4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606 and 610

[Docket No. FDA-1999-N-0114 (formerly 1999N-2337)]

RIN 0910-AB76

Hepatitis C Virus "Lookback" Requirements Based on Review of Historical Testing Records; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by removing the Hepatitis C Virus (HCV) "lookback" requirements regarding review of historical testing records. FDA is taking this action because the HCV "lookback" regulations based on review of historical testing records expired on August 24, 2015, due to the sunset provision provided under the regulation.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Gretchen Opper, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 24, 2007 (72 FR 48766), FDA published a final rule entitled "Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and

Blood Components at Increased Risk of Transmitting Hepatitis C Virus Infection ('Lookback')." Under § 610.48 (21 CFR 610.48) of the final rule, FDA established HCV "lookback" requirements based on review of historical testing records. The requirements under § 610.48 were to remain in effect for 8 years after the date of publication of the final rule in the Federal Register (§ 610.48(e)). Section 610.48(e) specifically provides that the section expired on August 24, 2015; therefore, FDA is removing this regulation from Title 21 of the Code of Federal Regulations.

FDA is also making conforming changes to other biologics regulations where § 610.48 is referenced.

FDA is revising the biologics regulations as follows:

- Removing and reserving § 610.48.
- Revising § 606.100(b)(19) (21 CFR 606.100(b)(19)) by removing the reference to § 610.48.
- Revising § 606.160(b)(1)(viii) by removing the reference to § 610.48.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comments are unnecessary because the amendments to the regulations provide only technical changes to remove and update information and are nonsubstantive.

List of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, 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, 21 CFR parts 606 and 610 are amended as follows:

PART 606--CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

§ 606.100 [Amended]

2. Amend § 606.100(b)(19) introductory text by removing "§§ 610.46, 610. 47, and 610.48" and adding in its place "§§ 610.46 and 610.47".

§ 606.160 [Amended]

3. Amend § 606.160(b)(1)(viii) by removing "§§ 610.46, 610.47, and, 610.48" and adding in its place "§§ 610.46 and 610.47".

PART 610--GENERAL BIOLOGICAL PRODUCTS STANDARDS

4. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 610.48 [Removed and Reserved]

5. Remove and reserve § 610.48.

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-32477 Filed: 12/24/2015 8:45 am; Publication Date: 12/28/2015]