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.

II. Scope of the Public Meeting

The public meeting is intended to review FDA's regulatory and scientific approach to levothyroxine sodium products, including manufacturing standards, in vitro dissolution studies, and bioavailability/bioequivalence methods.

The public meeting will also review clinical, scientific, and methodological issues relevant to the possible use of serum thyrotropin concentration as a pharmacodynamic measure of levothyroxine sodium bioequivalence.

The public meeting will include representatives from FDA and from the three medical societies. A series of brief presentations will frame the issues under consideration, followed by panel discussions involving speakers and moderators, with questions and comments from the audience. Other interested constituencies (e.g., patient advocacy and education groups, pharmaceutical sponsors, general public) will have an opportunity to provide input during the question and comment periods.

III. Registration, Agenda, and Presentations

No registration is required to attend the meeting. Seating will be on a first-come, first-served basis. If you need special accommodations due to a disability, please contact (see **FOR FURTHER INFORMATION CONTACT**).

The agenda for public meeting will be available on FDA's Center for Drug Evaluation and Research Web site at *http://www.fda.gov/cder/meeting/levothyroxine.htm* and at the meeting. After the meeting, the agenda, presentations, and transcript will be placed on file in the Division of Dockets Management under the docket number found in the heading of this document and on CDER's Web site identified previously.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the topics discussed in this document. Submit two copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

Copies of the transcript may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the meeting at a cost of 10 cents per page or on compact disc at a cost of $14.25 each. You may also examine the transcript at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 14, 2005.

Jeffery Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7883 Filed 4–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0133]

Draft ''Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,'' dated April 2005. The draft guidance document provides revisions to the previously published recommendations for assessing donor suitability and product safety when donors are diagnosed with or suspected of West Nile Virus (WNV) infections based on symptoms and laboratory tests. This draft guidance proposes revised deferral periods for such donors, and updates information on product retrieval and quarantine. When finalized, this guidance will supersede ''Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,'' dated May 2003.

DATES: Submit written or electronic comments on the draft guidance by May 20, 2005, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft 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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,'' dated April 2005. FDA developed the information in this draft guidance after consulting with other Public Health Service agencies of the Department of Health and Human Services.

This draft guidance:

- Applies to donors of blood and blood components intended for transfusion;
- Applies to donors of blood components intended for use in further manufacturing into injectable products or noninjectable products, including recovered plasma, Source Leukocytes, and Source Plasma;
- Provides updated scientific data;
- Removes the current recommendation for donor deferral based upon a reported history of headache with fever in the week before donation;
- Proposes new deferral periods for donors who are diagnosed with or suspected of WNV infections;
- Describes the use of the investigational nucleic acid test (NAT) for WNV in deferring reactive donors; and
- Provides information about the use of individual donor NAT testing to re-enter reactive donors if a blood establishment, at its discretion, chooses to reenter such donors.