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.

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: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007; (21 U.S.C. 360); Emergency Request.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13)). Title II of FDAAA (Public Law 110–85), enacted September 27, 2007, amends section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) to require all domestic and foreign device establishments to submit registration and device listing information to FDA by electronic means, and specifies the timeframes when establishments are required to submit such information. These new registration and listing requirements were in effect on October 1, 2007. The proposed collection of information concerns the information that owners/operators of device establishments must submit electronically in order to register their establishments and list their devices using FDA Form No. 3673. In addition, owners/operators seeking a waiver from the electronic submission requirements will need to submit a written request for a waiver to FDA with a complete explanation as to why their registration and listing information cannot be submitted electronically. See sections 222, 223, and 224 of FDAAA. Thus, FDA is requesting emergency processing of this new collection of information for electronic registration and listing, and information relating to requests for waivers.

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.

Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007; (21 U.S.C. 360); Emergency Request

Sections 222, 223, and 224 of FDAAA, which were in effect on October 1, 2007, require that device establishment registrations and listings under section 510 of the FD&C Act (including the submission of updated information) be submitted to the Secretary by electronic means, unless the Secretary grants a request for waiver of the requirement because the use of electronic means is not reasonable for the person requesting the waiver. FDA expects that 20,000 to 30,000 device establishments will need to register electronically between now and December 31, 2008. Section 224 of FDAAA requires that these establishments also must have an opportunity request waivers. Thus, emergency approval of this request is necessary to implement these provisions of the statute.

Section 222 of FDAAA amends section 510(b) of the FD&C Act to require domestic establishments to register annually during the period beginning October 1 and ending December 31 of each year. Section 222 of FDAAA also amends section 510(i)(1) of the FD&C Act to require foreign establishments to immediately register upon first engaging in one of the covered device activities described under the statute, and they must also register annually during the period beginning on October 1 and ending on December 31 of each year. In addition, section 223 of FDAAA amends section 510(j)(2) of the FD&C Act to require establishments to list their devices annually with FDA during the period beginning on October 1 and ending on December 31 of each year.

Under FDAAA, device establishment owners/operators are required to keep their registration and device listing information up-to-date using the agency's new electronic system. Owners/operators of new device establishments must use the electronic system to create new accounts, new registration records, and new device listings. Section 224 of FDAAA amends section 510(p) of the FD&C Act by allowing a person affected to request a waiver from the requirement to register electronically when the ''use of electronic means'' is not reasonable for the person.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the 2007 Amendments	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
222[2]	3673	2,600	1	2,704	0.5	1,352
223[2]	3673	24,382	1	24,382	0.25	6,095
224[2]		29,370	1	29,370	0.75	22,028
224[3]		2,600	1	2,600	0.5	1,300
224 (waiver request)[2]		20	1	20	1	20
224 (waiver request)[3]		1	1	1	1	1

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Section of the 2007 Amendments	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total Hours						30,796

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One time burden.
[3] Annual increase in burden.

The estimates in table 1 of this document are based on FDA's experience, data from the device registration and listing database, and our estimates of the time needed to complete the previously required forms. We estimate that the time needed to enter registration and listing information electronically using FDA Form 3673 will not differ significantly from the time needed to fill in the paper forms (FDA Forms 2891, 2891a, and 2892) that previously were used for this purpose because the information required is essentially identical.

In addition, under section 224 of FDAAA, device establishments owner/operators for whom registering and listing by electronic means is not reasonable may request a waiver from the Secretary. Because a device establishment's owner/operator required to register and list would only need to have access to a computer, Internet, and an e-mail address for registration and list by electronic means, the agency did not anticipate the receipt of a large number of requests for waiver. For the first few months of operation of the web-based system, i.e., October through December 2007, FDA received fewer than 10 requests for waivers from the requirement to submit registration and listing information electronically. As data for more than 16,000 establishments have been received electronically for the same period, these requests amount to less than 1 percent of the total number of establishments that have responded.

Based on information taken from our databases, FDA estimates that there are 29,370 owner/operators who collectively register a total of 33,490 device establishments. The number of respondents listed for section 224 of FDAAA in the burden table is 29,370, which corresponds to the number of owner/operators who annually register one or more establishments. In addition, FDA estimates that 4,988 owner/operators are initial importers who must register their establishments but who, under FDA's existing regulations, are not required to list their devices unless they initiate or develop the specifications for the devices or repackage or relabel the devices. The number of respondents included in the burden table for section 223 of FDAAA is 24,382, which corresponds to the number of owner/operators who list one or more devices annually (29,370 - 4,988 = 24,382).

To calculate the burden estimate for waiver requests under section 224 of FDAAA, we assume as stated previously that less than one tenth of one percent of the 33,490 total device establishments would request waivers from FDA. This means the total number of waiver requests would probably not exceed 20 requests (33,490 x 0.0006). We also estimate that the one-time burden on these establishments would be an hour of time for a mid-level manager to draft, approve, and mail a letter. In addition, FDA estimates the total number of establishments will increase by 2,600 new establishments each year. Of the 2,600 new registrants each year, we assume that less than one percent (i.e., 1) of these will also request waivers each year. The total, therefore, is 21 waiver requests, which could increase by only 1 additional request each year.

Dated: May 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–10194 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–D–0228] (formerly Docket No. 00D–1401)

Guidance for Industry and Food and Drug Administration Staff; Administrative Procedures for CLIA Categorization; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Administrative Procedures for CLIA Categorization.'' The guidance describes FDA's current practices concerning the administrative aspects of categorizing commercially available in vitro diagnostic tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The guidance discusses what manufacturers should submit to help expedite CLIA categorization by FDA.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Administrative Procedures for CLIA Categorization'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0491, ext. 117.

SUPPLEMENTARY INFORMATION:

I. Background

On February 28, 1992, the Department of Health and Human Services published the final laboratory standards regulations (57 FR 7002) implementing CLIA (42 U.S.C. 263a). The implementing regulations are codified at 42 CFR part 493. CLIA regulates laboratory testing and requires that clinical laboratories obtain a certificate