ways people can enter data into the electronic submission system to protect the database from corruption.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
720.1 through 720.4 (new submissions)	FDA 2512 and FDA 2512a	112	12.9	1,446	0.5	723
720.4 and 720.6 (amendments)	FDA 2512 and FDA 2512a	112	0.5	52	0.33	17
720.3 and 720.6 (notices of discontinuance)	FDA 2514	112	1	4	0.1	0.4
720.8 (requests for confidentiality)		1	1	1	1.5	1.5
Total						742

[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 the Cosmetic Product Voluntary Reporting Program. The estimated annual total hours burden is 75 percent of the burden reported in 2002 due to decreased submissions. However, the number of respondents doubled, and FDA attributes this to increased interest in the program. FDA expects the number of submissions to increase accordingly in the next 3 years.

Dated: October 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20307 Filed 10–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0124]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; 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 that a collection of information entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 16, 2005 (70 FR 35097), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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 OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0374. The approval expires on September 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20308 Filed 10–7–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0401]

Draft Guidance for Industry and FDA Staff: Compliance With the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices.'' The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), as amended by the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), requires that FDA issue guidance within 180 days of enactment (August 1, 2005) identifying the circumstances in which the name, abbreviation, or symbol identifying the manufacturer of an original device is not ''prominent and conspicuous.''

DATES: Submit written or electronic comments on this draft guidance so that they are received by close of business on November 10, 2005. FDA will not be able to consider comments received after that date in developing the final guidance. FDA may consider late comments at a future time if the