establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services may by regulation reasonably require to assure that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Device Act of 1990, signed into law on November 28, 1990, amends section 519 of the act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under part 803. Part 803 mandates the use of FDA Form 3500A for reporting to FDA on medical devices.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107–250, signed into law October 26, 2002, amended section 519 of the act. The amendment (section 303 of MDUFMA) required FDA to revise the MedWatch forms ''to facilitate the reporting of information . . . relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.''

IV. Proposed Modifications to Forms

The proposed modifications to Form FDA 3500 and Form FDA 3500A reflect changes that will bring the form into conformation with current regulations, rules, and guidances. Modifications were also made to better reflect the range of reportable products and language was changed slightly to provide clarity. The changes should allow reporters to better utilize available space for data entry and offer voluntary reporters the opportunity to better characterize the suspected adverse event, product problem or error and provide better quality safety-related data for agency evaluation.

In the proposed modification to current section D, Suspect Medical Device, the agency has relettered the form section and modified the formatting slightly, moving two of the data elements (''Device available for evaluation'' and ''Concomitant medical products'') to adjacent lettered sections on the form in order to improve the utilization of available space and allow for information on non-device products to share these data fields. The agency believes that these changes are compatible with the mandatory reporting instructions for devices (§ 803.33) and will allow mandatory reporters to continue to meet their reporting requirements.

FDA estimates the burden for completing the forms for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

FDA Center/21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CBER/CDER					
Form 3500	22,955	1	22,955	0.6	13,773
Form 3500A (§§ 310.305, 314.80, 314.98, 600.80)	600	579.9	347,940	1.1	382,734
CDRH					
Form 3500	3,433	1	3,433	0.6	2,060
Form 3500A (Part 803)	1,935	33	63,623	1.0	63,623
CFSAN					
Form 3500	847	1	847	0.6	508
Form 3500A (No Mandatory Requirements)	0	0	0	0	0
Total Hours					462,698
Form 3500					16,341
Form 3500A					446,357

(NOTE: CBER = Center for Biologics Evaluation and Research; CDER = Center for Drug Evaluation and Research; CDRH = Center for Devices and Radiological Health; and CFSAN = Center for Food Safety and Applied Nutrition). FDA Form 3500 is for voluntary reporting; FDA Form 3500A is for mandatory reporting).

The figures shown in table 1 of this document are based on actual fiscal year 2003 reports and respondents for each center and type of report.

Dated: December 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28138 Filed 12–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0454]

Dietary Supplements; Premarket Notification for New Dietary Ingredient Notifications; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to February 1, 2005, the comment period for a notice that appeared in the **Federal Register** of October 20, 2004 (69 FR 61680). In the notice, FDA solicited comments on FDA's premarket notification program for new dietary ingredients (NDIs) and announced a public meeting on that topic. The comment period closed on December 3, 2004. FDA is reopening the comment period in response to a request from trade associations representing firms in the dietary supplement industry for additional time to submit comments.

DATES: Submit written or electronic comments by February 1, 2005.

ADDRESSES: 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: Kelly Williams-Randolph, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2506, FAX: 301–436–2639, or e-mail: *Kelly.Williams@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 20, 2004, FDA published a notice announcing a public meeting on November 15, 2004, and soliciting comments on FDA's premarket notification program for NDIs with an opportunity for public comment for 45 days. FDA requested comments from industry, consumers, and other interested members of the public concerning the content and format requirements for NDI notifications made under section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b(a)(2)). FDA held this meeting to give the public an opportunity to provide information and views on topics outlined in the notice. The agency intends to consider all comments received in the meeting and sent to the docket in determining whether any future action is necessary or appropriate.

The agency has received a request from a number of trade associations for an extension of the comment period to and including February 1, 2005. The request set forth several reasons in support of allowing additional time to submit comments. First, according to the request, the 45-day comment period did not allow sufficient time for interested parties to adequately address the large number of detailed and specific questions put forth by FDA and the significant impact on industry, especially small businesses, of the issues raised in the notice. The request noted that the questions (many of which contained subparts) will require extended industry discussion to ensure broad input from member firms and to organize the information obtained from their member companies. Second, the request noted that the original December 3, 2004, deadline for submitting comments did not provide interested parties enough time to consider the transcript of the November 15, 2004, meeting in developing their comments. The request explained that an extension until February 1, 2005, would allow industry to submit more focused and detailed comments without significantly delaying the agency's consideration of the issues set forth in the meeting notice.

FDA has considered the request and is reopening the comment period for the October 20, 2004, notice until February 1, 2005. The agency agrees that reopening the comment period will allow adequate time for interested persons to submit comments without significantly delaying the agency's consideration of the issues set forth in the October 20, 2004, notice.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the issues raised in the October 20, 2004, notice. Submit a single copy of electronic comments or two paper copies of any 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 may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28135 Filed 12–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Directorate of Information Analysis and Infrastructure Protection (IAIP)

[DHS–2004–0032]

Open Meeting of National Infrastructure Advisory Council (NIAC)

AGENCY: Directorate of Information Analysis and Infrastructure Protection, DHS.

ACTION: Notice of meeting.

SUMMARY: The National Infrastructure Advisory Council (NIAC) will meet on Tuesday, January 11, 2005, from 1 p.m. to 4 p.m. at the Hamilton Crowne Plaza in Washington, DC. The meeting will be open to the public. Limited seating will be available. Reservations are not accepted.

The NIAC advises the President of the United States on the security of critical infrastructures which include banking and finance, transportation, energy, manufacturing, and emergency government services. At this meeting, the NIAC will be briefed on the status of several Working Group activities that the Council undertook at its last meeting.

DATES: The NIAC will meet Tuesday, January 11, 2005, from 1 p.m. to 4 p.m.

ADDRESSES: The NIAC will meet at the Hamilton Crowne Plaza, 14th and K Street, NW., Washington, DC. You may submit comments, identified by DHS Docket DHS–2004–0032 by one of the following methods:

- EPA Federal Partner EDOCKET Web Site: *http://www.epa.gov/feddocket.* Follow the instructions for submitting comments on the Web site.
- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Mail/Hand Delivery/Courier: Department of Homeland Security, Attn: Ms. Nancy J. Wong, Infrastructure Coordination Division, Directorate of Information Analysis and Infrastructure Protection/703–235–5352, Anacostia Navel Annex, 245 Murray Lane, SW., Building 410, Washington, DC 20528, 7:30 a.m. to 4 p.m.

Instructions: All submissions received must include the DHS–2004–0032. All comments received will be posted without change to *http://www.epa.gov/feddocket,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Nancy J. Wong, NIAC Designated Federal Official, telephone 703–235–5352.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

AGENDA OF COMMITTEE MEETING ON JANUARY 11, 2005

I. Opening of Meeting	Nancy J. Wong, U.S. Department of Homeland Security (DHS)/Designated Federal Officer, NIAC.
II. Roll Call of Members	Nancy J. Wong.
III. Opening Remarks and Introductions.	NIAC Chairman, Erle A. Nye, Chairman of the Board, TXU Corporation. NIAC Vice Chairman, John T. Chambers, Chairman and CEO, Cisco Systems, Inc.