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TITLE 21--FOOD AND DRUGS

CHAPTER 1--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
(CONTINUED)

PART 600--BIOLOGICAL PRODUCTS: GENERAL--Table of contents

Subpart B--Established Standards

Sec. 600.15 Temperatures during shipment

The following products shall be maintained during shipment at the specified temperatures:

(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 Rebullla 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..... | 1 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 and 24 C, if the label indicates storage between 20 and 24 C. |

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|---|--|
| 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 and 10 C during shipment. |
| Yellow Fever Vaccine..... | 0 C or colder |

(b) Exemptions. Exemptions or modifications shall be made only upon written approval, in the form of a supplement to the biologics license application, approved by the Director, Center for Biologics Evaluation and Research.

[39 FR 39872, Nov. 12, 1974, as amended at 49 FR 23833, June 8, 1984; 50 FR 4133, Jan. 29, 1985; 50 FR 9000, Mar. 6, 1985; 55 FR 11013, Mar 26, 1990; 59 FR 49351, Sept. 28, 1994; 64 FR 56449, Oct. 20, 1999]