amendment to Rule 30–3 of its Rules of Organization and Program Management governing Delegations of Authority to the Director of the Division of Market Regulation (''Director'').[1] The amendment adds new subparagraph (iii) to paragraph (a)(73) of Rule 30–3 authorizing the Director to extend deadlines for submission of comments to (a) applications for registration as a national securities exchange filed under Section 6 of the Exchange Act of 1934 (''Exchange Act''),[2] (b) applications for an exemption from registration based on limited volume filed under Section 6 of the Exchange Act, and (c) amendments to such applications.

The delegation of authority to the Director to extend deadlines for submission of comments is intended to conserve Commission resources by permitting Division staff to extend the deadline for submission of comments to such applications and amendments to such applications. The Division has received several applications for registration as a national securities exchange that must be published for comment. The Division anticipates that, when an application for registration as a national securities exchange or exemption from registration based on limited volume is filed and published for comment, there will be significant comment on the application. Granting the Division delegated authority to extend deadlines for submission of comments to applications and amendments to such applications filed pursuant to Section 6 of the Exchange Act will provide the Division with greater flexibility to respond to commenters' requests, and may expedite the process of publishing amendments to the Form 1. Nevertheless, the staff may submit matters to the Commission for consideration as it deems appropriate.

The Commission finds, in accordance with Section 553(b)(3)(A) of the Administrative Procedure Act,[3] that this amendment relates solely to agency organization, procedure, or practice, and does not relate to a substantive rule. Accordingly, notice, opportunity for public comment, and publication of the amendment prior to its effective date are unnecessary.

List of Subjects in 17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies), Organization and functions (Government agencies).

[1] 17 CFR 200.30–3.

[2] 15 U.S.C. 78f.

[3] 5 U.S.C. 553(b)(A).

Text of Amendment

In accordance with the preamble, the Commission hereby amends Title 17, Chapter II of the Code of Federal Regulations as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Subpart A—Organization and Program Management

1. The authority citation for Part 200, Subpart A, continues to read, in part, as follows:

Authority: 15 U.S.C. 77s, 78d–1, 78d–2, 78w, 78*ll*(d), 78mm, 79t, 77sss, 80a–37, 80b–11, unless otherwise noted.

* * * * *

2. Section 200.30–3, paragraph (a)(73), is amended by removing the word ''and'' at the end of paragraph (a)(73)(i); removing the period at the end of paragraph (a)(73)(ii) and adding;'' and''; and adding paragraph (a)(73)(iii) to read as follows:

§ 200.30–3 Delegation of authority to Director of Division of Market Regulation.

* * * * *

(a)* * *

(73) Pursuant to section 6(a) of the Act, 15 U.S.C. 78f(a), and Rule 6a–1 thereunder, 17 CFR 240.6a–1:

* * * * *

(iii) To extend deadlines for submission of comments to an application for registration as a national securities exchange, or for exemption from registration based on limited volume; and amendments to an application for registration as a national securities exchange, or for exemption from registration based on limited volume.

By the Commission.

Dated: July 31, 2001.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–19521 Filed 8–3–01; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606 and 640

[Docket No. 98N–0673]

Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. FDA is issuing this final rule 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, blood components, and Source Plasma.

DATES: This rule is effective September 5, 2001.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 19, 1999 (64 FR 45375), FDA published a proposed rule to amend the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma. The proposed rule was intended to make the regulations more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. The proposed rule was a companion document to a direct final rule published in the **Federal Register** of August 19, 1999 (64 FR 45366). Written comments were to be submitted on or before December 3, 1999. FDA stated that the effective date of the direct final rule would be February 11, 2000, unless any significant adverse comment was submitted to FDA during the comment period. If a significant adverse comment applies to an amendment, paragraph, or section of the 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.

Eight letters of comment were submitted to the docket. After reviewing the comments, the agency issued in the **Federal Register** on January 10, 2001 (66 FR 1834), a confirmation in part of the direct final rule and technical amendment which confirmed the effective date of February 11, 2000, for those provisions that did not receive

significant comment and a technical amendment which reinstated the former provisions that received significant adverse comments. The document also made editorial corrections to the regulations.

II. Comments on the Proposed Rule and FDA Responses

FDA received eight letters of comment on the proposed rule. The comments were submitted by manufacturers, blood establishments, trade associations, and individuals. Two of the eight comments specifically supported FDA's goal of removing, revising, or updating the specific regulations to be more consistent with current practices in the blood industry. Each of the eight comments submitted recommended changes to certain provisions of the rule. FDA summarizes and responds to the received comments in the following section.

A. Compatibility Testing (Proposed §§ 606.3(j) and 606.151(c))

The proposed rule would amend the sections by removing the reference to serological tests and making the definition more general to apply to all tests performed, including computer crossmatching to establish the matching of a donor's blood or blood components with that of a recipient.

(Comment 1) One comment on § 606.3(j) suggested that the proposed term ''tests performed'' be changed to another term such as ''procedures performed.'' Another comment noted that the same terminology occurs in § 606.151(c) and suggested that the phrase be changed to ''Procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum type.''

FDA agrees that the use of the proposed term ''tests performed'' in §§ 606.3(j) and 606.151(c) should be clarified. The use of the term ''tests performed'' could be interpreted to not allow for computer crossmatching. Therefore, FDA is amending these sections in the final rule. Section 606.3(j) will define compatibility testing to mean ''procedures performed to establish the matching of a donor's blood or blood components with that of a potential recipient'' and § 606.151(c) will require standard operating procedures for compatibility testing to include ''procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type.''

B. Use of Serum or Plasma for Compatibility Testing (Proposed § 606.151(b) and (c))

The proposed rule would amend these sections to be more consistent with current practices with respect to compatibility testing.

(Comment 2) Two comments on § 606.151(b) and (c) stated that the use of either serum or plasma should be permitted for compatibility testing/pretransfusion testing, as the use of plasma samples is not uncommon for some tests.

FDA agrees with the comment and has made the appropriate changes in the final rule to § 606.151(b) and (c).

C. Entering Blood Containers Prior to Issue (Proposed § 640.2)

The proposed rule would amend the section to be consistent with current practices with regard to entering containers of blood and blood components prior to issue.

(Comment 3) One comment on proposed § 640.2 requested clarification of the proposed language that ''blood containers shall not be entered prior to issue for any purpose except for blood collection.'' The comment asked if FDA intends to preclude activities such as filtering to make a unit leukoreduced, washing to make a unit IgA deficient, splitting to make a unit appropriate for a transfusion to a neonate, and pooling of platelets or cryoprecipitate since all these procedures involved entering the unit for special processing.

FDA does not intend to preclude activities such as those described in the comment, and is revising the first sentence in § 640.2(b) of the final rule to read ''[T]he blood container shall not be entered prior to issue for any purpose except for blood collection or if the method of processing requires the use of a different container.''

D. History of Hepatitis (Proposed §§ 640.3(c)(1) and 640.63(c)(11))

The proposed rule would amend these sections to specify that donors who have a history of hepatitis before the age of 11 could be eligible to be donors of Whole Blood or Source Plasma. The proposed change is consistent with current FDA recommendations in the FDA memorandum dated April 23, 1992, entitled ''Exemptions to Permit Persons With a History of Viral Hepatitis Before the Age of Eleven to Serve as Donors of Whole Blood and Plasma: Alternative Procedure.''

(Comment 4) One comment on proposed §§ 640.3(c)(1) and 640.63(c)(11) stated that reference is made to a person with a history of hepatitis ''after the age of eleven'' and that the meaning of ''after the age of eleven'' is unclear and needs further clarification.

FDA agrees and is changing the phrase to ''after the eleventh birthday'' for clarification in both sections.

E. Samples and Segments (Proposed §§ 640.4(g) and 640.15)

The proposed rule would amend these sections with regard to use of current terminology for test specimens.

(Comment 5) One comment stated that the proposed change of terminology from ''pilot tubes,'' ''pilot sample tubes,'' and ''pilot samples,'' to ''samples'' and ''segments'' in §§ 640.4(g) and 640.15 is confusing. The comment also asked if FDA meant to imply that ''segment identification'' must occur and if this excludes the more critical sample identification that must occur at the time of the collection of the unit.

FDA is not implying any procedural changes by changing the phrases ''pilot tubes'' and ''pilot sample tubes'' to ''samples'' and the phrase ''pilot samples'' to ''segments.'' FDA is making the changes as proposed, to reflect current terminology used for test specimens. The proposed headings and introductory text for §§ 640.4(g) and 640.15 are revised in the final rule to be consistent with the terminology change.

F. Rh Factor Terminology (Proposed § 640.5)

The proposed rule would amend the section to be more consistent with current terminology used in the determination of the Rh factors.

(Comment 6) One comment stated that in § 640.5 the use of the term ''D^u'' is inappropriate as the term ''weak D'' is currently accepted and reflects the significant changes in Anti-D reagents over the past years.

FDA agrees with the comment and is replacing the term ''Rh_o variant (D^u)'' with the term ''weak D (formerly D^u).''

G. Specified Timeframes for Component Preparation (Proposed §§ 640.16(a), 640.24(b), 640.34(a) through (d) and (e)(1), and 640.54(a)(2))

The proposed rule would amend these sections by changing the specific timeframes prescribed for certain practices and procedures in component preparation. The proposed changes would allow more flexibility by permitting different timeframes depending upon the directions for use of the particular blood collection device (blood collecting, processing, and storage system) being used.

(Comment 7) Four comments requested clarification of the phrase ''within the timeframe specified in the directions for use for the specific device.'' (See proposed §§ 640.16(a), 640.24(b), 640.34(a) through (d) and (e)(1), and 640.54(a)(2).) One comment stated that due to the solution components, the blood collection bags (or systems) are approved for use as ''drugs'' not ''devices.'' The comment requested clarification as to whether the proposed rule is applicable to blood collecting, processing, and storage systems approved as ''drugs.'' Another comment stated that manufacturers would now be required to include information concerning specified timeframes in their product labeling. Two comments requested that the current language be retained for the most part by keeping the present timeframes but that some added flexibility could be allowed by adding the phrase ''or within the timeframe specified in the directions for use of the specific device.'' The concern was that few, if any, manufacturers include this time period in their labeling and choose instead to refer to the regulations as well as industry standards. Another comment stated that the proposed rule as written would remove from 21 CFR part 640 detailed requirements for manufacturing blood components, and as a result these would be required as part of the drug or device product labels. The comment also stated that to add the detailed requirements to the drug or device product labels would be burdensome on manufacturers of manual blood collecting, processing, and storage systems, and it would take 2 to 3 years to exhaust existing product inventories and make appropriate changes.

FDA agrees that the use of the word ''device'' in the phrase ''within the timeframe specified in the directions for use for the specific device'' is inadequate and confusing in describing the blood collecting, processing, and storage system (or blood bag). The use of the word ''device'' is confusing because: (1) These systems are approved as ''drugs'' due to the solution components, and (2) the instructions for use are currently in the package inserts for the approved systems. Therefore, FDA is replacing the word ''device'' used in the proposed phrase with ''blood collecting, processing, and storage system'' so that the revised phrase reads ''within the timeframe specified in the directions for use for the blood collecting, processing, and storage system used.'' In response to the request for flexibility, FDA is retaining where appropriate the specific timeframes for component preparation, and adding the alternative phrase ''within the timeframe specified in the directions for use for the blood collecting, processing, and storage system.''

H. Reducing Repeat Testing in Plasmapheresis (Proposed § 640.23(a))

The proposed rule would amend the section by reducing the requirements for repeat testing of blood samples from donors participating in frequent plateletpheresis collection procedures.

In § 640.23(a) the agency proposed the revision ''Results of tests performed in accordance with § 640.5(b) and (c) for Platelets, Pheresis products shall be valid for a period not to exceed 3 months.''

(Comment 8) One comment stated that this revision may introduce the potential for error in that other tests, which should have been performed, will inadvertently be omitted. Another comment stated that with respect to the revision of § 640.23(a), the rationale why ABO/Rh testing is valid for only 3 months is not clear since donors do not change blood type and that the testing is done only to confirm that samples are from the correct donor.

After reviewing the comments, FDA recognizes that the issues concerning this section are more complex than can be addressed in this rule. Therefore, FDA is retaining the wording for this section as it is currently written. If an establishment wishes to perform testing at intervals other than those stated in the regulation, they may request a variance for alternative testing under § 640.120.

I. Timeframes for Freezing Plasma (Proposed §§ 640.34(b) and 640.54(a)(2))

The proposed rule would amend the sections concerning the timeframes for freezing plasma.

(Comment 9) Two comments on proposed § 640.34(b) concern the use of the term ''frozen solid.'' The comments stated that use of the proposed term ''frozen solid'' seems to imply that the FDA memorandum of November 13, 1989, entitled ''Eight-Hour Hold'' would no longer be in effect. The memorandum states that plasma should be placed in a freezer within 8 hours.

FDA agrees with the comment and the term ''frozen solid'' is replaced with the phrase ''separated and placed in a freezer within 8 hours'' in § 640.34(b) and for consistency, in the standards for cryoprecipitate in § 640.54(a)(2).

J. Availability of a Qualified Licensed Physician (Proposed § 640.62)

The proposed rule would require a qualified licensed physician to be available on the premises or available to attend the donor within 15 minutes when certain procedures concerning blood and blood products are performed.

(Comment 10) Five comments were submitted on the proposed revision in § 640.62 as to the availability of a licensed physician at a collection facility. One comment said that the new section was potentially confusing and compliance would be difficult at individual blood collection centers and at mobile activities. A second comment requested that ''the services of a licensed physician'' be changed to ''emergency medical services'' since the ability to call 911 is usually readily available. A third comment stated that the proposed rule did not give any rationale for the specification of the time constraint nor did the proposed rule define the phrase ''available to attend'' as indicative that the physician was physically present or whether telephone advice and consultation is authorized. A fourth comment stated that potential donor safety concerns could be better served through a requirement for documented standard operating procedures within the donor center as outlined in § 640.4(a) for the collection of whole blood. A fifth comment applauded the fact that the agency relaxed the requirement for the physical presence of a physician for plasmapheresis, and the collection of Source Plasma.

Due to the variety of comments received on this section, FDA is retaining the present language in § 640.62 and intends to address this requirement in a future rulemaking. Comments submitted concerning this section will be considered at that time.

III. Analysis of Impacts

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

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104-121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, this final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options to minimize any significant impact of a rule on small business entities. Because the final rule amendments have no compliance costs and do not result in any new requirements, the agency certifies that the final rule will not have a significant negative impact on a substantial number of small entities. Therefore under the Regulatory Flexibility Act, no further analysis is required. This final rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act 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 one year.

B. Environmental Impact

The agency has determined under 21 CFR 25.31(h) 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.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this final 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.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in that order and, consequently, a federalism summary impact statement is not required.

List of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

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 by the Commissioner of Food and Drugs, 21 CFR parts 606 and 640 are amended as follows:

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

1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 606.3 is amended by revising paragraph (j) to read as follows:

§ 606.3 Definitions.

* * * * *

(j) *Compatibility testing* means the procedures performed to establish the matching of a donor's blood or blood components with that of a potential recipient.

* * * * *

3. Section 606.151 is amended by revising paragraphs (b) and (c) to read as follows:

§ 606.151 Compatibility testing.

* * * * *

(b) The use of fresh recipient serum or plasma samples less than 3 days old for all pretransfusion testing if the recipient has been pregnant or transfused within the previous 3 months.

(c) Procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type.

* * * * *

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

4. 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.

5. Section 640.2 is amended by revising paragraph (b) to read as follows:

§ 640.2 General requirements.

* * * * *

(b) *Blood container.* The blood container shall not be entered prior to issue for any purpose except for blood collection or when the method of processing requires use of a different container. The container shall be uncolored and transparent to permit visual inspection of the contents and any closure shall be such as will maintain an hermetic seal and prevent contamination of the contents. The container material shall not interact with the contents under the customary conditions of storage and use, in such a manner as to have an adverse effect upon the safety, purity, or potency of the blood.

* * * * *

6. Section 640.3 is amended by revising paragraph (c)(1) to read as follows:

§ 640.3 Suitability of donor.

* * * * *

(c) * * *

(1) A history of viral hepatitis after the 11th birthday;

* * * * *

7. Section 640.4 is amended by revising the introductory text of paragraph (g) and paragraphs (g)(1), (g)(2), (g)(4), and (g)(5) to read as follows:

§ 640.4 Collection of the blood.

* * * * *

(g) *Samples and segments for laboratory tests.* Samples and segments for laboratory tests shall meet the following standards:

(1) One or more segments shall be provided with each unit of blood when issued or reissued except as provided in § 640.2(c)(2) and all segments shall be from the donor who is the source of the unit of blood.

(2) All samples for laboratory tests performed by the manufacturer and all segments accompanying a unit of blood shall be collected at the time of filling the original blood container.

* * * * *

(4) All segments accompanying a unit of blood shall be attached to the whole blood container before blood collection, in a tamperproof manner that will conspicuously indicate removal and reattachment.

(5) Segments for compatibility testing shall contain blood mixed with the appropriate anticoagulant.

* * * * *

8. Section 640.5 is amended by revising the introductory text and paragraph (c) to read as follows:

§ 640.5 Testing the blood.

All laboratory tests shall be made on a specimen of blood taken from the

donor at the time of collecting the unit of blood, and these tests shall include the following:

* * * * *

(c) *Determination of the Rh factors.* Each container of Whole Blood shall be classified as to Rh type on the basis of tests done on the sample. The label shall indicate the extent of typing and the results of all tests performed. If the test, using Anti-D Blood Grouping Reagent, is positive, the container may be labeled ''Rh Positive.'' If the test is negative, the results shall be confirmed by further testing which shall include tests for the ''weak D (formerly D^u).'' Blood may be labeled ''Rh Negative'' if further testing is negative. Units testing positive after additional more specific testing shall be labeled as ''Rh Positive.'' Only Anti-Rh Blood Grouping Reagents licensed under, or that otherwise meet the requirements of, this subchapter shall be used, and the technique used shall be that for which the reagent is specifically designed to be effective.

* * * * *

9. Section 640.15 is revised to read as follows:

§ 640.15 Segments for testing.

Segments collected in integral tubing shall meet the following standards:

(a) One or more segments shall be provided with each unit of Whole Blood or Red Blood Cells when issued or reissued.

(b) Before they are filled, all segments shall be marked or identified so as to relate them to the donor of that unit of red cells.

(c) All segments accompanying a unit of Red Blood Cells shall be filled at the time the blood is collected or at the time the final product is prepared.

10. Section 640.16 is amended by revising paragraph (a) to read as follows:

§ 640.16 Processing.

(a) *Separation.* Within the timeframe specified in the directions for use for the blood collecting, processing, and storage system used, Red Blood Cells may be prepared either by centrifugation, done in a manner that will not tend to increase the temperature of the blood, or by normal undisturbed sedimentation. A portion of the plasma sufficient to insure optimal cell preservation shall be left with the red cells except when a cryoprotective substance or additive solution is added for prolonged storage.

* * * * *

11. Section 640.24 is amended by revising paragraph (b) to read as follows:

§ 640.24 Processing.

* * * * *

(b) Immediately after collection, the whole blood or plasma shall be held in storage between 20 and 24 °C unless it must be transported from the collection center to the processing laboratory. During such transport, all reasonable methods shall be used to maintain the temperature as close as possible to a range between 20 and 24 °C until it arrives at the processing laboratory where it shall be held between 20 and 24 °C until the platelets are separated. The platelet concentrate shall be separated within 4 hours or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system.

* * * * *

12. Section 640.34 is amended by revising paragraphs (a) through (d) and (e)(1) to read as follows:

§ 640.34 Processing.

(a) *Plasma.* Plasma shall be separated from the red blood cells and shall be stored at -18 °C or colder within 6 hours after transfer to the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system unless the product is to be stored as Liquid Plasma.

(b) *Fresh Frozen Plasma.* Fresh frozen plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma shall be separated from the red blood cells, and placed in a freezer within 8 hours or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system, and stored at -18 °C or colder.

(c) *Liquid Plasma.* Liquid Plasma shall be separated from the red blood cells and shall be stored at a temperature of 1 to 6 °C within 4 hours after filling the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system.

(d) *Platelet Rich Plasma.* Platelet rich plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and manipulation of the donor's tissue. The plasma shall be separated from the red blood cells by centrifugation within 4 hours after completion of the phlebotomy or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system. The time and speed of the centrifugation shall have been shown to produce a product with at least 250,000 platelets per microliter. The plasma shall be stored at a temperature between 20 and 24 °C immediately after filling the final container. A gentle and continuous agitation of the product shall be maintained throughout the storage period, if stored at a temperature of 20 to 24 °C.

(e) * * *

(1) Platelets shall be separated as prescribed in subpart C of part 640, prior to freezing the plasma. The remaining plasma may be labeled as ''Fresh Frozen Plasma,'' if frozen within 6 hours after filling the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system.

* * * * *

13. Section 640.54 is amended by revising paragraph (a)(2) to read as follows:

§ 640.54 Processing.

(a) * * *

(2) The plasma shall be placed in a freezer within 8 hours after blood collection or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system. A combination of dry ice and organic solvent may be used for freezing: *Provided*, That the procedure has been shown not to cause the solvent to penetrate the container or leach plasticizer from the container into the plasma.

* * * * *

14. Section 640.63 is amended by revising paragraph (c)(11) to read as follows:

§ 640.63 Suitability of donor.

* * * * *

(c) * * *

(11) Freedom from a history of viral hepatitis after the 11th birthday;

* * * * *

Dated: June 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–19461 Filed 8–3–01; 8:45 am]

BILLING CODE 4160–01–S

POSTAL SERVICE

39 CFR Part 266

Privacy Act of 1974; Implementation

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service is amending its regulations implementing the Privacy Act of 1974, 5 U.S.C. 552a. This amendment modifies existing regulations (39 CFR 266.9) to exempt system of records, Office of Inspector