**TESTIMONY**

**OF**

**TODD SIMPSON**

**CHIEF INFORMATION OFFICER**

**FOOD AND DRUG ADMINISTRATION**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE**

**COMMITTEE ON SMALL BUSINESS**

**U.S. HOUSE OF REPRESENTATIVES**

**"EVALUATING THE PAPERWORK REDUCTION ACT**

**PART II: ARE BURDENS BEING REDUCED?"**

**OCTOBER 11, 2017**

**RELEASE ONLY UPON DELIVERY**

Chairman Chabot, Ranking Member Velazquez, and members of the committee, thank you for inviting me here today to testify about the Paperwork Reduction Act (PRA). My name is Todd Simpson, and I am the Chief Information Officer for the U.S. Food and Drug Administration (FDA), part of the Department of Health and Human Services (HHS or the Department).

FDA's mission is to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; that human and veterinary drugs are safe and effective; that there is reasonable assurance of the safety and effectiveness of devices intended for human use; that cosmetics are safe and properly labeled; and that public health and safety are protected from electronic product radiation. In addition, FDA promotes the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA balances the need to collect the information necessary to carry out our mission with the desire to minimize the burden on the businesses that feed the nation and develop life-saving medical products.

Background

According to 44 U.S.C. 3506, each Agency head is to designate a Chief Information Officer responsible for carrying out the responsibilities of the PRA. Under 5 CFR 1320.3, defining

"agency" as "any executive department", the agency head for our work is the Secretary of HHS. Accordingly, the hierarchy for PRA oversight from the Department to FDA is as follows:

- The Secretary of HHS
  - HHS Chief Information Officer
    - FDA Chief Information Officer
      - FDA PRA Staff

The FDA PRA staff acts as the liaison among FDA program offices, HHS, the Office of Management and Budget (OMB), and the public on all PRA-related matters, facilitating all communications seeking to fulfill the goals of the PRA.

FDA's current inventory of approved information collections is:

| Number of Approved Collections | Total Burden Hours | Total Responses | Total Cost |
|---|---|---|---|
| 274 | 181,533,621 | 946,776,091 | $3,736,696,238 |

Information Collection Activities

FDA seeks OMB approval for collections of information in any form or format, including those contained in **regulations**, **guidance documents**, **forms**, surveys and studies, focus groups, customer satisfaction surveys and message testing. FDA also seeks OMB approval for extensions of currently-approved collections of information.

FDA has several "generic clearances" in place for conducting focus groups, customer satisfaction surveys, rapid response surveys, and user and message testing. Generic clearances can be used when an agency seeks to conduct a series of collections of information using very similar methods, and generally cover collections of information that are voluntary, low-burden, and uncontroversial. The plan for the series of information collections goes through the normal public notice and comment procedures required by the PRA, but the agency is not required to seek further public comment on the specific information collections it conducts under the generic clearance. Instead, the agency may submit the information collection instrument (e.g., survey or questionnaire) directly to OMB for review and approval, which is typically brief.

*Regulations*

FDA regulations with collections of information may contain substantive regulatory requirements or can be administrative or procedural in nature. When FDA conducts notice-and-comment rulemaking to issue a new regulation, the comment period for the information collection provisions is normally 30 days (usually, a longer period of public comments is open on the substance of the rule). Comments related to the information collection are sent to OMB. At the time of publication, or shortly thereafter, FDA transmits the information collection request (ICR) to HHS, which reviews and certifies the proposed collection. HHS then sends the ICR on to OMB through the Regulatory Information Service Center (RISC) and Office of Information and Regulatory Affairs (OIRA) Combined Information System (ROCIS). OMB usually files comment on the proposed rule and approves any collections of information at the final rule stage.

For ongoing collections of information, such as those in regulations, FDA must go through PRA notice and comment procedures and request an extension of OMB approval every three years. For example, OMB Control Number 0910-0001, "FDA Approval to Market a New Drug," covers the information collection associated with the premarket approval requirements for new drugs and every three years since the initial approval in 1977, FDA has requested an extension of the approval from OMB.

*Guidance*

FDA guidance documents may contain an information collection that is already covered by an OMB approval. In the case of an information collection covered by OMB approval for a regulation, the guidance document would be uploaded in the ROCIS entry for that rulemaking as an "instrument" and would become part of the ICR for the regulation.

FDA also issues "stand-alone" guidance documents that may contain a new information collection requiring approval by OMB. Although FDA guidance documents are generally non-binding, collections of information authorized or mandated by statute are sometimes implemented through guidance, often because the statute directs FDA to issue guidance on how to comply with the statute. Also, FDA may determine it is preferable to issue guidance with recommendations on how to comply with the statute, rather than binding regulations prescribing the means of compliance.

*Forms*

FDA also uses forms as an efficient way to collect standardized information. For example, FDA has forms that healthcare professionals, patients, and consumers use to submit adverse event reports. The data from these reports helps FDA assess and evaluate the risk associated with the product. These forms, from FDA Form series 3500, allow FDA to consider what action may be necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

*Surveys*

FDA may conduct surveys prior to policy decisions or rulemaking in order to understand a target audience, behaviors, needs, and opinions. After a regulation or program is in place, formative research can help to refine and improve activities and communications. An example of a recurring FDA survey is the "Food Safety Survey" (approved under OMB Control Number 0910-0345). The supporting statement indicates that the data generated by this survey is a widely accepted source of information on consumer food handling practices and food safety-related knowledge, and is used to prepare important HHS reports such as Healthy People 2020. Telephone interviews are conducted using a random sample of 4,000 consumers, including at least 400 Hispanic-Americans and at least 400 African-Americans. Data from the survey is used in support of FDA's regulatory policy in diverse areas dealing with food safety and supports consumer education by enabling FDA to track consumer knowledge, attitudes, and practices concerning food safety.

The Center for Drug Evaluation and Research (CDER) and the Center for Tobacco Products (CTP) conduct many studies and consult with OMB about survey questions, statistical methods, and intended use of the information. Most studies and surveys request a one-time approval and do not need to be renewed. Discussions between FDA and OMB are often held to resolve differences of opinion on the methodology of surveys FDA wishes to conduct. At times, FDA must revise the data collection instrument (e.g., a questionnaire) to obtain OMB approval. With surveys and other studies, a contract is often involved and extensions may have to be requested if OMB's review and approval are not timely.

*Focus Groups*

Focus groups are one of the ways FDA can gather information to inform decisions on how to approach a rulemaking or guidance document. Under the generic clearance for FDA focus groups, FDA recently received approval of a focus group entitled, "Studies to Enhance FDA Communications Addressing Opioids and Other Potentially Addictive Pain Medications." Combating opioid misuse, abuse, and addiction has long been a priority for the Agency. Over the last decade or so, FDA has worked to pursue a targeted, science-based, multi-pronged approach that addresses misuse, abuse, and addiction at critical points in the development of an opioid product and in its use throughout the health care system.

In addition to extensive scientific analysis, FDA has focused on efforts to raise awareness and educate the public and health care professionals about opioids and their inherent safety risks, engaging in public communications and outreach through multiple avenues, such as public

meetings, public announcements, discussions with experts, and targeted public outreach. The Agency is committed to ongoing efforts to help enhance the safe and appropriate use of opioids and supports a variety of regulatory, educational, communication, and scientific activities aimed at achieving this goal, both on its own and in collaboration with other agencies and stakeholders. FDA has determined further research is needed in order to better understand how to most efficiently and effectively focus resources to educate and communicate about opioids and their safe and appropriate use to various stakeholder audiences.

As a result, this project is designed to provide FDA's Center for Drug Evaluation and Research (CDER) with a better understanding of current knowledge, practice, beliefs, behaviors, and perceptions about opioid use, misuse, and abuse among several key stakeholder audiences, including health care professionals, patients, and other members of the lay public. Gaining this knowledge will assist in more appropriately directed and focused communication efforts aimed at raising awareness and educating the public.

Reducing the Impact on Small Business

ROCIS reserves one field for the number of small entity respondents for which the information collection will have a significant impact. FDA Centers and program experts provide the details regarding the impact on small business. For instance, the Center for Devices and Radiological Health (CDRH) offered these details regarding the impact on small business in the supporting statement for OMB Control Number 0910-0844, "De Novo Classification Process (Evaluation of Automatic Class III Designation)":

Approximately 95% of U.S. medical device manufacturing establishments have fewer than 500 employees and would, therefore, be considered small businesses. Submission of a De Novo request is voluntary. Any impact on small businesses should be offset by the guidance and consumer assistance available through CDRH Learn training tools and the information posted on FDA's website. FDA aids small business by providing guidance and information through the Division of International and Consumer Education (DICE) within the Center for Devices and Radiological Health. DICE provides technical and non-financial assistance to small manufacturers, through a comprehensive program that includes seminars, workshops, and educational conferences, information materials, contact via email and the use of a toll-free telephone number. Other members of the Center staff are also available to respond to questions at any time.

Additionally, the Manufacturers Assistance Branch in the Center for Biologics Evaluation and Research (CBER) provides assistance and training to industry, including large and small manufacturers and trade associations, and responds to requests for information regarding CBER policies and procedures.

In the supporting statement for OMB Control Number 0910-0614, "Exceptions or Alternatives to Labeling Requirements for Products Held By the Strategic National Stockpile," CBER described the extra help it provides to small businesses:

> This collection of information applies to both small and well as [*sic*] large establishments. Although FDA must apply the statutory and regulatory requirements equally to all enterprises, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research, Office of Communications, Outreach, and Development, Division of Manufacturer's Assistance and Training, the Center for Drug Evaluation and Research, Office of Communication, Division of Drug Information, and the Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance provide assistance to small businesses subject to FDA's regulatory requirements.

In the supporting statement for OMB Control Number 0910-0014, "Investigational New Drug Regulations," the Center for Drug Evaluation and Research (CDER) explained:

> FDA's authority and responsibility to ensure the safe use of investigational drugs applies to small as well as to large businesses involved in sponsoring drug studies. FDA believes that its responsibility requires the equal application of the regulations to all businesses. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. A small business coordinator has been assigned to the Commissioner's staff to ensure that small businesses have an adequate opportunity to express their concerns and to keep FDA management apprised of how regulatory decisions might impact the small business community. To provide additional assistance to small businesses, FDA has established an office whose

exclusive concern is to provide small business with help in dealing with FDA regulatory requirements.

FDA's Tools and Resources

FDA provides tools, templates, and resources for Centers to use when drafting their information collection documents:

- Templates for drafting notices for publication in the Federal Register are made available by the Regulations Editorial Section, Office of Policy.

- FDA developed instructions and a template for completing the supporting statement that OMB reviews prior to taking action on an ICR. This template was developed by the FDA PRA Staff based on instructions from OMB and HHS and on the requirements of ROCIS.

- FDA established SOPs for use with information collection in guidance documents through a cooperative effort between the various Centers, the Office of Chief Counsel, and the Office of Policy.

- FDA provides training to Centers on the PRA process, including as a part of the Quality System for Regulations training offered by the Office of Policy.

Thank you again for inviting FDA to testify. I would be happy to answer any questions you may have.