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you must establish, maintain, and follow an appropriate system for the following actions:

(1) You must quarantine all previously collected in-date blood and blood components identified under paragraph (a)(1) of this section, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures, when notified by the collecting establishment.

(2) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components, consistent with the results of the supplemental (additional, more specific) test performed under paragraph (a)(2) of this section, or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA.

(3) When the supplemental (additional, more specific) test for HCV is positive or when the screening test is reactive and there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA, you must notify transfusion recipients of previous collections of blood and blood components at increased risk of transmitting HCV infection, or the recipient's physician of record, of the need for recipient HCV testing and counseling. You must notify the recipient's physician of record or a legal representative or relative if the recipient is a minor, adjudged incompetent by a State court, or if the recipient is competent but State law permits a legal representative or relative to receive information on behalf of the recipient. You must make reasonable attempts to perform the notification within 12 weeks after receiving the supplemental (additional, more specific) test results for evidence of HCV infection from the collecting establishment, or after receiving the donor's reactive screening test result for HCV if there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA.

(c) Actions under this section do not constitute a recall as defined in §7.3 of this chapter.

[72 FR 48799, Aug. 24, 2007]

§610.48 Hepatitis C virus (HCV) "lookback" requirements based on review of historical testing records.

(a) Establishments that collect Whole Blood or blood components, including Source Plasma and Source Leukocytes, must complete the following actions by February 19, 2009.

(b) If you are an establishment that collects Whole Blood or blood components, including Source Plasma and Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions:

(1) You must:

(i) Review all records of donor testing for hepatitis C virus (HCV) performed before February 20, 2008. The review must include records dating back indefinitely for computerized electronic records, and to January 1, 1988, for all other records. Record review, quarantine, testing, notification, and disposition performed before February 20, 2008 that otherwise satisfy the requirements under §610.47, are exempt from this section.

(ii) Identify donors who tested reactive for evidence of HCV infection. Donors who tested reactive by a screening test and negative by an appropriate supplemental (additional, more specific) test under §610.40(e) for evidence of HCV infection on the same donation are not subject to further action.

(iii) Identify the blood and blood components previously collected from such donors:

(A) Twelve months and less before the donor's most recent nonreactive screening tests, or

(B) Twelve months and less before the donor's reactive direct viral detection test, e.g., nucleic acid test and nonreactive antibody screening test, whichever is the lesser period.

(2) If you did not perform a supplemental (additional, more specific) test at the time of the reactive donation, you may perform a supplemental test or a licensed screening test with known greater sensitivity than the test of record using either a frozen sample from the same reactive donation or a

fresh sample from the same donor, if obtainable. If neither is available, proceed with paragraphs (b)(3), (b)(4), and (b)(5) of this section.

(3) You must, within 3 calendar days after identifying the blood and blood components previously collected from donors who tested reactive for evidence of HCV infection:

(i) Quarantine all previously collected in-date blood and blood components identified under paragraph (b)(1)(iii) of this section if intended for use in another person or for further manufacture into injectable products, except pooled components solely intended for further manufacturing into products that are manufactured using validated viral clearance procedures.

(ii) Notify consignees to quarantine all previously collected in-date blood and blood components identified under paragraph (b)(1)(iii) of this section if intended for use in another person or for further manufacture into injectable products, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures; and

(iii) Notify consignees of the donor's test results, including the results of a supplemental (additional, more specific) test or a licensed screening test with known greater sensitivity than the test of record, if available at that time.

(4) You must notify consignees of the results of the supplemental (additional, more specific) test or the licensed screening test with known greater sensitivity than the test of record for HCV, if performed, within 45 calendar days of completing the further testing. Notification of consignees must include the test results for blood and blood components identified under paragraph (b)(1)(iii) of this section that were previously collected from a donor who later tests reactive for evidence of HCV infection.

(5) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components consistent with the results of the further testing performed under paragraph (b)(2) of this section or the results of the reactive screening test if there is no available supplemental test

that is approved for such use by FDA, or if under an investigational new drug application (IND) or investigational device exemption (IDE), is exempted for such use by FDA.

(c) If you are a consignee of Whole Blood or blood components, including Source Plasma and Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions, which you must complete within 1 year of the date of notification by the collecting establishment:

(1) You must quarantine all previously collected in-date blood and blood components identified under paragraph (b)(1)(iii) of this section, except pooled blood components solely intended for further manufacturing into products that are manufactured using validated viral clearance procedures, when notified by the collecting establishment.

(2) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components, consistent with the results of the further testing performed under paragraph (b)(2) of this section, or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE is exempted for such use by FDA.

(3) When the supplemental (additional, more specific) test for HCV is positive; or the supplemental test is indeterminate, but the supplemental test is known to be less sensitive than the screening test; or the screening test is reactive and there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA; or if supplemental testing is not performed, you must make reasonable attempts to notify transfusion recipients of previous collections of blood and blood components at increased risk of transmitting HCV infection, or the recipient's physician of record, of the need for recipient HCV testing and counseling. You must notify the recipient's physician of record or a legal representative or relative if the recipient is a minor, adjudged incompetent by a State court, or if the recipient is competent but State law permits a legal

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representative or relative to receive information on behalf of the recipient.

(d) Actions under this section do not constitute a recall as defined in § 7.3 of this chapter.

(e) This section will expire on August 24, 2015.

[72 FR 48800, Aug. 24, 2007]

Subpart F—Dating Period Limitations

§ 610.50 Date of manufacture.

The date of manufacture shall be determined as follows:

(a) For products for which an official standard of potency is prescribed in either § 610.20 or § 610.21, or which are subject to official potency tests, the date of initiation by the manufacturer of the last valid potency test.

(b) For products that are not subject to official potency tests, (1) the date of removal from animals, (2) the date of extraction, (3) the date of solution, (4) the date of cessation of growth, or (5) the date of final sterile filtration of a bulk solution, whichever is applicable.

[38 FR 32056, Nov. 20, 1973, as amended at 42 FR 27582, May 31, 1977]

§ 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 be-

yond 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.