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TITLE 21--FOOD AND DRUGS

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

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

Subpart B--Establishment Standards

Sec. 600.15 Temperatures during shipment.

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

(a) Products.

Table with 2 columns: Product and Temperature. Rows include Cryoprecipitated AHF, Measles and Rubella Virus Vaccine Live, Measles Live and Smallpox Vaccine, Measles, Mumps, and Rubella Virus Vaccine Live, Measles and Mumps Virus Vaccine Live, Measles Virus Vaccine Live, Mumps Virus Vaccine Live, Fresh Frozen Plasma, Liquid Plasma, Plasma, Platelet Rich Plasma, Platelets, Poliovirus Vaccine Live Oral Trivalent, and Poliovirus Vaccine Live Oral Type I.

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.

(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]