SMG 3270.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

INFORMATION RESOURCES MANAGEMENT

PAPERWORK REDUCTION ACT/OMB CLEARANCE

OBTAINING OMB CLEARANCE FOR COLLECTIONS OF INFORMATION AS REQUIRED BY THE PAPERWORK REDUCTION ACT (PRA) OF 1995

Effective Date: April 12, 2018

1. PURPOSE

This guide identifies policies, procedures and responsibilities for the Food and Drug Administration (FDA) as required by the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), OMB, HHS and internal FDA policies when seeking OMB approval for collecting information from the public.

2. POLICY

The PRA establishes and defines policies and procedures for controlling paperwork burden imposed on the public by Federal agencies. The regulations located at 5 CFR Part 1320, “Controlling Paperwork Burdens on the Public; Regulatory Changes Reflecting Recodification of the Paperwork Reduction Act,” implement the information collection review and approval provisions as prescribed by the Act—its purpose being, “. . . to reduce, minimize and control burdens and maximize the practical utility and public benefit of the information created, collected, disclosed, maintained, used, shared and disseminated by or for the Federal government.” (5 CFR 1320.1)

Section 1320.3 defines the Agency as any executive department, meaning it applies to HHS, as a whole, and not separately as each Operating Division. According to 5 CFR 1320.7 each Agency Head is to designate a Senior Official responsible for

carrying out the responsibilities of the PRA. The hierarchy, then, for PRA oversight from the Department to FDA is as follows:

- The Senior Official at HHS is identified as the Assistant Secretary for Administration
    - HHS Chief Information Officer
        - FDA PRA Staff

The FDA PRA staff acts as the liaison between FDA program offices, HHS, OMB and the public on all PRA-related matters, facilitating all communications seeking to fulfill the management goals of the PRA which include:

A. reduce information collection burdens on the public;
B. increase program efficiency and effectiveness;
C. improve the quality, integrity and utility of information.

All requests for OMB approval of information collections must adhere to and follow clearance procedures set forth in the Act, OMB's regulations implementing the PRA, as well as guidance and standard practices provided by FDA's PRA staff, Office of the Chief Counsel , Office of Policy, HHS and OMB. They include, but are not limited to:

A. The Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520)

B. Controlling Paperwork Burdens on the Public (5 CFR 1320)

C. Standard Operating Procedures: Paperwork Reduction Act Statements for Guidances

D. PRA Training as provided by the FDA PRA Staff, HHS and OMB.

3. RESPONSIBILITIES

A. FDA PRA Staff

The Director of the FDA PRA staff acts as the agency's Reports Clearance Officer (RCO). The RCO delegates to FDA PRA desk officers the responsibility of facilitating the OMB review and approval process for center information collections. FDA's PRA desk officers work directly with center points of contact, HHS and OMB and the public.

The PRA staff strives to:

1. Manage and promote effective and efficient procedures by which FDA can obtain an OMB approval for an information collection.

2. Ensure compliance with the PRA while meeting the agency's information collection needs.

3. Provide training and expert advice to those needing to navigate the PRA approval process.

4. Facilitates communication between FDA centers, HHS and OMB, including negotiating special procedures for unique circumstances.

Duties of the desk officers may include, but are not limited to:

1. Maintain records and inventories of FDA's information collection activities.

2. Review and provide training, technical support and guidance to centers and program experts on PRA issues.

3. Review and ensure that all proposed rules, regulations, guidance documents, and studies meet the procedural standards for review and approval by OMB according to aforementioned resources.

4. Review and/or prepare the following notices for publication in the Federal Register:

   - 60-day notice requesting comments on the proposed information collection;

   - 30-day notice requesting comments and announcing that the information collection request (ICR) for review and approval is being submitted to OMB for review;

   - Approval notice announcing that OMB has approved the ICR, the assigned OMB number and expiration date.

B. Centers/Offices:

Assistant Reports Clearance Officers (ARCO). Each center/office has designated an ARCO and an alternate to carry out their PRA control functions. Centers may designate more than one ARCO, each having authority to clear and sign off on a document for the center. ARCOs function as the liaison between their various program offices and centers and the FDA PRA Staff. Their duties may include but are not limited to:

1. Provide technical support and guidance and assist program experts in understanding the requirements of the PRA.

2. Identify information collection.

3. Draft and/or review required procedural documents prior to submitting to PRA desk officer ensuring that the current templates are used and documents are complete.

4. Maintain records and inventories of their center's ICRs.

5. Assist in completing the ICB data call.

C. Program Office. The program office or program expert prepares the burden estimates, drafts and/or reviews the 60-day notice, prepares responses to comments received on the information collection, and drafts and/or reviews the supporting statement.

D. Office of Chief Counsel (OCC). OCC may advise center and program experts on the legal implications of the PRA. OCC may review notices and responses to comments if requested by the center or if the comments are considered to be controversial.

E. Regulations Policy and Management Staff (RPMS) and Regulations Editorial Staff (RES). The RPMS desk officers and RES editors review and ensure that all documents to be published in the Federal Register meet the OFR's standards for publication.

4. PROCESS

Information collection may be contained in a variety of documents such as rulemakings, guidance documents, studies, surveys, contracts, forms or new programs.

A. Center/Program office identifies information collection and drafts the PRA analysis and other required procedural documents. Some of the specific duties performed by center points of contact may include:

1. Identify the information collection.

2. Draft the PRA analysis (including estimating the annual burden) for publication in the Federal Register (in the form of a 60-day notice, NOA, or a rulemaking.)

3. Submit to FDA PRA desk officer for review.

4. Respond to PRA related comments received to Federal Register notices.

5. Draft the supporting statement.

6. Participate in any conference calls with HHS or OMB as needed for clarity of the information collection request.

7. Draft responses to comments received from the public on the information collection.

8. Work with FDA forms officer to obtain FDA form number for new forms and coordinate revisions to existing forms.

9. Check FDMS for comments received to 60-day notices.

10. Provide all related documents, e.g., guidance document, form, survey, focus group script.

11. Meet deadlines for documents due set by the PRA desk officer.

B. FDA PRA Staff. Reviews ICR and prepares and submits it in ROCIS through HHS to OMB for review and approval.

1. Provide guidance on the PRA to center and program experts.

2. Notify centers one year in advance of OMB expiration for existing approvals. Center Executive Officers are copied on this notification.

3. Review and approve PRA analysis in 60-day notice, emergency notice, NOA, PRA section in rules.

4. Send 60-day, 30-day and approval notices to RES for editing and publishing.

5. Check FDMS for comments received to 60-day notices.

6. Check with OMB to find out if comments were received on proposed rules.

7. Review the supporting statement and all other documents provided by the program in connection with the information collection.

8. Create ICR in ROCIS.

9. Send ICR to HHS for transmission to OMB.

10. Coordinate and participate in all discussions with HHS and OMB on PRA-related matters.

11. Set deadlines for documents due for center/program office.

5. DOCUMENTS

Information collection may be found in a variety of documents. These documents are sent by the center to the PRA desk officer as part of the OMB review and approval process. These documents may include:

A. Rulemakings
B. Guidance documents and accompanying Notices of Availability
C. Federal Register notices
D. Generic information collections
E. Forms
F. Study Protocols
G. Contracts
H. Supporting Statements

6. DOCUMENT REVIEW TIMES

OCC, RPMS and other offices within FDA that may review PRA-related documents have their own established timelines for completing PRA reviews. Those timelines are not included in this document. On occasion, special circumstances arise that may not allow for these timelines. Please coordinate with your FDA PRA desk officer and the Director of the PRA Staff when expedited review is necessary because of an unforeseen circumstance.

Under normal circumstances, once a document has been received at the PRA Staff the PRA desk officer will either “passback” or conclude review according to the following schedule:

A. Routine Documents: SEVEN business days.

B. Emergency Documents that are directly related to the emergency process of OMB approval defined at 5 CFR 1320.13: TWO business days.

C. Generic clearances: THREE business days.

D. Priority or rush documents: THREE business days.

7. SYSTEMS

There are various systems that the PRA Staff is required to use when facilitating the PRA review and approval process for information collections. Centers may also be required to use some of these systems. They include:

A. FDMS (user account required)
B. FRDTS (user account required)

C. Reginfo.gov (public website)
D. ROCIS (PRA Staff use only)

8. EFFECTIVE DATE

The effective date of this guide is April 12, 2018.

9. Document History – SMG 3270.1, Obtaining OMB Clearance for Collections of Information as Required by the Paperwork Reductions Act (PRA) of 1995

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/2005	N/a	PRA and Records Management Branch (HFA-250)	Mark Pincus, PRARMB Chief
Revision	12/14/2011	N/a	OMB/DCIOS/MB	Elizabeth Berbakos, MB Chief
Revision	04/11/2018	N/a	OIMT/RERM/PRA	JonnaLynn Capezzuto, Director, Paperwork Reduction Act Staff

Back to General Administration, Volume III (2000 - 3999)