4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA-2013-N-0011]

Change of Address; Biologics License Applications; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to update the address for applicants to submit biologics license applications (BLAs) and BLA amendments and supplements regulated by the Center for Drug Evaluation and Research (CDER). This action is being taken to ensure accuracy and clarity in the Agency's regulations.

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA is amending 21 CFR 600.2(b) to update the address for applicants to submit BLAs and BLA amendments and supplements regulated by CDER. The new address for all these submissions is CDER Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901B Ammendale Rd., Beltsville, MD 20705. This action is being taken to ensure accuracy and clarity in the Agency's regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update an address for the submission of BLAs and BLA amendments and supplements.

List of Subjects for 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 600 is amended as follows:

Part 600--BIOLOGICAL PRODUCTS: GENERAL

1. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa-25.

§ 600.2 [Amended]

2. Section 600.2 is amended in the first sentence of paragraph (b) by removing "CDER Therapeutic Biological Products Document Room" and adding in its place "CDER Central

Document Room", and by removing "12229 Wilkins Ave., Rockville, MD 20852" and adding in its place "5901B Ammendale Rd., Beltsville, MD 20705".

Dated: March 27, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

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