representatives of the Food and Drug Administration.

(b) Each foreign establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment shall designate only one United States agent and may designate the United States agent to act as its official correspondent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

(3) The foreign establishment shall report changes in the United States agent's name, address, or phone number to FDA within 5 days of the change.

(c) No device may be imported or offered for import into the United States except a device imported or offered for import pursuant to the investigational use provisions of part 812 of this chapter, unless it is the subject of a device listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment. The establishment registration and device listing information shall be in the English language.

Dated: January 26, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–12040 Filed 5–13–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 640

[Docket No. 98N–0608]

Revision of Requirements Applicable to Albumin (Human), Plasma Protein Fraction (Human), and Immune Globulin (Human); Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by removing, revising, or updating specific regulations applicable to blood derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. FDA is taking this action as part of the agency's ''Blood Initiative'' in which FDA is reviewing and revising, when appropriate, its regulations, policies, guidance, and procedures related to blood products, including blood derivatives. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. FDA is taking this action because the proposed changes are noncontroversial and FDA anticipates that it will receive no significant adverse comment.

DATES: Submit written comments on or before July 28, 1999. If FDA receives any significant adverse comment regarding this rule, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA then and will proceed to respond to the comments under this proposed rule using the usual notice and comment procedures. Any parties interested in commenting on this document should do so at this time.

If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on the direct final rule ends. The direct final rule will be effective September 27, 1999.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule will provide the procedural framework to finalize the rule in the event that the direct final rule receives any adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion rule will also be considered as comments regarding the direct final rule. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comment.

A significant comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not subjects of significant adverse comments.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on September 27, 1999. Additional information about FDA's direct rulemaking procedures is set forth in a guidance published in the **Federal**

Register of November 21, 1997 (62 FR 62466).

For a variety of reasons, FDA has decided to comprehensively review and, as necessary, revise its regulations, policies, guidance and procedures related to the licensing and regulation of blood products. FDA is issuing this companion proposed rule and the direct final rule, published elsewhere in this issue of the **Federal Register**, as part of the agency's ''Blood Initiative'' in which FDA is reviewing and revising, when appropriate, its regulations, policies, guidance, and procedures related to blood products, including plasma derivatives. The ''Blood Initiative'' is discussed in detail in the preamble to the direct final rule.

FDA emphasizes that for many of the changes discussed below, additional issues related to the regulations now being amended continue to be under consideration by the agency. Further, more substantive changes may be proposed at a later date. Accordingly, any comment recommending an additional change to these regulations will not be considered to be an ''adverse comment'' unless the comment demonstrates that the change being made in the direct final rule represents a major departure from current regulations or accepted industry standards, or cannot be implemented without additional amendments to the regulations.

II. Legal Authority

FDA is proposing to promulgate this new rule under the biologics products and communicable disease provisions of the Public Health Service Act (PHS Act) (42 U.S.C. 262–264) and the drug, device, and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 351–353, 355, 360, 360j, 371, and 374). Under these provisions of the PHS Act and the act, FDA has the authority to promulgate and enforce regulations designed to ensure that biological products are safe, pure, potent, and properly labeled and to prevent the introduction, transmission, and spread of communicable disease.

III. Highlights of the Proposed Rule

FDA is proposing to amend the biologics regulations by removing, revising, or updating specific regulations applicable to blood derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. In addition, minor editorial changes, such as correction of punctuation, would be made. As previously discussed, FDA is also issuing these amendments directly as a final rule because the agency believes they are noncontroversial and that there is little likelihood that there will be comments opposing the rule. FDA is identifying each of the changes included in the proposed rule as follows.

A. Identification of Plasma as the Source Material for Derivative Products

Sections 640.80(a), 640.90(a), and 640.100(a) (21 CFR 640.80(a), 640.90(a), and 640.100(a)) state the proper name and definition for Albumin (Human), Plasma Protein Fraction (Human) and Immune Globulin (Human), respectively. With the ubiquitous use of modern anticoagulants, these products are prepared solely from human plasma. Under the proposal, §§ 640.80(a), 640.90(a), and 640.100(a) would be changed from ''a sterile solution * * * human blood'' to ''a sterile solution * * * derived from human plasma.''

Sections 640.80(b), 640.90(b), and 640.100(b) discuss source material of Albumin (Human), Plasma Protein Fraction (Human), and Immune Globulin (Human), respectively. With modern practice, these products are no longer prepared from Whole Blood, sera, or human placentas. FDA is proposing to change §§ 640.80(b), 640.90(b), and 640.100(b) to clarify and update the requirements for source material. Sections 640.80(b), 640.90(b), and 640.100(b) would be changed to read ''The source material of * * * shall be plasma recovered from Whole Blood prepared as prescribed in §§ 640.1 through 640.5, or Source Plasma prepared as prescribed in §§ 640.60 through 640.76.''

B. Clarification for Microbial Contamination During Processing

Sections 640.81(c) and 640.91(c) (21 CFR 640.81(c) and 640.91(c)) discuss microbial contamination of source material and would be amended to clarify that ''All processing steps shall be conducted in a manner to minimize the risk of contamination from microorganisms, pyrogens, or other impurities.''

C. Clarification of Process for Heat Treatment

Sections 640.81(e) and 640.91(e) discuss heat treatment and would be amended to clarify that the heating process shall be continuous for the time and at the temperature currently specified in the regulations. In addition, FDA is proposing to correct §§ 640.81(e) and 640.91(e) by removing a degree sign to read ''60±0.5 C''.

D. Clarification for Stabilizer Used in Albumin (Human) and Plasma Protein Fraction (Human)

Under the proposal, §§ 640.81(f) and 640.91(f), *Stabilizer*, would be amended by clarifying the range for acceptable amounts of stabilizer(s) that shall be present in Albumin (Human) and Plasma Protein Fraction (Human), respectively. Consistent with the amount of stabilizer(s) currently used in these products, the regulations are amended to require either 0.08±0.016 millimole sodium caprylate, or 0.08±0.016 millimole sodium acetyltryptophanate and 0.08±0.016 millimole sodium caprylate per gram (/g) of protein. FDA is proposing the word ''present'' be substituted for ''added'' in §§ 640.81(f) and 640.91(f) to clarify that the regulation pertains to the amount of stabilizer in the final product. In addition, §§ 640.81(f) and 640.91(f) would be amended to simplify calculations of stabilizer(s) content in Albumin (Human) and Plasma Protein Fraction (Human). Under the proposal, manufacturers may employ the labeled value for the protein concentration. For example, if the measured protein concentration of a lot of 5 percent Albumin (Human) is 5.15 percent, the calculations of stabilizer(s) content may use the labeled value of 5 percent. Thus, under this proposal, if the measured concentration of sodium caprylate is 0.35 millimole/deciliter (dL) and the measured protein concentration is 5.15 percent (i.e., 5.15 g/dL), the sodium caprylate concentration may be calculated as 0.35 divided by 5, or 0.07 millimole/g of protein.

E. Revision of Terminology

Under the proposal, §§ 640.82(a) and 640.82(d), *Protein content* and *Sodium content*, respectively, would be amended by replacing ''content'' with ''concentration'' to be more precise.

Sections 640.82(c), 640.92(c), and 640.101(b) would be amended by changing the term from ''hydrogen ion concentration'' to ''pH'' to reflect the more commonly used terminology.

Section 640.82(e), *Heme content*, is replaced by *Potassium concentration*, which describes the acceptable potassium concentration of the final product. Heme concentration is well controlled by the procedures currently used to prepare plasma, and all recent lots of Albumin (Human) have heme concentrations well below the maximum specified in the current regulation. FDA is proposing to update the regulations by deleting the requirement for the determination of heme content and replacing it with a

requirement that ''the potassium concentration of the final product shall not exceed 2 milliequivalents per liter.'' All licensed manufacturers are currently manufacturing Albumin (Human) with a potassium concentration that does not exceed 2 milliequivalents per liter. This proposed revision is also consistent with the current requirements in § 640.92(e) for the closely related product, Plasma Protein Fraction.

FDA is proposing that §§ 640.84(a)(1), 640.84(a)(4), 640.92(a), 640.92(d), 640.92(e), and 640.94(a), be amended by replacing ''content'' with 1''concentration'' to be more precise.Under the proposal, § 640.84(b) would be removed to be consistent with changes made to § 640.80(a) and (b). Sections 640.84(a)(1) through (a)(4) would be redesignated as § 640.84(a) through (d).

F. Correction of Spelling

Under the proposal, § 640.91(b)(2) and (c) would be amended by correcting the spelling of ''coefficient'' and ''contamination,'' respectively.

G. Revision of Range for Protein Concentration

Under the proposal, § 640.92(a), *Protein concentration*, would be corrected by changing ''5.0±0.3'' to ''5.0±0.30'' to reflect the precision of the value.

H. Revision of general requirements and sterilization and heating for Immune Globulin (Human).

Under the proposal, §§ 640.101(e)(3) and (e)(4) would be removed to be consistent with current practice. The use of the current attenuated strain of measles used in the manufacture of measles vaccines licensed in the United States results in products that do not require the concomitant administration of measles antibodies. Moreover, the labeling for measles vaccines contains appropriate precautions regarding the effect of Immune Globulin (Human). With the availability of a highly effective vaccine, passive prophylaxis for poliomyelitis with Immune Globulin (Human), which had only minimal effectiveness, was discontinued many years ago.

FDA is proposing to remove § 640.101(f), *Samples and protocols*, to be consistent with current policy. Current policy permits manufacturers of biological products, including plasma derivatives, to request exemption from lot release by the Center for Biologics Evaluation and Research (CBER). After review of the data submitted in support of such a request, the Director, CBER, may grant the request, thus decreasing the regulatory burden on the manufacturer and permitting distribution of the product as soon as the manufacturer has completed all necessary quality control procedures on a particular lot.

FDA is proposing to amend § 640.102(e), *Sterilization and heating*, by removing ''* * * 30 to * * *''. The effect of the regulation would be unchanged by this proposed revision.

I. Revision of Determination of Protein Composition of Final Product for Immune Globulin (Human)

Section 640.103(b) describes the protein composition of the Immune Globulin (Human) final product in terms of absolute electrophoretic mobility. This value was computed from measurements made by moving boundary electrophoresis. For at least 25 years, the instrumentation necessary for performing moving boundary electrophoresis has not been commercially available. Accordingly, as such equipment was becoming less available, all licensed manufacturers of Immune Globulin (Human) calibrated more modern methods against moving boundary electrophoresis and amended their product license applications for Immune Globulin (Human) to provide for the use of the more modern methods. In addition, using more modern methods of manufacturing and measurement, manufacturers are now routinely making a more highly purified product. Accordingly, FDA is proposing to amend § 640.103(b) to read ''At least 96 percent of the total protein shall be immunoglobulin G (IgG), as determined by a method that has been approved for each manufacturer by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.''

J. Revision of Minimum Levels for Measles Neutralizing Antibody and Poliomyelitis Neutralizing Antibody

FDA is proposing to revise § 640.104(b)(2), consistent with current accepted practice, by eliminating a specified numerical value for the measles neutralizing antibody level. This change would allow more flexibility for industry and FDA, in that the regulations will no longer become outdated each time a new reference standard is used. The regulation would be changed to read ''A measles neutralizing antibody level that, when compared with that of a reference material designated by the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, as indicated in paragraph (c) of this section, demonstrates adequate potency. The Director, CBER, shall notify manufacturers when a new reference material will be used and will advise manufacturers of an appropriate antibody level taking into account a comparison of the new reference material to the previous reference material.''

FDA is proposing to revise § 640.104(b)(3), consistent with current accepted practice, by eliminating a specified numerical value for the poliomyelitis neutralizing antibody level. This change allows more flexibility for industry and FDA, in that the regulations will no longer become outdated each time a new reference standard is used. The regulation is changed to read ''A poliomyelitis Type 1, Type 2, or Type 3 neutralizing antibody level that, when compared with that of a reference material designated by the Center for Biologics Evaluation and Research, Food and Drug Administration, as indicated in paragraph (c) of this section, demonstrates adequate potency. The Director, CBER, shall notify manufacturers when a new reference material will be used and will advise manufacturers of an appropriate antibody level taking into account a comparison of the new reference material to the previous reference material.''

K. Revision of Nomenclature for Reference Immune Globulin

FDA is proposing to amend § 640.104(c)(1) and (c)(2) by removing the word ''Serum'' to reflect the more precise nomenclature of ''Reference Immune Globulin * * *''

IV. Analysis of Impacts

A. Review Under Executive Order 12866 and the Regulatory Flexibility Act and the Unfunded Mandates Act of 1995.

FDA has examined the impact of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U. S. C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impact; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order.

The agency believes that this proposed rule is consistent with the

regulatory philosophy and principles identified in the Executive Order. This proposed rule is not a significant regulatory action as defined by the Executive Order and therefore is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small business entities. Because the proposed rule amendments have no compliance costs and do not result in any new requirements, the agency certifies that the proposed rule will not have a significant negative economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. This proposed rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act of 1995 because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, and tribal governments in the aggregate, or by the private sector in any 1 year.

B. Environmental Impact

The agency has determined under 21 CFR 25.31(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. The Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Request for Comments

Interested persons may, on or before July 28, 1999, submit to the Docket Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 640 be amended as follows:

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

1. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

2. Section 640.80 is amended by revising the last sentence in paragraph (a) and by revising paragraph (b) to read as follows:

§ 640.80 Albumin (Human).

(a) * * * The product is defined as a sterile solution of the albumin derived from human plasma.

(b) *Source material.* The source material of Albumin (Human) shall be plasma recovered from Whole Blood prepared as prescribed in §§ 640.1 through 640.5, or Source Plasma prepared as prescribed in §§ 640.60 through 640.76.

* * * * *

3. Section 640.81 is amended by revising the first sentence of paragraph (c) and the last sentence in paragraph (e), and by revising paragraph (f) to read as follows:

§ 640.81 Processing.

* * * * *

(c) *Microbial contamination.* All processing steps shall be conducted in a manner to minimize the risk of contamination from microorganisms, pyrogens, or other impurities. * * *

* * * * *

(e) *Heat treatment.* * * * Heat treatment shall be conducted so that the solution is heated continuously for not less than 10 or more than 11 hours at an attained temperature of 60±0.5 °C.

(f) *Stabilizer.* Either 0.08±0.016 millimole sodium caprylate, or 0.08±0.016 millimole sodium acetyltryptophanate and 0.08±0.016 millimole sodium caprylate per gram of protein shall be present as a stabilizer(s). Calculations of the stabilizer concentration may employ the labeled value for the protein concentration of the product as referred to in § 640.84(d).

* * * * *

4. Section 640.82 is amended by revising the headings in paragraphs (a) and (c), and by revising paragraphs (d) and (e) to read as follows:

* * * * *

§ 640.82 Tests on final product.

* * * * *

(a) *Protein concentration.* * * *

* * * * *

(c) *pH.* * * *

(d) *Sodium concentration.* The sodium concentration of the final product shall be 130 to 160 milliequivalents per liter.

(e) *Potassium concentration.* The potassium concentration of the final product shall not exceed 2 milliequivalents per liter.

* * * * *

5. Section 640.84 is amended by revising the introductory paragraph, by removing paragraph (a) introductory text and paragraph (b), by redesignating paragraphs (a)(1) through (a)(4) as paragraphs (a) through (d), respectively, and by revising newly redesignated paragraphs (a) and (d) to read as follows:

§ 640.84 Labeling.

In addition to the labeling requirements of §§ 610.60, 610.61, and 610.62 of this chapter, the container and package labels shall contain the following information:

(a) The osmotic equivalent in terms of plasma, and the sodium concentration in terms of a value or a range in milliequivalents per liter;

* * * * *

(d) The protein concentration, expressed as a 4 percent, 5 percent, 20 percent, or 25 percent solution.

6. Section 640.90 is amended by revising the last sentence in paragraph (a) and by revising paragraph (b) to read as follows:

§ 640.90 Plasma Protein Fraction (Human).

(a) * * * The product is defined as a sterile solution of protein composed of albumin and globulin, derived from human plasma.

(b) *Source material.* The source material of Plasma Protein Fraction (Human) shall be plasma recovered from Whole Blood prepared as prescribed in §§ 640.1 through 640.5, or Source Plasma prepared as prescribed in §§ 640.60 through 640.76.

* * * * *

7. Section 640.91 is amended by revising paragraphs (b)(2) and (f), and by revising the first sentence in paragraph (c) and the last sentence in paragraph (e) to read as follows:

§ 640.91 Processing.

* * * * *

(b) * * *

(2) Contains less than 5 percent protein with a sedimentation coefficient greater than 7.0 S.

(c) *Microbial contamination.* All processing steps shall be conducted in a manner to minimize the risk of contamination from microorganisms, pyrogens, or other impurities. * * *

* * * * *

(e) * * * Heat treatment shall be conducted so that the solution is heated continuously for not less than 10 or more than 11 hours at an attained temperature of 60±0.5 °C.

(f) *Stabilizer.* Either 0.08±0.016 millimole sodium caprylate, or 0.08±0.016 millimole sodium acetyltryptophanate and 0.08±0.016 millimole sodium caprylate per gram of protein shall be present as a stabilizer(s). Calculations of the stabilizer concentration may employ the labeled value 5 percent for the protein concentration of the product.

* * * * *

8. Section 640.92 is amended by revising the headings of paragraphs (a) and (c), and by revising paragraphs (d) and (e) to read as follows:

§ 640.92 Tests on final product.

* * * * *

(a) *Protein concentration.* * * *

* * * * *

(c) *pH.* * * *

(d) *Sodium concentration.* The sodium concentration of the final product shall be 130 to 160 milliequivalents per liter.

(e) *Potassium concentration.* The potassium concentration of the final product shall not exceed 2 milliequivalents per liter.

* * * * *

9. Section 640.94 is amended by revising paragraph (a) to read as follows:

§ 640.94 Labeling.

* * * * *

(a) The osmotic equivalent in terms of plasma, and the sodium concentration in terms of a value or a range in milliequivalents per liter.

* * * * *

10. Section 640.100 is amended by revising the last sentence in paragraph (a), and by revising paragraphs (b) and (c) to read as follows:

§ 640.100 Immune Globulin (Human).

(a) * * * The product is defined as a sterile solution containing antibodies derived from human plasma.

(b) *Source material.* The source material of Immune Globulin (Human) shall be plasma recovered from Whole Blood prepared as prescribed in §§ 640.1 through 640.5, or Source Plasma prepared as prescribed in §§ 640.60 through 640.76.

(c) *Additives in source material.* The source material shall contain no additives other than citrate or acid citrate dextrose anticoagulant solution, unless it is shown that the processing method yields a product free of the additive to such an extent that the safety, purity, and potency of the product will not be affected adversely.

§ 640.101 [Amended]

11. Section 640.101 *General requirements* is amended by removing the heading of paragraph (b) ''*Hydrogen ion concentration*'' and by adding in its place ''*pH*'' and by removing paragraphs (e)(3), (e)(4), and (f).

12. Section 640.102 is amended by revising the last sentence of paragraph (e) to read as follows:

640.102 Manufacture of Immune Globulin (Human).

* * * * *

(e) * * * At no time during processing shall the product be exposed to temperatures above 45 °C and after sterilization the product shall not be exposed to temperatures above 32 °C for more than 72 hours.

13. Section 640.103 is amended by revising paragraph (b) to read as follows:

§ 640.103 The final product.

* * * * *

(b) *Protein composition.* At least 96 percent of the total protein shall be immunoglobulin G (IgG), as determined by a method that has been approved for each manufacturer by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.

14. Section 640.104 is amended by revising paragraphs (b)(2), (b)(3), (c)(1), and (c)(2) to read as follows:

§ 640.104 Potency.

* * * * *

(b) * * *

(2) A measles neutralizing antibody level that, when compared with that of a reference material designated by the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, as indicated in paragraph (c) of this section, demonstrates adequate potency. The Director, CBER, shall notify manufacturers when a new reference material will be used and will advise manufacturers of an appropriate antibody level taking into account a comparison of the new reference material to the previous reference material.

(3) A poliomyelitis Type 1, Type 2, or Type 3 neutralizing antibody level that, when compared with that of a reference material designated by the Center for Biologics Evaluation and Research, Food and Drug Administration, as indicated in paragraph (c) of this section, demonstrates adequate potency. The Director, CBER, shall notify manufacturers when a new reference material will be used and will advise manufacturers of an appropriate antibody level taking into account a comparison of the new reference material to the previous reference material.

(c) * * *

(1) Reference Immune Globulin for correlation of measles antibody titers.

(2) Reference Immune Globulin for correlation of poliomyelitis antibody titers, Types 1, 2, and 3.

Dated: April 20, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–11898 Filed 5-13-99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–106905–98]

RIN 1545–AW09

Allocation of Loss With Respect to Stock and Other Personal Property; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed regulations relating to the allocation of loss recognized on the disposition of stock and other personal property.

DATES: The public hearing originally scheduled for Wednesday, May 26, 1999, at 10 a.m., is cancelled.

FOR FURTHER INFORMATION CONTACT: Michael L. Slaughter of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking; notice of proposed rulemaking by cross-reference to temporary regulations; and notice of public hearing that appeared in the **Federal Register** on Monday, January 11, 1999 (64 FR 1571), announced that a public hearing was scheduled for