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In the Federal Register of October 9, 2008 (73 FR 59635), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized.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 The guidance announced in this notice finalizes the draft guidance dated October 2008.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 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.


Leslie Kux,  
Acting Assistant Commissioner for Policy.

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