TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
600.80(c)(1) and (e)	90	168.07	15,126	1	15,126
600.80(c)(2)	90	72.78	6,550	28	183,400
600.81	90	3.59	323	1	355
600.90	5	1	5	1	5
Total					198,886

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
600.12	116	57.16	6,630	32	212,160
600.12(b)(2)	320	6.12	1,958	24	46,992
600.80(i)	90	394.27	35,484	1	35,484
Total					294,636

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

Dated: April 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7824 Filed 4–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0123]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Need for Online Medical Device Information

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey of customers who should be served by FDA's Center for Devices and Radiological Health (CDRH) Web site, in order to determine the kind and quality of services they want.

DATES: Submit written or electronic comments on the collection of information by June 20, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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: Peggy Robbins, Office of Management Programs (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 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.

Survey of Need for Online Medical Device Information

Executive Order 12862 directs agencies to identify the customers who are, or should be, served by the agency, and to survey customers to determine the kind and quality of services they want.

This proposed survey will collect data about the information customers want

when looking up medical devices on the Internet. It will focus on the ways individuals find, use, and rate existing sources of online medical device information. FDA will use this data to understand more about its customers and to make improvements to its own Web site.

FDA will administer this survey to individuals who use the Internet to look for information about medical devices. The survey will consist of three components: A screening tool of 5,000 to identify appropriate respondents, an online survey of 500 customers, and a telephone followup interview with 50 customers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screening tool	5,000	1	5,000	.05	250
Online survey	500	1	500	.25	125
Telephone followup	50	1	50	.5	25
Total					400

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

Dated: April 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7882 Filed 4–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0137]

Levothyroxine Sodium Therapeutic Equivalence; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on the therapeutic equivalence of levothyroxine sodium drug products. This will be a workshop involving FDA staff and representatives of three medical societies: The American Thyroid Association (ATA), the Endocrine Society, and the American Association of Clinical Endocrinologists (AACE). The purpose of the public meeting is to discuss FDA's regulatory standards and methodological approaches for determining therapeutic equivalence between levothyroxine sodium drug products. The agency is seeking comments and input from interested constituencies, including patient advocacy and education groups, and pharmaceutical sponsors.

DATES: The public meeting will be held on May 23, 2005, from 8:30 a.m. to 5 p.m. Submit written or electronic comments by July 23, 2005.

ADDRESSES: The public meeting will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594, 202–314–6421. The center can be reached by Metro using the L'Enfant Plaza station on the green, yellow, blue, and orange lines. For directions, see *http://ntsb.gov/events/newlocation.htm*. (FDA has verified the Web site address, but FDA is not responsible for any changes to the Web site after this document publishes in the **Federal Register**.)

Submit written comments 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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Rose Cunningham, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–443–5595, e-mail: *cunninghamr@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 14, 1997 (62 FR 43535), FDA declared that oral drug products containing levothyroxine sodium were considered new drugs and subject to regulation as such. The document called for new drug applications (NDAs) for levothyroxine sodium products from sponsors wishing to market such products in the United States after August 14, 2000. This deadline was eventually extended to August 14, 2001.

The NDAs submitted for levothyroxine sodium products included literature references supporting the safety and effectiveness of levothyroxine sodium for the proposed indications and full manufacturing information supporting the purity, potency, and stability of the products. Manufacturers were required to target 100 percent of the labeled levothyroxine sodium content at release. (Some manufacturers had historically added a ''stability overage'' to give their products a longer shelf-life.) In addition, bioavailability and in vitro dissolution studies were required to establish that the products were readily and consistently absorbed across the range of dosage strengths proposed to be marketed. To assist manufacturers, in December 2000, FDA published a guidance on the conduct of in vivo pharmacokinetic and bioavailability studies and in vitro dissolution tests on these products.

FDA has approved seven NDAs for levothyroxine sodium products. None were originally rated as interchangeable with any other. Since their approval, FDA has approved supplemental NDAs from some sponsors demonstrating the therapeutic equivalence (interchangeability) of their products to other approved levothyroxine sodium products. The agency has also approved one levothyroxine sodium product under an abbreviated new drug application (ANDA).

ATA, the Endocrine Society, and AACE have questioned FDA's regulatory and scientific standards for determination of therapeutic equivalence of levothyroxine sodium products, particularly FDA's bioequivalence methodology.