CBSA Code	Nonurban Area	Wage Index
35	North Dakota	0.7182
36	Ohio	0.8714
37	Oklahoma	0.7492
38	Oregon	0.9906
39	Pennsylvania	0.8385
40	Puerto Rico[1]	0.4047
41	Rhode Island[1]	-----
42	South Carolina	0.8656
43	South Dakota	0.8549
44	Tennessee	0.7723
45	Texas	0.7968
46	Utah	0.8116
47	Vermont	0.9919
48	Virgin Islands	0.6830
49	Virginia	0.7896
50	Washington	1.0259
51	West Virginia	0.7454
52	Wisconsin	0.9667
53	Wyoming	0.9287
65	Guam	0.9611

[1] All counties within the State are classified as urban, with the exception of Massachusetts and Puerto Rico. Massachusetts and Puerto Rico have areas designated as rural; however, no short-term, acute care hospitals are located in the area(s) for RY 2009. The rural Massachusetts wage index is calculated as the average of all contiguous CBSAs. The Puerto Rico wage index is the same as RY 2008.

[FR Doc. 08–1213 Filed 5–1–08; 4:00 pm]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0272]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with the submission of notifications of health claims or nutrient content claims based on authoritative statements of scientific bodies of the U.S. Government.

DATES: Submit written or electronic comments on the collection of information by July 7, 2008.

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: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration,5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's 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.

Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (OMB Control Number 0910–0374)—Extension

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA

Modernization Act of 1997, provides that any person may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences (NAS). Under this section of the act, a person that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the **Federal Register** of June 11, 1998 (63 FR 32102), FDA announced the availability of a guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body.'' The guidance provides the agency's interpretation of terms central to the submission of a notification and the agency's views on the information that should be included in the notification. The agency believes that the guidance will enable persons to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the act. In addition to the information specifically required by the act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. FDA intends to review the notifications the agency receives to ensure that they comply with the criteria established by the act.

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

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act/Basis of Burden	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(2)(C) (health claims)	2	1	2	450	900
Guidance for notifications	3	1	3	1	3
Total					1,153

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with health claims, nutrient content claims, and other similar notification procedures that fall under the agency's jurisdiction. FDA estimates that it will receive one nutrient content claim notification and two health claim notifications per year.

Section 403(r)(2)(G) and 403(r)(3)(C) of the act requires that the notification include the exact words of the claim, a copy of the authoritative statement, a concise description of the basis upon which such person relied for determining that this is an authoritative statement as outlined in the act, and a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which a health claim refers or to the nutrient level to which the nutrient content claim refers. This balanced representation of the scientific literature is expected to include a bibliography of the scientific literature on the topic of the claim and a brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement.

Since the claims are based on authoritative statements of a scientific body of the Federal government or NAS, FDA believes that the information that is required by the act to be submitted with a notification will be readily available to a respondent. However, the respondent will have to collect and assemble that information. Based on communications with firms that have submitted notifications, FDA estimates that it will take a respondent 250 hours to collect and assemble the information required by the statute for nutrient content claim notifications and 450 hours to collect and assemble the information required by the statute for health claim notifications.

Under the guidance, notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. The guidance applies to both nutrient content claim and health claim notifications. FDA has determined that this information should be readily available to a respondent and, thus, the agency estimates that it will take a respondent 1 hour to incorporate the information into the notification.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–10180 Filed 5–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0269]

Agency Emergency Processing Under Office of Management and Budget Review; Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the requirement established by the Food and Drug Administration Amendments Act of 2007 (FDAAA), that device establishments must submit registration and listing information by electronic means using FDA Form 3673, unless the Secretary of Health and Human Services (the Secretary) grants them a waiver from the electronic submission requirement.

DATES: Fax written comments on the collection of information by June 6, 2008.