FDA is announcing the availability of a document entitled “Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products” dated January 2011. The guidance document provides manufacturers of cellular and gene therapy products with recommendations for developing tests to measure potency. The recommendations are intended to clarify the potency information that could support an investigational new drug application (IND) or a biologics license application (BLA). Because potency measurements are designed specifically for a particular product, the guidance does not make recommendations regarding specific types of potency assays, nor does it propose acceptance criteria for product release.

In the Federal Register of October 9, 2008 (73 FR 59635), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes the addition of text related to adjuvant testing and modification of assay parameters for validation studies. In addition, editorial and formatting changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2008.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under 0910–0139; the collections of information in 21 CFR part 314 have been approved under 0910–0014; the collections of information in 21 CFR part 601 has been approved under 0910–0338.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.
I. Background

An important part of CDER’s commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry’s drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA’s Office of Regulatory Affairs District Offices in the firms’ respective regions. Firms interested in offering a site tour or learning more about this training opportunity should respond by submitting a proposed agenda to Beth Duvall-Miller (see DATES and FOR FURTHER INFORMATION CONTACT).

Dated: February 9, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

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