating § 610.53(a) concerning minimum dating periods. Further, FDA is making minor clarifying changes in the regulations. One of these changes includes revising the terms "Reference Measles Immune Globulin" and "Reference Poliomyelitis Immune Globulin" found in § 640.104 concerning potency of immune serum globulins to read "Reference Immune Serum Globulin". The reference standard labeled "Reference Immune Serum Globulin" contains antibodies to both measles and polio.

The agency has determined under 21 CFR 25.24(d)(10) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Paperwork Reduction Act of 1980

FDA is continuing unchanged any collection of information requirements, as defined in the Paperwork Reduction Act of 1980, in the various sections of the biologics regulations being amended by this final rule.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt. The economic impact of this rule has been assessed in accordance with Executive Order 12291. Based on the assessment, the agency concludes that the rule does not warrant designation as a major rule under any of the criteria specified under section 1(b) of Executive Order 12291. The assessment done to make this determination in on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

List of Subjects in 21 CFR Parts 600, 606, 610, 620, 630, 640, and 660

Biologics; Blood, Labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 510, 701, 52 Stat. 1040-1042 as amended, 1049-1051 as amended, 1055-1056 as amended, 76 Stat. 794-795 as amended (21 U.S.C. 321, 351, 352, 360, 371)); the Public Health Service Act (secs. 351, 352, 353, 361, 58 Stat. 702-703 as amended, 81 Stat. 536 (42 U.S.C. 262, 263, 263a, 264)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. Part 600 is amended:

§ 600.13 [Amended]

a. In § 600.13 *Retention samples* by revising "Whole Blood (Human), Cryoprecipitated Antihemophilic Factor (Human), Platelet Concentrate (Human), Red Blood Cells (Human), Single Donor Plasma (Human), and Source Plasma (Human)," to read "Whole Blood, Cryoprecipitated AHF, Platelets, Red Blood Cells, Plasma, and Source Plasma".

b. In § 600.15 by revising paragraph (a) to read as follows:

§ 600.15 Temperatures during shipment.

* * * * *

(a) *Products.*

Product	Temperature
Cryoprecipitated AHF	-18 °C or colder.
Measles and rubella virus vaccine live.	10 °C or colder.
Measles live and smallpox vaccine.	Do.
Measles, mumps, and rubella virus vaccine live.	Do.
Measles and mumps virus vaccine live.	Do.
Measles virus vaccine live	Do.
Mumps virus vaccine live	Do.
Fresh frozen plasma	-18 °C or colder.
Liquid plasma	° to 10 °C.
plasma	-18 °C or colder.
Platelet rich plasma	Between 1 and 10 °C if the label indicates storage between 1 and 6 °C, or all reasonable methods to maintain the temperature as close as possible to a range between 20 and 24 °C, if the label indicates storage between 20 and 24 °C.
Platelets	Between 1 and 10 °C if the label indicates storage between 1 and 6 °C, or all reasonable methods to maintain the temperature as close as possible to a range between 20 to 24 °C, if the label indicates storage between 20 and 24 °C.
Poliovirus vaccine live oral trivalent.	0 °C or colder.
Poliovirus vaccine live oral type I.	Do.
Poliovirus vaccine live oral type II.	Do.
Poliovirus vaccine live oral type III.	Do.
Red blood cells (liquid product).	Between 1 and 10 °C.
Red blood cells frozen	-65 °C or colder.
Rubella and mumps virus vaccine live.	10 °C or colder.
Rubella virus vaccine live	Do.
Smallpox vaccine (liquid product).	0 °C or colder.
Source plasma	-5 °C or colder.
Source plasma liquid	10 °C or colder.
Whole blood	Blood that is transported from the collecting facility to the processing facility shall be transported in an environment capable of continuously cooling the blood toward a temperature range of 1 ° to 10 °C, or at a temperature as close as possible to 20 ° to 24 °C for a period not to exceed 6 hours. Blood transported from the storage facility shall be placed in an appropriate environment to maintain a temperature range between 1 to 10 °C during shipment.
Yellow fever vaccine	0 °C or colder.

* * * * *

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

2. Part 606 is amended:

a. By revising the part heading to read as set out above.

§ 606.120 [Amended]

b. In § 606.120 *Labeling* in paragraph (b)(2) by revising "Source Plasma (Human)" to read "Source Plasma" and in paragraph (b)(9) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF" and "Source Plasma (Human)" to read "Source Plasma".

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

3. Part 610 is amended:

§ 610.11 [Amended]

a. In § 610.11 *General safety* in paragraph (g) by revising "Whole Blood (Human)," "Red Blood Cells (Human)," "Cryoprecipitated Antihemophilic Factor (Human)," "Platelet Concentrate (Human)," and "Single Donor Plasma (Human)" to read "Whole Blood," "Red Blood Cells," "Cryoprecipitated AHF," "Platelets," and "Plasma", respectively.

§ 610.12 [Amended]

b. In § 610.12 *Sterility* in paragraph (g)(4) removing "Leukocyte Typing Serum" and by revising "Whole Blood (Human)," "Cryoprecipitated Antihemophilic Factor (Human)," "Platelet Concentrate (Human)," "Red Blood Cells (Human)," "Single Donor Plasma (Human)," and "Source Plasma (Human)," to read "Whole Blood," Cryoprecipitated AHF," "Platelets," "Red Blood Cells," "Plasma," and "Source Plasma", respectively, and in paragraph (g)(7) by removing, "and Fibrinogen (Human)" and by revising

"Normal Serum Albumin (Human)," to read "Albumin (Human) and".

§ 610.13 [Amended]

c. In § 610.13 *Purity* in paragraph (a)(2)(ii) by revising "Measles Virus Vaccine, Live, Attenuated; Measles-Smallpox Vaccine, Live; Rubella Virus Vaccine, Live;" to read "Measles Virus Vaccine Live, Measles Live and Smallpox Vaccine, Rubella Virus Vaccine Live,"; in paragraph (a)(2)(iii) by revising "Modified Plasma (Bovine); Thrombin; Fibrinogen; Streptokinase; and Streptokinase-Streptodornase;" to read "Thrombin and Streptokinase;" in the introductory text of paragraph (b) by revising "Cryoprecipitated Antihemophilic Factor (Human); Single Donor Plasma (Human); Source Plasma (Human);" to read "Cryoprecipitate; Plasma; Source Plasma;" in paragraph (b)(1)(i) by removing the phrase "and at least 30 milligrams for Fibrinogen (Human)"; and in paragraph (b)(1)(ii) by removing "Streptokinase-Streptodornase, Aggregated Radio-Iodinated (I^{131}) Albumin (Human), Radio-Chromated (Cr^{51}) Serum Albumin (Human), Radio-Iodinated (I^{125}) Serum Albumin (Human), and Radio-Iodinated (I^{131}) Serum Albumin (Human),".

§ 610.15 [Amended]

d. In § 610.15 *Constituent materials* in paragraph (a) by revising "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral".

§ 610.51 [Removed]

e. By removing § 610.51 *Periods of cold storage.*

§ 610.52 [Removed]

f. By removing § 610.52 *Dating period.*

g. By revising § 610.53, to read as follows:

§ 610.53 Dating periods for licensed biological products.

(a) *General.* The minimum dating periods in paragraph (c) of this section are based on data relating to usage, clinical experience, or laboratory tests that establish the reasonable period beyond which the product cannot be expected to yield its specific results and retain its safety, purity, and potency, provided the product is maintained at the recommended temperatures. The standards prescribed by the regulations in this subchapter are designed to ensure the continued safety, purity, and potency of the products and are based on the dating periods set forth in paragraph (c) of this section. Package labels for each product shall recommend storage at the stated temperatures.

(b) *When the dating period begins.* The dating period for a product shall begin on the date of manufacture, as prescribed in § 610.50. The dating period for a combination of two or more products shall be no longer than the dating period of the component with the shortest dating period.

(c) *Table of dating periods.* In using the table in this paragraph, a product in column A may be stored by the manufacturer at the prescribed temperature and length of time in either column B or C, plus the length of time in column D. The dating period in column D shall be applied from the day the product leaves the manufacturer's storage, provided the product has not exceeded its maximun storage period, as prescribed in column B or C. If a product is held in the manufacturer's storage beyond the period prescribed, the dating period for the product being distributed shall be reduced by a corresponding period.

Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
A	B	C	D
Adenovirus vaccine live oral	6 months	Not applicable	6 months.
Albumin (human)	3 years	do	(a) 5 years.
	do	do	(b) 3 years, provided labeling recommends storage at room temperature, no warmer than 37 °C.
	Not applicable	do	(c) 10 years, if in a hermetically sealed metal container and provided labeling recommends storage between 2 and 8 °C.
Allergenic extracts labeled "No U.S. Standard of Potency":			
1. With 50 percent or more glycerin	3 years	do	3 years.
2. With less than 50 percent glycerin	18 months	do	18 months.
3. Products for which cold storage conditions are inappropriate.	Not applicable	do	18 months (from date of manufacture), provided labeling recommends storage at 30 °C or colder.
4. Powders and tablets	do	do	5 years (from date of manufacture), provided labeling recommends storage at 30 °C or colder.
5. Freeze-dried products:			
a. Unreconstituted	do	do	4 years (from date of manufacture).
b. Reconstituted	do	do	18 months (cannot exceed 4-year unreconstituted dating period plus an additional 12 months).
Allergenic Extracts, alum precipitated labeled "No. U.S. Standard of Potency".	18 months	do	18 months.
Anthrax vaccine adsorbed	2 years	do	1 year.
Antibody to hepatitis B surface Antigen:			
1. Antibody to hepatitis B surface antigen	6 months	do	6 months.
2. Lyophilized coated red blood cells	do	do	Do.
3. Enzyme conjugated products	do	do	Do.
Iodinated (I^{125})	Not applicable	do	45 days (from date of manufacture).
Antihemophilic factor (human)	do	do	1 year (from date of manufacture).
Antihuman globulin liquid	do	do	2 years.
Anti-inhibitor coagulant complex			2 years at 4 °C ±2 °C.
Antirabies serum	1 year	2 years	2 years.
Antivenin (*crotalidae*) polyvalent	do	do	5 years with an initial 10 percent excess of potency, provided labeling recommends storage at 37 °C or colder.
Antivenin (*latrodectus mactans*)	do	do	5 years with an initial 10 percent excess of potency.
Antivenin (*Micrurus fulvius*)	do	do	5 years with an initial 10 percent excess of potency.
Asparaginase	Not applicable	do	18 months from the date of the last valid potency test.
BCG vaccine	1 year	Not applicable	6 months.

Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
A	B	C	D
Blood Grouping Serums:			
1. Liquid	Not applicable	Not applicable	2 years.
2. Dried	1 year	2 years	5 years.
Blood group substance AB	do	do	2 years.
Blood group substance A	do	do	Do.
Blood group substance B	do	do	Do.
Botulism antitoxin	do	do	5 years with an initial 20 percent excess of potency.
Cholera vaccine	do	Not applicable	18 months.
Coccidioidin	do	do	3 years.
Collagenase	Not applicable	do	4 years (from date of manufacture), provided labeling recommends storage at 37 °C or colder.
Cryoprecipitated AFH	do	do	12 months from the date of collection of source blood, provided labeling recommends storage at −18 °C or colder.
Diphtheria Antitoxin:			
1. Liquid	1 year	2 years	5 years with an initial 20 percent excess of potency.
2. Dried	do	do	5 years with an initial 10 percent excess of potency.
Diphtheria and tetanus toxoids and pertussis vaccine adsorbed	do	do	18 months.
Diphtheria and tetanus toxoids, absorbed	do	do	2 years.
Diphtheria toxin for schick test	do	do	1 year.
Diphtheria toxoid	do	do	2 years.
Diphtheria toxoid adsorbed	do	do	Do.
Diphtheria toxoid-schick test control	Not applicable	Not applicable	1 year.
Factor IX complex	do	do	1 year (from date of manufacture).
Fibrinolysin (human)	1 year	2 years	2 years.
Fibrinolysin and desoxyridonuclesse combined (bovine)	do	do	3 years, provided labeling recommends storage at 30 °C or colder.
Fibrinolysin and desoxyribonuclease combined (bovine) with chloramphenicol	do	do	3 years, provided labeling recommends storage at 30 °C or colder.
Hepatitis B surface antigen:			
1. Unlyophilied coated red blood cells	Not applicable	do	14 days (from date of manufacture).
2. Iodinated (^{125}I) product	do	do	45 days (from date of manufcture).
3. Enzyme conjugated product	6 months	do	6 months
Histoplasmin	1year	do	2 years.
Immunoglobulins:			
1. Hepatitis B immune globulin (human)	Not applicable	do	1 year.
2. Immune globulin (human)	3 years	do	3 years.
3. Immune globulin intravenous (human)	1 year	do	1 year.
4. Lymphocyte immune globulin, anti-thymocyte globulin (equine).	Not applicable	Not applicable	2 years.
5. Pertussis immune globulin (human)	3 years	do	3 years from date the dried or frozen bulk product is placed in final solution.
6. Rabies immune globulin (Human)	1 year	do	1 year.
7. Rh_0(D) immune globulin (human)	6 months	do	6 months.
8. Tetanus immune globuline (human)	1 year	do	3 years with an initial 10 percent excess of potency.
9. Vaccinia immune globulin (human)	3 year	do	3 years.
10. Vari-cella-zoster immune globulin (human)	1 year	do	1 year.
Hepatitis B vaccine	2 years at 2 to 8 °C	Not applicable	3 years.
Influenza virus vaccine	1 year	do	18 months.
Limulus amebocyte lysate	Not applicable	Not applicable	18 months (from date of manufacture).
Measles, mumps, and rubella virus vaccine live	do	1 year (−20 °C or colder)	1 year.
Measles and mumps virus vaccine live	do	do	1 year.
Measles and rubella virus vaccine live	do	do	Do.
Measles live and smallpox vaccine	Not applicable	do	1 year (from date of manufacture).
Measles virus vaccine live	do	do	1 year.
Meningococcal polysaccharide vaccine group A:			
1. Final bulk powder	do	2 years (−20 °C or colder)	Not applicable.
2. Final container	Not applicable	3 years (−20 °C or colder)	2 years (−20 °C or colder).
Meningococcal polysaccharide vaccine group C:			
1. Final bulk powder	do	2 years (−20 °C or colder)	Not applicable.
2. Final container	do	3 years (−20 °C or colder)	2 years (−20 °C or colder).
Meningococcal polysaccharide vaccine groups A and C combined.	do	do	Do.
Meningococcal polysaccharide vaccine groups vaccine groups A, C, Y, and W135 combined.	do	do	do.
Mumps skin test antigen	1 year	do	18 months.
Mumps virus vaccine live	Not applicable	1 year (−20 °C or colder)	1 year.
Normal horse serum	1 year	2 years	5 years.
Pertussis vaccine	do	Not applicable	18 months.
Pertussis vaccine adsorbed	do	do	Do.
Plague vaccine	do	do	Do.
Plasma products:			
1. Fresh frozen plasma	Not applicable	do	1 year from date of collection of source blood (−18 °C or colder).
2. Liquid plasma	do	do	(a) 26 days from date of collection of source blood (between 1 and 6 °C). (b) 40 days from date of collection of source blood only when CPDA-1 solution is used as the anticoagulant (between 1 and 6 °C).
3. Plasma	do	do	5 years from date of collection of source blood (−18 °C or colder).
4. Platelet rich plasma	do	do	72 hours from time of collection of source blood, provided labeling recommends storage (20 to 24 °C or between 1 and 6 °C). 5 days if certain approved containers are used (20 to 24 °C).

Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
A	B	C	D
5. Source leukocytes	do	do	In lieu of expiration date, the collection date shall appear on the label.
6. Source plasma	do	do	10 years (at the recommended storage temperature stated on the label).
7. Therapeutic exchange plasma	do	do	10 years.
Plasma protein fraction (human)	1 year	do	(a) 5 years. (b) 3 years provided labeling recommends storage at room temperature, no warmer than 30 °C.
Platelets	Not applicable	do	72 hours from time of collection of source blood, provided labeling recommends storage at 20 to 24 °C or between 1 and 6 °C. 5 days if certain approved containers are used (20 to 24 °C).
Pneumococcal vaccine polyvalent:			
1. Final bulk powder	do	15 months after potency assay (−20 °C or colder).	Not applicable.
2. Final container	do	Not applicable	2 years (after date of manufacture).
Poliovirus vaccine inactivated	1 year	do	1 year.
Poliovirus vaccine live oral trivalent:			
1. Frozen	Not Applicable	1 year (−10 °C or colder)	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus vaccine live oral type I:			
1. Frozen	do	1 year (−10 °C or colder)	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus vaccine live oral type II:			
1 Frozen	do	1 year (−10 °C or colder)	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus vaccine live oral type III:			
1 Frozen	do	1 year (−10 °C or colder)	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Polyvalent bacterial antigens with "No U.S. Standard of Potency" liquid.	1 year	Not applicable	18 months.
Polyvalent bacterial vaccines with "No U.S. Standard of Potency" liquid.	do	do	Do.
Rabies Vaccine:			
1 Dried	do	2 years	Do.
2. Liquid	3 months	Not applicable	6 months.
Reagent red blood cells	Not applicable	do	35 days from earliest date of collection.
ACD red blood cells	do	do	(a) 21 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing. (b) 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.
CPD red blood cells	do	do	(a) 21 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing. (b) 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.
CPDA-1 red blood cells	do	do	(a) 35 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing. 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.
Red blood cells deglycerolized	do	do	24 hours after removal from storage at −65 °C or colder, provided labeling recommends storage between 1 and 6 °C.
Red blood cells frozen	do	do	3 years from date of collection of source blood, provided labeling recommends storage at −65 °C or colder.
Rubella and mumps virus vaccine live	do	1 year (−20 °C or colder)	1 year.
Rubella virus vaccine live	do	°C.	Do.
Skin test antigens for cellular hypersensitivity	6 months	Not applicable	Do.

Product A	Manufacturer's storage period 1 to 5 °C (unless otherwise stated) B	Manufacturer's storage period 0 °C or colder (unless otherwise stated) C	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated) D
Smallpox Vaccine:			
1. Liquid	Not applicable	9 months (−10 °C or colder, if product is maintained as glycerinated or equivalent vaccine in bulk or final containers).	3 months, provided labeling recommends storage at 0 °C or colder.
2. Dried	6 months	Not applicable	18 months.
Streptokinase	do	2 years	Do.
Tetanus and diphtheria toxoids adsorbed for adult use	1 year	Not applicable	2 years.
Tetanus antitoxin:			
1. Liquid	do	2 years	5 years with an initial 20 percent excess of potency.
2. Dried	do	do	5 years with an initial 10 percent excess of potency.
Tetanus toxoid adsorbed	do	do	2 years.
Thrombin	do	do	3 years.
Thrombin impregnated pad	Not applicable	Not applicable	1 year, or 6 months at 20 to 24 °C.
Tuberculin:			
1. Purified protein derivative, diluted	6 months	do	1 year.
2. Old or purified protein derivative, dried on multiple puncture device:	1 year (not to exceed 30 °C; do not refrigerate).	do	2 years, provided labeling recommends storage at a temperature not to exceed 30 °C. Do not refrigerate.
3. Old on multiple puncture device	do	do	Do.
Typhoid vaccine	1 year	do	18 months.
ACD whole blood	Not applicable	do	21 days from date of collection, provided labeling recommends storage between 1 and 6 °C.
CPD whole blood	do	do	Do.
CPDA-1 whole blood	do	do	35 days from date of collection, provided labeling recommends storage between 1 and 6 °C.
Heparin whole blood	do	do	48 hours from date of collection, provided labeling recommends storage between 1 and 6 °C.
Yellow fever vaccine	do	1 year (−20 °C or colder)	1 year, provided labeling recommends storage at 5 °C or colder.

(d) *Exemptions.* Exemptions or modifications shall be made only upon written approval, in the form of an amendment of the product license, issued by the Director, Office of Biologics Research and Review (HFN-800), Center for Drugs and Biologics.

PART 620—ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS

4. Part 620 is amended:

§ 620.4 [Amended]

a. In § 620.4 *Potency test* in paragraph (g) by revising "Poliomyelitis Vaccine" to read "Poliovirus Vaccine Inactivated".

Subpart C—[Amended]

b. By revising the heading of Subpart C to read "Subpart C—Anthrax Vaccine Adsorbed".

§ 620.20 [Amended]

c. In § 620.20 by revising the section heading to read "§ 620.20 *Anthrax Vaccine Adsorbed*" and in the text by revising "Anthrax Vaccine, Adsorbed" to read "Anthrax Vaccine Adsorbed".

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

5. Part 630 is amended:

Subpart A—[Reserved]

a. By revising the heading of Subpart A to read "Subpart A—Poliovirus Vaccine Inactivated".

§ 630.1 [Amended]

b. In § 630.1 by revising the section heading to read "§ 630.1 *Poliovirus Vaccine Inactivated*" and in the text of paragraphs (a) and (c) by revising "Poliomyelitis Vaccine" to read "Poliovirus Vaccine Inactivated".

§ 630.2 [Amended]

c. In § 630.2 by revising the section heading to read "*Poliovirus Vaccine Inactivated*" and in paragraph (e)((3) by revising "poliomyelitis vaccine" to read "Poliovirus Vaccine Inactivated".

§ 630.3 [Amended]

d. In § 630.3 *Potency test* in the introductory paragraph by revising "poliomyelitis vaccine" to read Poliovirus Vaccine Inactivated".

§ 630.4 [Amended]

e. In § 630.4 *Tests for safety* in paragraph (b)((1) by revising "poliomyelitis vaccine" to read "poliovirus vaccine" and in paragraph (e)(5)((ii) by revising "poliomyelitis" to read "poliovirus".

§ 630.6 [Amended]

f. In § 630.6 *Equivalent methods* in the text by revising "poliomyelitis vaccine" to read "Poliovirus Vaccine Inactivated".

Subpart B—[Amended]

g. By revising the heading of Subpart B to read "Subpart B—Poliovirus Vaccine Live Oral".

h. In § 630.10 in paragraphs (a) and (b)(2) by revising "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral" and by revising the section heading to read "*§ 630.10 Poliovirus Vaccine Live Oral.*"

* * * * *

§ 630.12 [Amended]

i. In § 630.12 *Animal source; quarantine; personnel* in paragraphs (a)(1) and (b) by revising "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral".

§ 630.13 [Amended]

j. In § 630.13 by revising the section heading to read "*§ 630.13 Manufacture of Poliovirus Vaccine Live Oral.*"

§ 630.18 [Amended]

k. In § 630.18 *Equivalent methods* in the text by revising "Poliovirus Vaccine, Live, Oral," to read "Poliovirus Vaccine Live Oral".

Subpart D—[Amended]

1. By revising the heading of Subpart D to read "Subpart D—Measles Virus Vaccine Live".

§ 630.30 [Amended]

m. In § 630.30 by revising the section heading to read "§ 630.30 *Measles Virus Vaccine Live*" and in paragraphs (a) and (b)(2) by revising "Measles Virus Vaccine, Live, Attenuated," to read "Measles Virus Vaccine Live".

§ 630.36 [Amended]

n. In § 630.36 *General requirements* in paragraph (d) by revising "Measles Virus Vaccine, Live, Attenuated," to read "Measles Virus Vaccine Live".

§ 630.37 [Amended]

o. In § 630.37 *Equivalent methods* in the text by revising "Measles Virus Vaccine, Live, Attenuated," to read "Measles Virus Vaccine Live".

Subpart F—[Amended]

p. By revising the heading of Subpart F to read "Subpart F—Mumps Virus Vaccine Live".

§ 630.50 [Amended]

q. In § 630.50 by revising the section heading to read "§ 630.50 *Mumps Virus Vaccine Live*" and in paragraphs (a) and (b)(2) by revising "Mumps Virus Vaccine, Live," to read "Mumps Virus Vaccine Live".

§ 630.51 [Amended]

r. In § 630.51 *Clinical trials to qualify for license* in the text by revising "Mumps Virus Vaccine, Live," to read "Mumps Virus Vaccine Live".

§ 630.52 [Amended]

s. In § 630.52 by revising the section heading to read "§ 630.52 *Manufacture of Mumps Virus Vaccine Live*".

§ 630.56 [Amended]

t. In § 630.56 *General requirements* in paragraph (b) by revising "Mumps Virus Vaccine, Live," to read "Mumps Virus Vaccine Live" and in paragraph (e) by revising "Mumps Virus Vaccine, Live" to read "Mumps Virus Vaccine Live".

§ 630.57 [Amended]

u. In § 630.57 *Equivalent methods* in the text by revising "Mumps Virus Vaccine, Live," to read "Mumps Virus Vaccine Live".

Subpart G—[Amended]

v. By revising the heading of Subpart G to read "Subpart G—Rubella Virus Vaccine Live".

§ 630.60 [Amended]

w. In § 630.60 by revising the section heading to read "§ 630.60 *Rubella Virus Vaccine Live*" and in paragraph (a) by revising "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live" and in paragraph (d)(1) by revising "Rubella Virus Vaccine, Live," to read "Rubella Virus Vaccine Live".

§ 630.61 [Amended]

x. In § 630.61 *Clinical trials to qualify for license* in the text by revising "Rubella Virus Vaccine, Live," to read "Rubella Virus Vaccine Live".

§ 630.62 [Amended]

y. In § 630.62 *Production* in paragraph (b) by revising "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live".

§ 630.66 [Amended]

z. In § 630.66 *General requirements* in paragraph (b) by revising "Rubella Virus Vaccine, Live," to read "Rubella Virus Vaccine Live" and in paragraph (d) by revising "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live".

§ 630.67 [Amended]

aa. In § 630.67 *Equivalent methods* in the text by revising "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live".

Subpart I—[Amended]

bb. By revising the heading of Subpart I to read "Subpart I—Measles Live and Smallpox Vaccine".

§ 630.80 [Amended]

cc. In § 630.80 by revising the section heading to read "§ 630.80 *Measles Live and Smallpox Vaccine*" and in paragraph (a) by revising "Measles-Smallpox Vaccine, Live" to read "Measles Live and Smallpox Vaccine".

§ 630.84 [Amended]

dd. In § 630.84 *Potency tests* in the introductory paragraph by revising "Measles-Smallpox Vaccine, Live," to read "Measles Live and Smallpox Vaccine".

§ 630.87 [Amended]

ee. In § 630.87 *Equivalent methods* in the text by revising "Measles-Smallpox Vaccine, Live" to read "Measles Live and Smallpox Vaccine".

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

5. Part 640 is amended:

Subpart A—[Amended]

a. By revising the heading of Subpart A to read "Subpart A—Whole Blood".

§ 640.1 [Amended]

b. In § 640.1 by revising the section heading to read "§ 640.1 *Whole blood*" and in the text by revising "Whole Blood (Human)" to read "Whole Blood".

§ 640.2 [Amended]

c. In § 640.2 *General requirements* in paragraph (a) by revising "Whole Blood (Human)" to read "Whole Blood".

§ 640.3 [Amended]

d. In § 640.3. in paragraphs (a) and (f) by revising "Whole Blood (Human)" to read "Whole Blood".

§ 640.4 [Amended]

e. In § 640.4 *Collection of the blood* in paragraphs (c) and (h) by revising "Heparinized Whole Blood (Human)" to read "Heparin Whole Blood" and in paragraph (i) by revising "Platelet Concentrate (Human)" and "platelet concentrate" to read "Platelets" and "platelets", respectively.

§ 640.5 [Amended]

f. In § 640.5 *Testing the blood* in paragraphs (a) through (e) by revising "Whole Blood (Human)" to read "Whole Blood" and in paragraph (c) by revising "Anti-Rh_o (Anti-D) Typing Serum" to read "Anti-D Blood Grouping Serum".

§ 640.6 [Amended]

g. § 640.6 by revising the section heading to read "§ 640.6 *Modifications of Whole Blood*" and in the introductory paragraph by revising "Whole Blood (Human)" to read "Whole Blood" and in paragraph (c) by revising "Whole Blood (Human), modified," to read "Whole Blood Cryoprecipitate Removed".

§ 640.7 [Amended]

h. In § 640.7 *Labeling* in the introductory text of paragraph (g) by revising "Whole Blood (Human), Modified" to read "Whole Blood Cryoprecipitate Removed" and in paragraph (g)(1) by revising "Modified" to read "Cryoprecipitate Removed".

Subpart B—[Amended]

i. By revising the heading of Subpart B to read "Subpart B—Red Blood Cells".

§ 640.10 [Amended]

j. In § 640.10 by revising the section heading to read "§ 640.10 *Red Blood Cells*" and in the text by revising "Red Blood Cells (Human)" to read "Red Blood Cells".

§ 640.11 [Amended]

k. In § 640.11 *General requirements* in paragraph (a) by revising "Red Blood Cells (Human)" to read "Red Blood Cells".

§ 640.12 [Amended]

l. In § 640.12 *Suitability of donor* in the text by revising "Red Blood Cells (Human)" to read "Red Blood Cells".

§ 640.13 [Amended]

m. In § 640.13 *Collection of the blood* in paragraph (b) by revising "Whole Blood (Human)" to read "Whole Blood".

§ 640.15 [Amended]

n. In § 640.15 *Pilot samples* in paragraphs (a) and (d) by revising "Red Blood Cells (Human)" to read "Red Blood Cells".

§ 640.16 [Amended]

o. In § 640.16 *Processing* in paragraph (a) by revising "red blood cells (human)" to read "Red Blood Cells" and in paragraph (c) by revising "Red Blood Cells (Human)" to read "Red Blood Cells".

§ 640.17 [Amended]

p. In § 640.17 *Modifications for specific products* in the text by revising "Red Blood Cells (Human)" to read "Red Blood Cells" and by revising "Red Blood Cells (Human), Frozen" to read "Red Blood Cells Frozen".

§ 640.18 [Amended]

q. In § 640.18 *Labeling* in the introductory paragraph by revising "Red Blood Cells (Human)" to read "Red Blood Cells"; in paragraph (a) by revising "Whole Blood (Human)" to read "Whole Blood"; in paragraph (b) by revising "Red Blood Cells (Human), Frozen, and Red Blood Cells (Human), Deglycerolized" to read "Red Blood Cells Frozen and Red Blood Cells Deglycerolized"; and in paragraph (d) by revising "Whole Blood (Human)" to read "Whole Blood".

Subpart C—[Amended]

r. By revising the heading of Subpart C to read "Subpart C—Platelets".

§ 640.20 [Amended]

s. In § 640.20 by revising the section heading to read "§ 640.20 *Platelets*" and in paragraphs (a) and (b) by revising "Platelets Concentrate (Human)" to read "Platelets".

§ 640.22 [Amended]

t. In § 640.22 *Collection of source material* in paragraph (a) by revising "Platelet Concentrate (Human)" to read "Platelets".

§ 640.23 [Amended]

u. In § 640.23 *Testing the blood* in paragraph (a) by revising "Platelet Concentrate (Human)" to read "Platelets".

§ 640.24 [Amended]

v. In § 640.24 *Processing* in paragraphs (a) and (e) by revising "Platelet Concentrate (Human)" to read "Platelets"; in paragraph (b) by revising "platelet concentrate is" to read "platelets are"; and in paragraph (d) by revising "platelet concentrate" to read "platelets".

§ 604.25 [Amended]

w. In § 640.25 *General requirements* in paragraph (a), the introductory text of paragraph (c), and paragraph (c) (1) and (2) by revising "Platelet Concentrate (Human)" to read "Platelets".

Subpart D—[Amended]

x. By revising the heading of Subpart D to read "Subpart D—Plasma".

§ 640.30 [Amended]

y. In § 640.30 by revising the section heading to read "§ 640.30 *Plasma*", in paragraphs (a) and (b) by revising "Single Donor Plasma (Human)" to read "Plasma", and in paragraph (b)(2) by revising "Whole Blood (Human)" to read "Whole Blood".

§ 640.32 [Amended]

z. In § 640.32 *Collection of source material* in paragraph (a) by revising "Single Donor Plasma (Human); Single Donor Plasma (Human), Fresh Frozen; and Single Donor Plasma (Human), Liquid," to read "Plasma, Fresh Frozen Plasma, and Liquid Plasma"; and by revising "Single Donor Plasma (Human), Platelet Rich" to read "Platelet Rich Plasma".

§ 640.33 [Amended]

aa. In § 640.33 *Testing the blood* in paragraph (b) by revising "Single Donor Plasma (Human)" to read "Plasma".

§ 640.34 [Amended]

bb. In § 640.34 *Processing* in paragraph (a) by revising "Single Donor Plasma (Human)" to read "Plasma" and "Single Donor Plasma (Human), Liquid" to read "Liquid Plasma"; in paragraph (b) by revising "Single Donor Plasma (Human), Fresh Frozen" to read "Fresh Frozen Plasma"; in paragraph (c) by revising "Single Donor Plasma (Human), Liquid" to read "Liquid Plasma"; in paragraph (d) by revising "Single Donor Plasma (Human), Platelet Rich" to read "Platelet Rich Plasma"; in the introductory text of paragraph (e) by revising "Single Donor Plasma (Human)" to read "Plasma" and by revising "Platelet Concentrate (Human) and/or Cryoprecipitated Antihemophilic Factor (Human) from Single Donor Plasma (Human)" to read "Platelets and/or Cryoprecipitated AHF from Plasma"; in paragraph (e)(1) by revising "Platelet Concentrate (Human)" to read "Platelets" and "Single Donor Plasma (Human), Fresh Frozen" to read "Fresh Frozen Plasma"; in paragraph (e)(2) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF" and "Single Donor Plasma (Human)" to read "Plasma"; in paragraph (e)(3) by revising "Platelet Concentrate (Human) and Cryoprecipitated Antihemophilic Factor (Human)" to read "Platelets and Cryoprecipitated AHF" and "Single Donor Plasma (Human)" to read "Plasma"; and in paragraph (g)(2) by revising "Single Donor Plasma (Human), Platelet Rich; and Single Donor Plasma (Human), Liquid" to read "Platelet Rich Plasma and Liquid Plasma".

§ 640.35 [Amended]

cc. In § 640.35 *Labeling* in the introductory paragraph by revising "Single Donor Plasma (Human)" to read "Plasma" and in paragraph (s) by changing the proper name "Whole Blood (Human)" to read "Whole Blood".

Subpart F—[Amended]

dd. By revising the heading of Subpart F to read "Subpart F—Cryoprecipitate".

§ 640.50 [Amended]

ee. In § 640.50 by revising the section heading to read "§ 640.50 *Cryoprecipitated AHF*" and in paragraphs (a) and (b) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

§ 640.52 [Amended]

ff. In § 640.52 *Collection of source material* in paragraph (a) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF" and "Platelet Concentrate (Human)" to read "Platelets".

§ 640.53 [Amended]

gg. In § 640.53 *Testing the blood* in paragraphs (a) and (c) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

§ 640.54 [Amended]

hh. In § 640.54 *Processing* in paragraphs (a)(3) and (b)(1) and (3) by revising "Cryoprecipitated

Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

§ 640.55 [Amended]

ii. In § 640.55 *U.S. Standard preparation* in the text by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

§ 640.56 [Amended]

jj. In § 640.56 *Quality control test for potency* in paragraphs (a), (b), and (c)(1) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

Subpart G—[Amended]

kk. By revising the heading of Subpart G to read "Subpart G—Source Plasma".

§ 640.60 [Amended]

ll. In § 640.60 by revising the section heading to read "§ 640.60 *Source Plasma*" and in the text by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.63 [Amended]

mm. In § 640.63 *Suitability of donor* in paragraph (a) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.64 [Amended]

nn. In § 640.64 by revising the section heading to read "§ 640.64 *Collection of blood for Source Plasma*" and in paragraphs (a) and (c) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.67 [Amended]

oo. In § 640.67 *Test for hepatitis B surface antigen* by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.68 [Amended]

pp. In § 640.68 *Processing* in paragraphs (a), (b), and (c) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.69 [Amended]

qq. In § 640.69 *General requirements* in paragraph (a), (b), and (c) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.70 [Amended]

rr. In § 640.70 *Labeling* in the introductory text of paragraph (a) by revising "Source Plasma (Human)" to read "Source Plasma" and in paragraph (b) by revising "Source Plasma (Human)" to read "Source Plasma" and by revising "Source Plasma (Human) Salvaged" to read "Source Plasma Salvaged".

§ 640.71 [Amended]

ss. In § 640.71 *Manufacturing responsibility* in the introductory texts of paragraphs (a) and (b) and in paragraph (b) (1) and (2) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.72 [Amended]

tt. In § 640.72 *Records* in paragraphs (a)(1) and (b) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.74 [Amended]

uu. In § 640.74 by revising the section heading to read "§ 640.74 *Modification of Source Plasma*" and in paragraphs (a) and (b) by revising "Source Plasma (Human)" to read "Source Plasma" and in paragraph (b) by revising "Liquid Source Plasma (Human)" to read "Source Plasma Liquid".

§ 640.75 [Amended]

vv. In § 640.75 *Alternate procedures* in the text by revising "Source Plasma (Human)" to read "Source Plasma".

ww. In § 640.76 in paragraphs (a), (b), and (c) by revising "Source Plasma (Human)" to read "Source Plasma" and by revising "Source Plasma (Human) Salvaged" to read "Source Plasma Salvaged".

Subpart H—[Amended]

xx. By revising the heading of Subpart H to read "Subpart H—Albumin (Human)".

§ 640.80 [Amended]

yy. In § 640.80 by revising the section heading to read "§ 640.80 *Albumin (Human)*" and in paragraph (a), introductory text of (b), and paragrah (b)(1) by revising "Normal Serum Albumin (Human)" to read "Albumin (Human)".

§ 640.81 [Amended]

zz. In § 640.81 *Processing* in paragraphs (e) and (g) by revising "Normal Serum Albumin (Human)" to read "Albumin (Human)".

§ 640.82 [Amended]

aaa. In § 640.82 *Tests on final product* in paragraph (f) by revising "Normal Serum Albumin (Human)" to read "Albumin (Human)".

bbb. In § 640.85 in the introductory paragraph by revising "Normal Serum Albumin (Human)" to read "Albumin (Human)".

§ 640.86 [Amended]

ccc. In § 640.86 *Equivalent methods* by revising "Normal Serum Albumin (Human)" to read "Albumin (Human)".

Subpart J—[Amended]

ddd. By revising the heading of Subpart J to read "Subpart J—Immune Globulin (Human)".

§ 640.100 [Amended]

eee. In § 640.100 by revising the section heading to read "§ 640.100 *Immune Globulin (Human)*" and in paragraphs (a) and (b) by revising "Immune Serum Globulin (Human)" to read "Immune Globulin (Human)".

§ 640.101 [Amended]

fff. In § 640.101 *General requirements* in paragraph (e)(3) by revising "Measles Virus Vaccine, Live, Attenuated" to read "Measles Virus Vaccine Live" and in the introductory text of paragraph (f) by revising "Immune Serum Globulin (Human)" to read "Immune Globulin (Human)".

§ 640.102 [Amended]

ggg. In § 640.102 by revising the section heading to read "§ 640.102 *Manufacture of Immune Globulin (Human)*" and in paragraph (d) by revising "Immune Serum Globulin (Human)" to read "Immune Globulin (Human)".

§ 640.104 [Amended]

hhh. In § 640.104 *Potency* in paragraphs (b)(2) and (c)(1) by revising "Reference Measles Immune Globulin" to read "Reference Immune Serum Globulin"; in paragraph (b)(2) by revising "Measles Virus Vaccine, Live, Attenuated" to read "Measles Virus Vaccine Live"; and in paragraphs (b)(3) and (c)(2) by revising "Reference Poliomyelitis Immune Globulin" to read "Reference Immune Serum Globulin".

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

7. Part 660 is amended:

§ 660.23 [Amended]

a. In § 660.23 *Red blood cell preparations* in paragraph (a) by revising "Reagent Red Blood Cells (Human)" to read "Reagent Red Blood Cells".

b. In § 660.25 by revising paragraph (a)(5)(iii), to read as follows:

§ 660.25 Potency test without reference preparations.

* * * * *

(a) * * *

(5) * * *

(iii) For Anti-U, Anti-Kp^a, Anti-Kp^c, Anti-Js^a, Anti-Js^b, Anti-Fy^b, Anti-N, Anti Le^a, Anti-Le^b, Anti-Di^a, Anti-Mg, Anti-

Jk^b, Anti-Xg^a, Anti-Co^b, and Wr^a at least 2+ reaction with undiluted serum.

* * * * *

c. In § 660.28 by revising paragraph (d), to read as follows:

§ 660.28 Labeling.

* * * * *

(d) *Names of antibodies.*

Blood group designation for container label	Optional synonym for package label and package insert
Anti-A	None.
Anti-A_1	Do.
Anti-B	Do.
Anti-A, B	Do.
Anti-Di^a	(Anti-$Diego^a$).
Anti-Fy^a	(Anti-$Duffy^a$).
Anti-Fy^b	(Anti-$Duffy^b$).
Anti-I	None.
Anti-Jk^a	(Anti-$Kidd^a$).
Anti-Jk^b	(Anti-$Kidd^b$).
Anti-Js^a	(Anti-Sutter).
Anti-Js^b	(Anti-Matthews).
Anti-K	(Anti-Kell).
Anti-k	(Anti-Celiano).
Anti-Kp^a	(Anti-Penney).
Anti-Kp^b	(Anti-Rautenborg).
Anti-Le^a	(Anti-$Lewis^a$).
Anti-Le^b	(Anti-$Lewis^b$).
Anti-M	None.
Anti-N	Do.
Anti-M^a	(Anti-Gilfeather).
Anti-P_1	None.
Anti-D	(Anti-Rh_o).
Anti-CD	(Anti-Rh_o').
Anti-DE	(Anti-Rh_o'').
Anti-CDE	(Anti-Rh_o''').
Anti-C	(Anti-rh').
Anti-E	(Anti-rh'').
Anti-c	(Anti-hr').
Anti-e	(Anti-hr'').
Anti-C^w	(Anti-rh^w).
Anti-S	None.
Anti-s	Do.
Anti-U	Do.
Anti-Wr^a	(Anti-$Wright^a$).
Anti-Js^a	(Anti-Sutter).
Anti-Co^b	(Anti-$Colton^b$).
Anti-Xg^a	None.

Effective date. Any product subject to this final rule that is initially introduced or initially delivered for introduction into interstate commerce on or after January 29, 1986 shall bear labeling including the new proper name of the product established herein.

(Secs. 201, 501, 502, 510, 701, 52 Stat. 1040–1042 as amended, 1049–1051 as amended, 1055–1056 as amended, 76 Stat. 794–795 as amended (21 U.S.C. 321, 351, 352, 360, 371); secs. 351, 352, 353, 361, 58 Stat. 702–703 as amended, 81 Stat. 536 (42 U.S.C. 262, 263, 263a, 264))

Dated: January 18, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 85–2001 Filed 1–28–85; 8:45 am]

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