

refer to a single source. The proposed rule amendments also include provisions that add flexibility to the regulations that should lower the cost of compliance.

Some aspects of the proposed rule amendments do establish new label requirements and provisions. One such requirement is that the label must reflect updated testing requirements. The agency believes these requirements, including the requirement for the label to reflect updated testing requirements, conform to current industry practice and do not impose an additional burden.

The proposed rule requires a change in the instruction circular to reflect current testing practices. Existing labeling regulations do not allow the circular to reflect current required testing or to adjust to future changes in required testing or plasma thawing procedures. The agency believes the instruction circular would already be in compliance with the proposed rule amendments and reflect current requirements and practices if compliance were permitted by existing regulations. By adding flexibility to the rules regarding the instruction circular, the proposed rule lowers the overall cost of compliance. Moreover, as the instruction circular is updated regularly, the agency believes any required changes can be made in the ordinary revision cycle and that this rule will not impose an additional burden.

The proposed rule amendments also update the temperature requirements for storage and shipping of blood and blood components. The agency believes that these requirements reflect current industry practice and do not impose an additional burden.

In general, the agency believes the proposed rule will have no compliance costs, because any requirements are either industry practice or would be industry practice absent existing prohibitions. Because the agency believes these proposed rule amendments have no compliance costs, the agency certifies they will not have a significant economic impact on a substantial number of small entities.

IV. The Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under

the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). As previously described, FDA is proposing to consolidate regulations so blood establishments may find all applicable labeling standards under one section of regulations. The regulations for labeling of all blood and blood components would be moved from other sections of the regulations to § 606.121. Since the agency believes the proposed rule amendments conform to current industry practice, FDA is not estimating the burden of the proposed rule. The information collection requirements under §§ 606.121 and 606.122 are approved under OMB control number 0910–0116.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(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.

VI. Federalism

FDA has analyzed this proposed 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 the 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 the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposed rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Proposed Effective Date

The agency is proposing that any final rule that may issue based upon this proposed rule become effective 180 days after its date of publication in the **Federal Register**.

IX. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Krotitschke, R., "Stability of Fresh Frozen Plasma: Results of 36-Month Storage at -20 °C, -25 °C, -30 °C, and -40 °C," *Infusion Therapy and Transfusion Medicine*, 27:174–180, 2000.

List of Subjects

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 600, 610, 606, and 640 be amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

2. Section 600.15 is amended in the table in paragraph (a) by revising the entries for Cryoprecipitated AHF, Fresh Frozen Plasma, and Source Plasma to read as follows:

§ 600.15 Temperatures during shipment.

* * * * *

(a) Products.

Product	Temperature
Cryoprecipitated AHF	-25 °C or colder if expiration is 24 months or -18 to -25 °C if expiration is 3 months.
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