4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. FDA-2016-N-1170]

Standard Preparations, Limits of Potency, and Dating Period Limitations for Biological Products; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of September 16, 2016, for the final rule that appeared in the Federal Register of May 4, 2016. The direct final rule amends the general biological products standards relating to dating periods and removes certain standards relating to standard preparations and limits of potency. FDA is taking this action to update outdated requirements, and accommodate new and evolving technology and testing capabilities without diminishing public health concerns. This action is part of FDA's retrospective review of its regulations in response to an Executive order. This document confirms the effective date of the direct final rule.

DATES: Effective date of final rule published in the Federal Register of May 4, 2016 (81 FR 26687), confirmed: September 16, 2016.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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 May 4, 2016 (81 FR 26687), FDA solicited comments concerning the direct final rule for a 75-day period ending July 18, 2016. FDA stated that the effective date of the direct final rule would be on September 16, 2016, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: Therefore, under the biological products provisions of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, and 264) and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, and 381), and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended. Accordingly, the amendments issued thereby are effective.

Dated: August 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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