**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
[Docket No. FDA–2014–N–0987]  

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications  

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; Guidance for Industry; Availability.” This guidance replaces the draft of the same name that published on February 19, 2014, and replaces the 2000 draft guidance for industry on “Analytical Procedures and Methods Validation” and the 1987 FDA guidance for industry on “Submitting Samples and Analytical Data for Methods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 guidelines at any time.  

**SUPPLEMENTARY INFORMATION**

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Leroy A. Richardson,  
Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–18301 Filed 7–24–15; 8:45 am]  
BILLING CODE 4163–18–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 This guidance replaces the 2000 draft guidance for industry on the same name that published on February 19, 2014, and replaces the 1987 FDA guidance for industry on “Submitting Samples and Analytical Data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 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., 4th 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