I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Assay Development for Immunogenicity Testing of Therapeutic Proteins.” This guidance was created by a working group that consisted of staff from the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Because clinicians rely on the observed immunogenicity rates listed in the “Immunogenicity” section of drug labeling, development of validated, sensitive immune assays is critical to patient care. This guidance discusses immunogenicity testing during drug product development and provides recommendations on assay development, clinical aspects of assay validation, assay validation, assay testing implementation, and other aspects of immunogenicity testing.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on the development of immune assays for assessment of the immunogenicity of therapeutic proteins during clinical trials. 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. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.