



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0103]

Analytical Procedures and Methods Validation for Drugs and Biologics; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Analytical Procedures and Methods Validation for Drugs and Biologics." This guidance supersedes the draft of the same name that published on February 19, 2014, and replaces the 2000 draft guidance for industry on "Analytical Procedures and Methods Validation" and the 1987 FDA guidance for industry on "Submitting Samples and Analytical Data for Methods Validation." This guidance discusses how to submit analytical procedures and methods validation data to support the documentation of the identity, strength, quality, purity, and potency of drug substances and drug products.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4<sup>th</sup> Floor, Silver Spring, MD 20993, or to the Office of Communication, Outreach and Development, Center for

Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lucinda Buhse, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2130, Silver Spring, MD 20993-0002, 240-402-4595, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is announcing the availability of a guidance for industry entitled "Analytical Procedures and Methods Validation for Drugs and Biologics." This guidance supersedes the draft of the same name that published on February 19, 2014, and replaces the 2000 draft guidance for industry on "Analytical Procedures and Methods Validation" and the 1987 FDA guidance for industry on "Submitting Samples and Analytical Data for Methods Validation." It discusses how to submit analytical procedures and methods validation data to support the documentation of the identity, strength, quality, purity, and potency of drug substances and drug products, and how to assemble information and present data to support analytical methodologies.

The recommendations in this guidance apply to new drug applications, abbreviated new drug applications, biologics license applications, and supplements to these applications. The principles in this guidance also apply to Type II drug master files. This guidance does not address investigational new drug application (IND) methods validation specifically, but the principles being discussed may be helpful to sponsors preparing INDs.

This guidance complements the International Conference on Harmonisation guidance "Q2(R1) Validation of Analytical Procedures: Text and Methodology."

In the Federal Register of February 19, 2014 (79 FR 9467), this guidance was published as a draft guidance. We have carefully reviewed and considered the comments that were received on the draft guidance and have made changes for clarification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on analytical procedures and methods validation. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 211, 21 CFR part 314, and 21 CFR part 601 have been approved under OMB control numbers 0910-0139, 0910-0001, and 0910-0338.

### III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

### IV. Electronic Access

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

Dated: July 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.