TABLE 1.—SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS (PDN) FOR THIRD SET OF 10 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substance	PDN ID	Priority data needs
	46C	Two-generation reproductive study following oral exposure.
	46D	Developmental toxicity study that includes neurodevelopmental end points following oral exposure.
	46E	Exposure levels in humans living near hazardous waste sites.
	46F	Exposure levels of children.
	46G	Potential candidate for subregistry of exposed persons.

Dated: August 7, 2001.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 01–20373 Filed 8–13–01; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0335]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day'' Basis

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 a collection of information on nutrition labeling of dietary supplements on a ''per day'' basis.

DATES: Submit written or electronic comments on the collection of information by October 15, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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: (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.

Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day'' Basis

Section 403(q)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(F)) provides that dietary supplements must bear nutrition labeling in a manner that is appropriate for the product and that is specified in regulations issued by FDA. FDA issued regulations establishing the requirements for dietary supplements in nutrition labeling in 21 CFR 101.36 in the September 23, 1997, final rule (62 FR 49826). FDA published a proposed rule in the **Federal Register** of January 12, 1999 (64 FR 1765), to amend its nutrition labeling regulations for dietary supplements. This amendment would provide that the quantitative amount and the percentage of the daily value of a dietary ingredient may be voluntarily presented on a ''per day'' basis in addition to the required ''per serving'' basis. The proposed rule stated that this voluntary information may be provided if a dietary supplement label recommends that the dietary supplement be consumed more than once per day. These proposed provisions are in response to a citizen petition submitted by a manufacturer and marketer of dietary supplements. This proposed action would provide suppliers of dietary supplements flexibility to present additional label information voluntarily to consumers.

Respondent Description: Suppliers of dietary supplements.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating & Maintenance Costs	Total Hours
101.36(e)	85	10	850	0.25	$83,000	213

[1] There are no capital costs associated with this collection of information.

These estimates are based on agency communications with industry and FDA's knowledge of, and experience with, food labeling. FDA estimated in the September 23, 1997, final rule (62 FR 49826 at 49846) that there was a maximum of 850 suppliers of dietary supplements and that, on average, each supplier had 40 products whose labels required revision. FDA estimates that only 10 percent, or 85 of the dietary supplement suppliers, would revise the labels of their products to incorporate nutrition levels for the daily use of their products. FDA also estimates that daily use levels for nutrition information would generally be placed on at most 25 percent, or at most 10 of a firm's estimated 40 products, although this number would vary by firm based on the types of products that it produces. FDA also believes that the burden associated with the proposed disclosure of nutrition information on a daily use basis for dietary supplements would be a one-time burden for the small number of firms that would decide voluntarily to add this additional information to the labels for their products. FDA estimates that at least 90 percent of firms would coordinate the addition of daily use nutrition information with other changes in their labels, in which case the voluntary cost of transmitting the information to consumers in labeling would be subsumed almost entirely in the cost of these other voluntary or required labeling changes. The incremental cost for these 76 firms would be approximately $50 per label for 760 labels, or $38,000 total. For the remaining 9 firms that would not coordinate changes with other labeling changes, FDA estimates that the cost would be approximately $500 per label (64 FR 1765 at 1769) for 90 labels, or $45,000 total. The estimated total operating costs in table 1 of this document are, therefore, $83,000. Respondents are already required to disclose the quantitative amount and the percentage of the daily value of a dietary ingredient on a per serving basis as part of the nutrition information for dietary supplements. Respondents may also provide such information on a per unit basis. The information provided for under the proposed rule would be generated by simple extrapolation from that information.

Dated: August 7, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20299 Filed 8–13–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0050]

Agency Information Collection Activities; Announcement of OMB Approval; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Premarket Approval of Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 16, 2001 (66 FR 27147), 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 0910–0231. The approval expires on August 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: August 7, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20301 Filed 8–13–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0078]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer (DTC) Promotion Drugs; Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by September 13, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer (DTC) Promotion Drugs; Survey

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is