

presented reports relevant and therefore unable to rate a report) and that 65 percent of the eligible sample will complete, resulting in 319 completes. It

should take about 30 minutes to complete the Stakeholder Survey. Mathematica will conduct semi-structured Key Informant Interviews, on

average lasting 50 minutes, with 23 respondents.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Expert Survey	54	1	.33	18
Expert Consultation	15	1	.17	3
Stakeholder Survey	319	1	.50	160
Key Informant Interviews	23	1	.83	19
Total	411			200

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Expert Survey	54	17.8	\$92.25	\$1,642
Expert Consultation	15	2.5	** 92.25	231
Stakeholder Survey	319	59.5	*** 48.72	7,771
Key Informant Interviews	23	19.1	38.68	739
Total	411			10,383

* May 2013 National Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics.

** Based on average wage for physicians and surgeons.

*** Based on average wage for medical and health services managers.

**** Based on average wage for social scientists and related workers.

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 30 2014.

Richard Kronick,

AHRQ Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10305]

Agency Information Collection Activities: Proposed Collection; Extension of Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Agency information collection activities: Proposed collection; comment request; extension of comment period.

SUMMARY: This notice extends the comment period for a 60-day notice request for proposed information collection request associated with the notice [Document Identifier: CMS-10305] entitled "Medicare Part C and Part D Data Validation" that was published in the June 13, 2014 (79 FR 33927) **Federal Register**. The comment period for the information collection request, which would have ended on

August 12, 2014, is extended to August 26, 2014.

DATES: The comment period for the information collection request published in the June 13, 2014, **Federal Register** (79 FR 33927) is extended to August 26, 2014.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

In the FR Doc. 2014-13863 of June 13, 2014 (79 FR 33927), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the document entitled "Medicare Part C and Part D Data Validation." There were technical delays with making the information collection request publicly available; therefore, in this notice we are extending the comment period from the date originally listed in the June 13, 2014, notice.

Dated: August 7, 2014.

Martique Jones,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2014-19027 Filed 8-11-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1030]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Allergen Labeling and Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice invites comments on the information collection provisions of the labeling requirements for major food allergens in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the information collection provisions of the draft guidance entitled, "Draft Guidance

for Industry: Food Allergen Labeling Exemption Petitions and Notifications."

DATES: Submit either electronic or written comments on the collection of information by October 14, 2014.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Allergen Labeling and Reporting—(OMB Control Number 0910-NEW)

I. Background

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II, Pub. L. 108-282) amended the FD&C Act by defining the term "major food allergen" and stating that foods regulated under the FD&C Act are misbranded unless they declare the presence of each major food allergen on the product label using the name of the food source from which the major food allergen is derived. Section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)) sets forth the requirements for declaring the presence of each major food allergen on the product label. Section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)) defines a major food allergen as "[m]ilk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans" and also as a food ingredient that contains protein derived from such foods. The definition excludes any highly refined oil derived from a major food allergen and any ingredient derived from such highly refined oil.

In some cases, the production of an ingredient derived from a major food allergen may alter or eliminate the allergenic proteins in that derived ingredient to such an extent that it does not contain allergenic protein. In addition, a major food allergen may be used as an ingredient or as a component of an ingredient such that the level of allergenic protein in finished food products does not cause an allergic response that poses a risk to human health. Therefore, FALCPA provides two mechanisms through which such ingredients may become exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient "does not cause an allergic response that poses a risk to human health" (section 403(w)(6) of the FD&C Act (21 U.S.C. 343(w)(6))). Alternately, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient "does not contain allergenic protein" or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act (21 U.S.C. 348) that the ingredient "does not cause an allergic response that poses a risk to human health" (section 403(w)(7) of the FD&C Act (21 U.S.C. 343(w)(7))).