

## TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

| Form name                  | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|----------------------------|-----------------------|------------------------------------|--|--------------------|
| Pre-Assessment .....       | 1600                  | 1                                  | 25/60                                  | 667                |
| Post-Assessment .....      | 1600                  | 1                                  | 25/60                                  | 667                |
| Follow-up Assessment ..... | 1600                  | 1                                  | 25/60                                  | 667                |
| Total .....                | .....                 | .....                              | .....                                  | 2001               |

Office of the Secretary specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Darius Taylor,**

*Deputy, Information Collection Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: HHS-OS-0990-0379-60D]

### 60-Day Notice for Extension of Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

**AGENCY:** U.S. Department of Health and Human Services (HHS).

**ACTION:** Notice and request for comments. Request for an extension of approval by OMB.

**SUMMARY:** HHS, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on the "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). This collection was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery. This notice announces our intent to submit this collection to OMB for approval and solicits comments on specific aspects for the proposed information collection,

**DATES:** Consideration will be given to all comments received by June 2, 2014.

**ADDRESSES:** Submit comments by one of the following methods:

- *Web site:* [www.regulations.gov](http://www.regulations.gov).

Direct comments to Docket ID OMB-2010-0021.

- *Email:*

*Information.CollectionClearance@hhs.gov.*

- *Phone:* (202) 690-6162.

Comments submitted in response to this notice may be made available to the public through relevant Web sites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690-6162.

#### SUPPLEMENTARY INFORMATION:

*Title:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

*Abstract:* The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide

an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and

- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

**Current Actions:** Extension of approval for a collection of information.

**Type of Review:** Extension.

**Affected Public:** Individuals and households, businesses and organizations.

**Estimated Number of Respondents:** 9,000,000 over 3 years.

Below we provide projected average estimates for the next three years:

**Average Expected Annual Number of Activities:** 15.

**Average Number of Respondents per Activity:** 200,000.

**Annual Responses:** 3,000,000.

**Frequency of Response:** Once per request.

**Average Minutes per Response:** 10.

**Burden hours:** 500,000 hours annually.

**Request for Comments:** Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary

for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

All written comments will be available for public inspection [Regulations.gov](http://Regulations.gov).

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 Office of Management and Budget control number.

**Darius Taylor,**

*Deputy, Information Collection Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-D-0261]

### Food and Drug Administration

#### The Meaning of "Spouse" and "Family" in the Food and Drug Administration's Regulations After the Supreme Court's Ruling in *United States v. Windsor*—Questions and Answers: Guidance for Industry, Consumers, and Food and Drug Administration Staff; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a guidance entitled "The Meaning of 'Spouse' and 'Family' in FDA's Regulations after the Supreme Court's Ruling in *United States v. Windsor*—Questions and Answers: Guidance for Industry, Consumers, and FDA Staff." This guidance informs the public of FDA's interpretation of the effects of the Supreme Court's decision in *United States v. Windsor* on several of its regulations. This guidance has an immediate implementation date because FDA has determined that prior public participation is not feasible or appropriate.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4830. Send one self-addressed adhesive label to assist that office in processing your requests. 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, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Daniel W. Sigelman, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4254, Silver Spring, MD 20993, 301-796-4706, email: [daniel.sigelman@fda.hhs.gov](mailto:daniel.sigelman@fda.hhs.gov).