



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA-2017-N-7007]

RIN 0910-AH49

Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published in the *Federal Register* of January 26, 2018, a direct final rule to amend the general biologics regulations relating to time of inspection requirements and to also remove duties of inspector requirements. The comment period closed April 11, 2018. FDA is withdrawing the direct final rule because the Agency received significant adverse comment.

DATES: The direct final rule published at January 26, 2018 (83 FR 3586), is withdrawn effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Melissa Segal, 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: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on January 26, 2018 (83 FR 3586) is withdrawn.

Dated: May 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-09589 Filed: 5/4/2018 8:45 am; Publication Date: 5/7/2018]