4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0225]

Announcement of Center for Biologics Evaluation and Research's Move to the Food and Drug Administration's White Oak Campus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Center for Biologics Evaluation and Research (CBER) will be moving its offices and laboratories from various Rockville and Bethesda, MD, locations to the FDA White Oak campus in Silver Spring, MD. The move will commence on or about May 1, 2014, and will end approximately 8 weeks later, on or about July 1, 2014. During this time persons may continue to send applications and other submissions electronically via the FDA Electronic Submissions Gateway to CBER for review, evaluation, or other handling. However, persons should send submissions on paper or on electronic media (CD, DVD), as well as lot release samples to CBER's new mailing addresses once they take effect. CBER's new mailing addresses, including the dates they take effect, as well as other information concerning CBER's move to the FDA White Oak campus in Silver Spring, MD, will be provided on the FDA Web site at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm, as they become available. During the period required for relocation of files, equipment, and Agency personnel, CBER will make every effort to meet its review time frames

and minimize any potential delay. Should delays affecting receipt and review of applications and other submissions occur, we intend to update the FDA Web site as needed.

FOR FURTHER INFORMATION CONTACT: John Reilly, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.) and section 351 of the Public Health Service Act (42 U.S.C. 262), CBER is responsible for receiving, reviewing, evaluating, and taking appropriate actions on a variety of regulated activities, including but not limited to:

(1) Investigational new drug applications and investigational device exemption applications for certain products for which CBER has been assigned responsibility;

(2) Biologics license applications submitted for biological products;

(3) New drug applications, abbreviated new drug applications, premarket approval applications, and premarket notifications for which CBER has been assigned responsibility; and

(4) Protocols and samples submitted for official release (lot release).

In an effort to consolidate, FDA is moving CBER's offices and laboratories from various Rockville and Bethesda, MD, locations to the FDA White Oak campus in Silver Spring, MD. The move will commence on or about May 1, 2014, and will end approximately 8 weeks later, on or about July 1, 2014. During this time, persons may continue to send applications and other submissions electronically via the FDA Electronic Submissions Gateway to CBER for review, evaluation, or other handling. However, persons should send submissions on paper or on

electronic media (CD, DVD) (including lot release protocols) to CBER's new mailing addresses once they take effect. CBER's new mailing addresses, including the dates they take effect, as well as other information concerning CBER's move to the FDA White Oak campus in Silver Spring, MD, will be provided on the FDA Web site at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm as they become available.

Lot release samples should be sent to the appropriate new mailing address when it takes effect. Please note, however, that because of the relocation of CBER's Sample Custodian (the person(s) responsible for receiving official samples, including lot release samples) to the FDA White Oak campus, CBER will not be able to receive lot release samples during the 2 weeks surrounding this personnel move. This pause will allow us to assure the orderly transfer of lot release samples to the FDA White Oak campus in the weeks immediately before and after this move. Therefore, lot release samples should be shipped to CBER either (1) before the pause, using the current address, or (2) after the pause, using the new address once it takes effect. See the FDA Web site at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm for the dates of this pause. We also plan to communicate directly with those manufacturers affected by this temporary interruption in CBER's receipt of lot release samples.

During the period required for relocation of files, equipment, and Agency personnel, CBER will make every effort to meet its review time frames and minimize any potential delay. Should delays affecting receipt and review of applications and other submissions occur, we intend to update the FDA Web site as needed.

II. Comments

Persons who have questions or wish further information concerning CBER's move to the FDA White Oak campus in Silver Spring, MD, may access the FDA Web site at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm for more information. CBER intends to update this Web site periodically.

Dated: February 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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