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§ 610.53 Dating periods for licensed biological products.

(a) *General.* The minimum dating periods in paragraph (c) of this section are based on data relating to usage, clinical experience, or laboratory tests that establish the reasonable period beyond which the product cannot be expected to yield its specific results and retain its safety, purity, and potency, provided the product is maintained at the recommended temperatures. The standards prescribed by the regulations in this subchapter are designed to ensure the continued safety, purity, and potency of the products and are based on the dating periods set forth in paragraph (c) of this section. Package labels for each product shall recommend storage at the stated temperatures.

(b) *When the dating period begins.* The dating period for a product shall begin

on the date of manufacture, as prescribed in § 610.50. The dating period for a combination of two or more products shall be no longer than the dating period of the component with the shortest dating period.

(c) *Table of dating periods.* In using the table in this paragraph, a product in column A may be stored by the manufacturer at the prescribed temperature and length of time in either column B or C, plus the length of time in column D. The dating period in column D shall be applied from the day the product leaves the manufacturer's storage, provided the product has not exceeded its maximum storage period, as prescribed in column B or C. If a product is held in the manufacturer's storage beyond the period prescribed, the dating period for the product being distributed shall be reduced by a corresponding period.

A	B	C	D
Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
Adenovirus Vaccine Live Oral	6 months	Not applicable	6 months.
Albumin (Human)	3 yearsdo	(a) 5 years.
dodo	(b) 3 years, provided labeling recommends storage at room temperature, no warmer than 37 °C.
	Not applicabledo	(c) 10 years, if in a hermetically sealed metal container and provided labeling recommends storage between 2 and 8 °C.
Allergenic Extracts labeled "No U.S. Standard of Potency":			
1. With 50 percent or more glycerin ...	3 yearsdo	3 years.
2. With less than 50 percent glycerin	18 monthsdo	18 months.
3. Products for which cold storage conditions are inappropriate.	Not applicabledo	18 months (from date of manufacture), provided labeling recommends storage at 30 °C or colder.
4. Powders and tabletsdodo	5 years (from date of manufacture), provided labeling recommends storage at 30 °C or colder.
5. Freeze-dried products:			
a. Unreconstituteddodo	4 years (from date of manufacture).
b. Reconstituteddodo	18 months (cannot exceed 4-year unreconstituted dating period plus an additional 12 months).
Allergenic Extracts, Alum Precipitated labeled "No U.S. Standard of Potency".	18 monthsdo	18 months.
Anthrax Vaccine Adsorbed	2 yearsdo	1 year.
Antibody to Hepatitis B Surface Antigen:			
1. Antibody to Hepatitis B Surface Antigen.	6 monthsdo	6 months.
2. Lyophilized coated red blood cellsdodo	Do.
3. Enzyme conjugated productsdodo	Do.
Iodinated (¹²⁵ I) products	Not applicabledo	45 days (from date of manufacture).
Antihemophilic Factor (Human)dodo	1 year (from date of manufacture).
Anti-Human Globulin Liquiddodo	2 years.
Anti-Inhibitor Coagulant Complexdodo	Do.
Antrabies Serum	1 yeardo	Do.

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A Product	B Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	C Manufacturer's storage period 0 °C or colder (unless otherwise stated)	D Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
Antivenin (<i>Crotalidae</i>) Polyvalentdodo	5 years with an initial 10 percent excess of potency, provided labeling recommends storage at 37 °C or colder.
Antivenin (<i>Latrodectus Mactans</i>)dodo	5 years with an initial 10 percent excess of potency.
Antivenin (<i>Micurus fulvius</i>)dodo	Do.
Asparaginase	Not applicabledo	18 months from the date of the last valid potency test.
BCG Vaccine	1 year	Not applicable	6 months.
Blood Grouping Reagents			
1. Liquid	Not applicable	Not applicable	2 years.
2. Dried	1 year	2 years	5 years.
Blood Group Substance ABdodo	2 years.
Blood Group Substance Adodo	Do.
Blood Group Substance Bdodo	Do.
Botulism Antitoxindo	Not applicable	5 years with an initial 20 percent excess of potency.
Cholera Vaccinedodo	18 months.
Coccidioidindodo	3 years.
Collagenase	Not applicabledo	4 years (from date of manufacture), provided labeling recommends storage at 37 °C or colder.
Cryoprecipitated AFHdodo	12 months from the date of collection of source blood, provided labeling recommends storage at -18 °C or colder.
Diphtheria Antitoxin:			
1. Liquid	1 yeardo	5 years with an initial 20 percent excess of potency.
2. Drieddo	2 years	5 years with an initial 10 percent excess of potency.
Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed.do	Not applicable	18 months.
Diphtheria and Tetanus Toxoids, Adsorbed.dodo	2 years.
Diphtheria Toxin for Schick Testdodo	1 year.
Diphtheria Toxoiddodo	2 years.
Diphtheria Toxoid Adsorbeddo	2 years	Do.
Diphtheria Toxoid-Schick Test Control	Not applicable	Not applicable	1 year.
Factor IX Complexdodo	1 year (from date of manufacture).
Fibrinolysin (Human)	1 year	2 years	2 years.
Fibrinolysin and Desoxyribonuclease Combined (Bovine).dodo	3 years, provided labeling recommends storage at 30 °C or colder.
Fibrinolysin and Desoxyribonuclease Combined (Bovine) with Chloramphenicol.dodo	Do.
Hepatitis B Surface Antigen:			
1. Unlyophilized coated red blood cells.	Not applicabledo	14 days (from date of manufacture).
2. Iodinated (¹²⁵ I) productdodo	45 days (from date of manufacture).
3. Enzyme conjugated product	6 monthsdo	6 months.
Histoplasmin	1 year	Not applicable	2 years.
Immunoglobulins:			
1. Hepatitis B Immune Globulin (Human).	Not applicabledo	1 year.
2. Immune Globulin (Human)	3 yearsdo	3 years.
3. Immune Globulin Intravenous (Human).	Not applicabledo	1 year.
4. Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine).do	Not applicable	2 years.
5. Pertussis Immune Globulin (Human).	3 yearsdo	3 years from date the dried or frozen bulk product is placed in final solution.
6. Rabies Immune Globulin (Human)	1 yeardo	1 year.
7. Rh ₀ (D) Immune Globulin (Human)	6 monthsdo	6 months.
8. Tetanus Immune Globulin (Human)	1 yeardo	3 years with an initial 10 percent excess of potency.
9. Vaccinia Immune Globulin (Human)	3 yearsdo	3 years.
10. Varicella-Zoster Immune Globulin (Human).	Not applicabledo	1 year.
Hepatitis B Vaccine	2 years at 2 to 8 °C.	Not applicable	3 years.

A Product	B Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	C Manufacturer's storage period 0 °C or colder (unless otherwise stated)	D Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
Influenza Virus Vaccine	1 yeardo	18 months.
Limulus Amebocyte Lysate	Not applicable	Not applicable	18 months (from date of manufacture).
Measles, Mumps, and Rubella Virus Vaccine Live.do	1 year (–20 °C or colder).	1 year.
Measles and Mumps Virus Vaccine Livedodo	1 year.
Measles and Rubella Virus Vaccine Livedodo	Do.
Measles Live and Smallpox Vaccine	Not applicabledo	1 year (from date of manufacture).
Measles Virus Vaccine Livedodo	1 year.
Meningococcal Polysaccharide Vaccine Group A:			
1. Final bulk powderdo	2 years (–20 °C or colder).	Not applicable.
2. Final container	Not applicable	3 years (–20 °C or colder).	2 years.
Meningococcal Polysaccharide Vaccine Group C:			
1. Final bulk powderdo	2 years (–20 °C or colder).	Not applicable.
2. Final containerdo	3 years (–20 °C or colder).	2 years.
Meningococcal Polysaccharide Vaccine Groups A and C combined:			
1. Final bulk powderdo	2 years (–20 °C or colder).	Not applicable.
2. Final containerdo	3 years (–20 °C or colder).	2 years.
Meningococcal Polysaccharide Vaccine Groups A, C, Y, and W135 combined:			
1. Final bulk powerdo	2 years (–20 °C or colder).	Not applicable.
2. Final containerdo	3 years (–20 °C or colder).	2 years.
Mumps Skin Test Antigen	6 months	Not applicable	18 months.
Mumps Virus Vaccine Live	Not applicable	1 year (–20 °C or colder).	1 year.
Normal Horse Serum	1 year	2 years	5 years.
Pertussis Vaccinedo	Not applicable	18 months.
Pertussis Vaccine Adsorbeddodo	Do.
Plague Vaccinedodo	Do.
Plasma products:			
1. Fresh Frozen Plasma	Not applicabledo	1 year from date of collection of source blood (–18 °C or colder).
2. Liquid Plasmadodo	(a) 26 days from date of collection of source blood (between 1 and 6 °C). (b) 40 days from date of collection of source blood only when CPDA–1 solution is used as the anticoagulant (between 1 and 6 °C).
3. Plasmadodo	5 years from date of collection of source blood (–18 °C or colder).
4. Platelet Rich Plasmadodo	72 hours from time of collection of source blood, provided labeling recommends storage (20 to 24 °C or between 1 and 6 °C). 5 days if certain approved containers are used (20 to 24 °C).
5. Source Leukocytesdodo	In lieu of expiration date, the collection date shall appear on the label.
6. Source Plasmadodo	10 years (at the recommended storage temperature stated on the label).
7. Therapeutic Exchange Plasmadodo	10 years.
Plasma Protein Fraction (Human)	1 yeardo	(a) 5 years. (b) 3 years provided labeling recommends storage at room temperature, no warmer than 30 °C.
Platelets	Not applicabledo	72 hours from time of collection of source blood, provided labeling recommends storage at 20 to 24 °C or between 1 and 6 °C. 5 days if certain approved containers are used (20 to 24 °C).

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Pneumococcal Vaccine Polyvalent: 1. Final bulk powderdo	24 months after potency assay (–20 °C or colder).	Not applicable.
2. Final containerdo	Not applicable	2 years (from date of manufacture).
Poliovirus Vaccine Inactivated	1 yeardo	1 year.
Poliovirus Vaccine Live Oral Trivalent: 1. Frozen	Not applicable	1 year (–10 °C or colder).	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquiddo	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus Vaccine Live Oral Type I: 1. Frozendo	1 year (–10 °C or colder).	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquiddo	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus Vaccine Live Oral Type II: 1. Frozendo	1 year (–10 °C or colder).	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquiddo	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus Vaccine Live Oral Type III: 1. Frozendo	1 year (–10 °C or colder).	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquiddo	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Polyvalent bacterial antigens with "No U.S. Standard of Potency" liquid.	1 yeardo	18 months.
Polyvalent bacterial vaccines with "No U.S. Standard of Potency" liquid.dodo	Do.
Rabies Vaccine: 1. Drieddo	2 years	Do.
2. Liquid	3 months	Not applicable	6 months.
Reagent red blood cells	Not applicable	Not applicable	Thirty-five days from earliest date of collection if kept in liquid form (indefinite storage of reagent red blood cell source material at –65 °C or colder).
ACD Red Blood Cellsdodo	(a) 21 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing.
			(b) 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.
CPD Red Blood Cellsdodo	(a) 21 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing.
			(b) 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.

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CPDA–1 Red Blood Cellsdodo	(a) 35 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing. (b) 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.
Red Blood Cells Deglycerolizeddodo	24 hours after removal from storage at –65 °C or colder, provided labeling recommends storage between 1 and 6 °C.
Red Blood Cells Frozendodo	3 years from date of collection of source blood, provided labeling recommends storage at –65 °C or colder.
Rubella and Mumps Virus Vaccine Livedo	1 year (–20 °C or colder).	1 year.
Rubella Virus Vaccine Livedodo	Do.
Skin Test Antigens for Cellular Hypersensitivity.	6 months	Not applicable	Do.
Smallpox Vaccine:	Not applicable	9 months (–10 °C or colder, if product is maintained as glycerinated or equivalent vaccine in bulk or final containers).	3 months, provided labeling recommends storage at 0 °C or colder.
1. Liquid	Not applicable	9 months (–10 °C or colder, if product is maintained as glycerinated or equivalent vaccine in bulk or final containers).	3 months, provided labeling recommends storage at 0 °C or colder.
2. Dried	6 months	Not applicable	18 months.
Streptokinase	Not applicabledo	Do.
Tetanus and Diphtheria Toxoids Adsorbed for Adult Use.	1 yeardo	2 years.
Tetanus Antitoxin:dodo	5 years with an initial 20 percent excess or potency.
1. Liquiddodo	5 years with an initial 10 percent excess or potency.
2. Drieddo	2 years	2 years.
Tetanus Toxoiddo	Not applicable	Do.
Tetanus Toxoid Adsorbeddodo	Do.
Thrombindo	2 year	3 years.
Thrombin Impregnated Pad	Not applicable	Not applicable	1 year, or 6 months at 20 to 24 °C.
Tuberculin:	6 monthsdo	1 year.
1. Purified Protein Derivative, diluted	1 year (not to exceed 30 °C; do not refrigerate).do	2 years, provided labeling recommends storage at a temperature not to exceed 30 °C. Do not refrigerate.
2. Old or Purified Protein Derivative dried on multiple puncture device.	1 yeardo	Do.
3. Old on multiple puncture device	1 yeardo	18 months.
Typhoid Vaccine	Not applicabledo	21 days from date of collection, provided labeling recommends storage between 1 and 6 °C.
ACD Whole Blooddodo	Do.
CPD Whole Blooddodo	Do.
CPDA–1 Whole Blooddodo	35 days from date of collection, provided labeling recommends storage between 1 and 6 °C.
Heparin Whole Blooddodo	48 hours from date of collection, provided labeling recommends storage between 1 and 6 °C.
Yellow Fever Vaccinedo	1 year (–20 °C or colder).	1 year, provided labeling recommends storage at 5 °C or colder.

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

[50 FR 4134, Jan. 29, 1985, as amended at 51 FR 15607, Apr. 25, 1986; 51 FR 19750, June 2, 1986; 52 FR 37450, Oct. 7, 1987; 53 FR 12764, Apr. 19, 1988; 62 FR 15110, Mar. 31, 1997; 64 FR 56453, Oct. 20, 1999]

Subpart G—Labeling Standards

§ 610.60 Container label.

(a) *Full label.* The following items shall appear on the label affixed to each container of a product capable of bearing a full label:

- (1) The proper name of the product;
- (2) The name, address, and license number of manufacturer;
- (3) The lot number or other lot identification;
- (4) The expiration date;
- (5) The recommended individual dose, for multiple dose containers.
- (6) The statement: “‘Rx only’” for prescription biologicals.
- (7) If a Medication Guide is required under part 208 of this chapter, the statement required under § 208.24(d) of this chapter instructing the authorized dispenser to provide a Medication Guide to each patient to whom the drug is dispensed and stating how the Medication Guide is provided, except where the container label is too small, the required statement may be placed on the package label.

(b) *Package label information.* If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.

(c) *Partial label.* If the container is capable of bearing only a partial label, the container shall show as a minimum the name (expressed either as the proper or common name), the lot number or other lot identification and the name of the manufacturer; in addition, for multiple dose containers, the recommended individual dose. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.

(d) *No container label.* If the container is incapable of bearing any label, the

items required for a container label may be omitted, provided the container is placed in a package which bears all the items required for a package label.

(e) *Visual inspection.* When the label has been affixed to the container a sufficient area of the container shall remain uncovered for its full length or circumference to permit inspection of the contents.

[38 FR 32056, Nov. 20, 1973, as amended at 47 FR 22518, May 25, 1982; 63 FR 66400, Dec. 1, 1998; 67 FR 4907, Feb. 1, 2002]

§ 610.61 Package label.

The following items shall appear on the label affixed to each package containing a product:

- (a) The proper name of the product;
- (b) The name, address, and license number of manufacturer;
- (c) The lot number or other lot identification;
- (d) The expiration date;
- (e) The preservative used and its concentration, or if no preservative is used and the absence of a preservative is a safety factor, the words “no preservative”;
- (f) The number of containers, if more than one;
- (g) The amount of product in the container expressed as (1) the number of doses, (2) volume, (3) units of potency, (4) weight, (5) equivalent volume (for dried product to be reconstituted), or (6) such combination of the foregoing as needed for an accurate description of the contents, whichever is applicable;
- (h) The recommended storage temperature;
- (i) The words “Shake Well”, “Do not Freeze” or the equivalent, as well as other instructions, when indicated by the character of the product;
- (j) The recommended individual dose if the enclosed container(s) is a multiple-dose container;
- (k) The route of administration recommended, or reference to such directions in an enclosed circular;
- (l) Known sensitizing substances, or reference to an enclosed circular containing appropriate information;
- (m) The type and calculated amount of antibiotics added during manufacture;