

<sup>22</sup> [http://www.qualityforum.org/Publications/2013/02/MAP\\_Pre-Rulemaking\\_Report\\_-\\_February\\_2013.aspx](http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx).

<sup>23</sup> [http://www.qualityforum.org/Publications/2013/03/2012\\_NQF\\_Measure\\_Gap\\_Analysis.aspx](http://www.qualityforum.org/Publications/2013/03/2012_NQF_Measure_Gap_Analysis.aspx).

<sup>24</sup> e.g., Hospital Consumer Assessment of Healthcare Providers and Systems [HCAHPS] being tested only in the hospital inpatient setting, creating a gap in patient experience measurement in the hospital outpatient, ambulatory surgical center, and long-term care hospital settings.

### III. Secretarial Comments on the 2014 Annual Report to Congress and the Secretary

This 2014 Annual Report to Congress and the Secretary describes NQF's work in 2013 to fulfill the requirements specified in section 1890 of the Social Security Act. Of particular interest to the Department, in 2013, NQF continued work initiated in 2010 to develop recommendations on the National Quality Strategy by convening diverse stakeholder groups to reach consensus on quality measurement priorities. NQF also began work in several priority areas that the National Quality Strategy addresses, such as improving population health within communities, improving patient safety in high-priority areas, and helping consumers leverage quality information to make informed healthcare coverage decisions—a critically important area as more people choose the health care coverage that is best for them through the health insurance marketplaces created by the Affordable Care Act.

We are also pleased that during the year, NQF furthered its work on performance measures by adding 27 measures to its portfolio. We note that although the number of measures endorsed in 2013 is significantly lower than in the preceding year, the meetings that were convened in 2013 to endorse measures took place as the initial four-year contract was ending. Under the new contract, NQF began to develop new measures candidates, but those did not reach the stage of endorsement review by the end of the year.

Moreover, in 2013, the Measure Applications Partnership (MAP), a public-private partnership convened by NQF: (1) Recommended measures for federal public reporting and payment programs; (2) developed “families of measures” for high-priority areas; and (3) provided input on measures for vulnerable populations, including Medicare-Medicaid enrollees and adults enrolled in Medicaid.

NQF also continued to address the need to fill measurement gaps in priority areas. Under the second contract, NQF began working with key stakeholders to make recommendations for performance measurement development in five priority topic areas: (1) Adult immunization; (2) Alzheimer's disease and related dementias; (3) care coordination; (4) health workforce; and (5) person-centered care and outcomes.

These and the other activities described in the 2014 Annual Report to Congress and the Secretary, published above, reflect the wide scope of work required for comprehensive,

methodologically sound measurement of health care quality and continued improvement of health care in the United States. HHS thanks NQF for its insightful and informative work conducted in 2013.

### IV. Future Steps

As previously noted, the work reflected in the 2014 Annual Report to Congress and the Secretary was produced under both HHS' initial four-year contract with the NQF which expired in July, 2013 and a subsequent, four-year contract. In 2014 and beyond, HHS will continue to work with the consensus-based entity and all stakeholders on ongoing measure endorsement and maintenance to continuously improve the set of measures available for widespread application. HHS will also work with NQF on more targeted and strategic issues such as measures regarding the quality of home and community-based care for people with disabilities, the use of information technology in quality measurement, and improving population health. All of these initiatives will help to fulfill the triple aims of the National Quality Strategy: Better health care, healthier people and communities, and more affordable care for all Americans.

### V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: July 7, 2014.

**Sylvia M. Burwell,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2014–16391 Filed 7–15–14; 8:45 a.m.]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–N–0222]

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; User Fee Waivers, Reductions, and Refunds for Drug and Biological Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by August 15, 2014.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0693. Also include the FDA docket number found in brackets in the heading of this document.

**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](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### User Fee Waivers, Reductions, and Refunds for Drug and Biological Products (OMB Control Number 0910–0693)—Extension

The guidance provides recommendations for applicants planning to request waivers or reductions in user fees assessed under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 21 U.S.C. 379h) (the FD&C Act). The guidance describes the types of waivers and reductions permitted under the user fee provisions of the FD&C Act, and the procedures for submitting requests for waivers or reductions. It also includes recommendations for submitting information for requests for reconsideration of denials of waiver or reduction requests, and for requests for appeals. The guidance also provides clarification on related issues such as user fee exemptions for orphan drugs.

We estimate that the total annual number of waiver requests submitted for all of these categories will be 120, submitted by 100 different sponsors. We estimate that the average burden hours for preparation of a submission will total 16 hours. Because FDA may request additional information from the applicant during the review period, we have also included in this estimate time to prepare any additional information.

The reconsideration and appeal requests are not addressed in the FD&C Act but are discussed in the guidance. We estimate that we will receive 3 requests for reconsideration annually,

and that the total average burden hours for a reconsideration request will be 24 hours. We estimate that we will receive 1 request annually for an appeal of a user fee waiver determination, and that the time needed to prepare an appeal would be approximately 12 hours. We have included in this estimate both the time needed to prepare the request for appeal and the time needed to create and send a copy of the request for an appeal to the Associate Director for Policy at the Center for Drug Evaluation and Research.

The burden for filling out and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) has not been included in the burden analysis, because that information

collection is already approved under OMB control number 0910–0297. The collections of information associated with a new drug application or biologics license application have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively.

We have included in the burden estimate the preparation and submission of application fee waivers for small businesses, because small businesses requesting a waiver must submit documentation to FDA on the number of their employees and must include the information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval. Because the Small Business

Administration (SBA) makes the size determinations for FDA, small businesses must also submit information to the SBA. The submission of information to SBA is already approved under OMB control number 3245–0101.

In the **Federal Register** of March 4, 2014 (79 FR 12201), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments. However, these comments did not address the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| User fee waivers, reductions, and refunds for drug and biological products | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|----------------------------------------------------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| FD&C Act sections 735 and 736 .....                                        | 100                   | 1.2                                | 120                    | 16                          | 1,920       |
| Reconsideration Requests .....                                             | 3                     | 1                                  | 3                      | 24                          | 72          |
| Appeal Requests .....                                                      | 1                     | 1                                  | 1                      | 12                          | 12          |
| Total .....                                                                | .....                 | .....                              | .....                  | .....                       | 2,004       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 11, 2014.

**Peter Lurie,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 2014–16709 Filed 7–15–14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2010–N–0062]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exception From General Requirements for Informed Consent

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by August 15, 2014.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0586. Also include the FDA docket number found in brackets in the heading of this document.

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

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Exception From General Requirements for Informed Consent—(OMB Control Number 0910–0586)—Extension

In the **Federal Register** of June 7, 2006 (71 FR 32827), FDA issued an interim final rule to amend its regulations to establish a new exception from the general requirements for informed consent, to permit the use of investigational in vitro diagnostic

devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. The Agency took this action because it was concerned that, during a potential terrorism event or other potential public health emergency, delaying the testing of specimens to obtain informed consent may threaten the life of the subject. In many instances, there may also be others who have been exposed to, or who may be at risk of exposure to, a dangerous chemical, biological, radiological, or nuclear agent, thus necessitating identification of the agent as soon as possible. FDA created this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational.

Section 50.23(e)(1) (21 CFR 50.23(e)(1)) provides an exception to the general rule that informed consent is required for the use of an investigational in vitro diagnostic device. This exception applies to those situations in which the in vitro investigational diagnostic device is used to prepare for, and respond to, a chemical, biological, radiological, or nuclear terrorism event or other public health emergency, if the investigator and an independent