ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
International Panel Physicians (All sites).	TB Indicators Excel Spreadsheet.	353	1	7.5	2,648
TOTAL					2,648

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–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 that a collection of information entitled, ''Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 10, 2014, the Agency submitted a proposed collection of information entitled, ''Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0796. The approval expires on June 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18295 Filed 7–24–15; 8:45 am]

BILLING CODE 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., 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

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/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: July 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18270 Filed 7–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 80 FR 37639–37640 dated July 1, 2015).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (RM). Specifically, this notice: (1) Establishes the Office of Policy and Planning (RMA); (2) transfers the current Office of Policy Coordination (RM10) function to the newly established Office of Policy and Planning (RMA); and (3) abolishes the Office of Policy and Coordination (RM10).

Chapter RM—Maternal and Child Health Bureau

Section RM—00, Mission

To provide national leadership, in partnership with key stakeholders, to improve the physical and mental health, safety and well-being of the maternal and child health (MCH) population which includes all of the nation's women, infants, children, adolescents, and their families, including fathers and children with special health care needs.

Section RM–10, Organization

Delete the organization for the Maternal and Child Health Bureau (RM) in its entirety and replace with the following:

The Maternal and Child Health Bureau (RM) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The Maternal and Child Health Bureau includes the following components:

(1) Office of the Associate Administrator (RM);

(2) Office of Operations and Management (RM1);

(3) Office of Policy and Planning (RMA);

(4) Division of Services for Children with Special Health Needs (RM2);

(5) Division of Child, Adolescent and Family Health (RM3);

(6) Division of MCH Workforce Development (RM4);

(7) Division of Healthy Start and Perinatal Services (RM5);

(8) Division of State and Community Health (RM6);

(9) Division of Home Visiting and Early Childhood Systems (RM8); and

(10) Office of Epidemiology and Research (RM9).

Section RM–20, Functions

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (RM). Specifically, this notice: (1) Establishes the Office of Policy and Planning (RMA); (2) transfers the Office of Policy Coordination (RM10) function to the newly established Office of Policy and Planning (RMA); and (3) abolishes the Office of Policy and Coordination (RM10).

Delete the function for the Office of Policy Coordination (RM10), and replace in its entirety.

Office of Policy and Planning (RMA)

The Office of Policy and Planning (OPP) serves as the Maternal and Child Health Bureau (MCHB) focal point for the development of MCHB policy and program planning. Specifically, the Office: (1) Supports the Office of the Associate Administrator in identifying, planning, and implementing policy and program priorities across MCHB; (2) works closely with the Office of the Associate Administrator to develop strategic plans, facilitate program alignment, and support special initiatives; (3) advises and assists in the development, coordination and management of program and policy documents, and responses to departmental and HRSA initiatives; and (4) coordinates with other components within HRSA and HHS, federal agencies, state and local governments, and other public and private organizations on issues affecting MCHB programs and policies.