DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

2014 Medical Countermeasures Initiative Regulatory Science Symposium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: 2014 Medical Countermeasures initiative (MCMi) Regulatory Science Symposium. The symposium is intended to provide a forum for the exchange of scientific ideas for medical countermeasure development and evaluation, communicate progress on regulatory science efforts related to the development and advancement of medical countermeasures, facilitate innovative directions, and inform stakeholders on medical countermeasure-related scientific progress and accomplishments.

Date and Time: This symposium will be held on June 2 and 3, 2014, from 8 a.m. to 5 p.m. Persons interested in attending the symposium in person or viewing via Web cast must register by May 23, 2014, at 5 p.m. EST.

Location: The symposium will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact: Rakesh Raghuwanshi, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4283, 301–796–4769, FAX: 301–847–8615, email: *AskMCMi@fda.hhs.gov.*

Registration: If you wish to attend the symposium or view via Web cast, you must register at *http://www.fda.gov/medicalcountermeasures* by May 23, 2014, at 5 p.m. EST. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), and (4) email address.

There is no fee to register for the symposium and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. If you need special accommodations due to a disability, please enter pertinent information in the ''Notes'' section of the electronic registration form when you register.

Dated: February 11, 2014.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2014–03358 Filed 2–14–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0006]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Food and Drug Administration Modernization Act of 1997 (FDAMA), the Food and Drug Administration (FDA) is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct.

FOR FURTHER INFORMATION CONTACT: Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Food and Drug Administration Modernization Act

Section 130(a) of FDAMA (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new provision requiring reports of certain postmarketing studies, including clinical trials, for human drug and biological products (section 506B of the FD&C Act (21 U.S.C. 356b)). Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of a postmarketing study or clinical trial that an applicant has been required to, or has agreed to, conduct by requiring the applicant to submit a report annually providing information on the status of the postmarketing study/clinical trial. This report must also include reasons, if any, for failure to complete the study/clinical trial. These studies and clinical trials are intended to further define the safety, efficacy, or optimal use of a product, and therefore play a vital role in fully characterizing the product.

Under FDAMA, commitments to conduct postmarketing studies or clinical trials included both studies/clinical trials that applicants agreed to conduct, as well as studies/clinical trials that applicants were required to conduct under FDA regulations.[1]

B. The Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the President signed Public Law 110–85, the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 901, in Title IX of FDAAA, created a new section 505(*o*) of the FD&C Act authorizing FDA to require certain studies and clinical trials for human drug and biological products approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act (42 U.S.C. 262). Under FDAAA, FDA has been given additional authority to require applicants to conduct and report on postmarketing studies and clinical trials to assess a known serious risk, assess signals of serious risk, or identify an unexpected serious risk related to the use of a product. This new authority became effective on March 25, 2008. FDA may now take enforcement action against applicants who fail to conduct studies and clinical trials required under FDAAA, as well as studies and clinical trials required under FDA regulations (see sections 505(*o*)(1), 502(z), and 303(f)(4) of the FD&C Act (21 U.S.C. 355(*o*)(1), 352(z), and 333(f)(4))).

Although regulations implementing FDAMA postmarketing authorities use

[1] Before passage of FDAAA, FDA could require postmarketing studies and clinical trials under the following circumstances: To verify and describe clinical benefit for a human drug approved in accordance with the accelerated approval provisions in section 506(b)(2)(A) of the FD&C Act (21 CFR 314.510 and 601.41); for a drug approved on the basis of animal efficacy data because human efficacy trials are not ethical or feasible (21 CFR 314.610(b)(1) and 601.91(b)(1)); and for marketed drugs that are not adequately labeled for children under section 505B of the FD&C Act (Pediatric Research Equity Act; Pub. L. 108–155).