ESTIMATE OF ANNUALIZED BURDEN TABLE

Types of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
State Health Departments	Electronic STD Case report	50	52	20/60	867
Territorial Health Agencies	Electronic STD Case report	5	52	20/60	87
City and county health departments	Electronic STD Case report	2	52	20/60	35
Totals					989

Dated: August 16, 2012.

Ron A. Otten,

Director, Office of Science Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–20675 Filed 8–21–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: New Collection]

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Support Document Exchange System (CSDES).

Description: The federal Office of Child Support Enforcement (OCSE) is implementing a new application, the Child Support Document Exchange System (CSDES), within the Federal Parent Locator Service (FPLS) Child Support Services Portal (CSSP). The CSDES will collect and maintain certain child and spousal support case-related records provided by a state IV–D child support agency to facilitate the dissemination of IV–D child and spousal support information to authorized users acting on behalf of a state IV–D child support agency. 42 U.S.C. 666(c)(1)(A)(B)(C) and (D) and 42 U.S.C. 653(a)(1).

The purpose of the information collection is to provide technical assistance to the states to help them establish effective systems for collecting child and spousal support. 42 U.S.C. 652(a)(7). This will help state IV–D agencies in fulfilling the federal requirement to transmit requests for child support case information and provide requested information electronically to the greatest extent possible. 45 CFR 303.7(a)(5).

It is anticipated that the implementation of the CSDES will reduce delays, costs, and barriers associated with interstate case processing; increase state collections; improve document security; standardize data sharing; and increase state participation; thereby improving overall child and spousal support outcomes.

Respondents: State Child Support Agencies

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Data Entry Screens	54	4,272	.01667	3,845

Estimated Total Annual Burden Hours: 3,845.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–20565 Filed 8–21–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0564]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dietary Supplement Labeling Requirements and Recommendations Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the

Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 21, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0642. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@fda.hhs.gov*.

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.

Dietary Supplement Labeling Requirements and Recommendations Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act—(OMB Control Number 0910–0642)—Extension

In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA) (Pub. L. 109–462, 120 Stat. 3469) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The DSNDCPA also amended the FD&C Act to add section 403(y) (21 U.S.C. 343(y)), which requires the label of a dietary supplement marketed in the United States to include a domestic address or domestic telephone number through which the product's manufacturer, packer or distributor may receive a report of a serious adverse event associated with the dietary supplement.

In the **Federal Register** of September 1, 2009 (74 FR 45221), FDA announced the availability of a guidance document entitled, ''Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The guidance document contains questions and answers related to the labeling requirements in section 403(y) of the FD&C Act and provides guidance to industry on the use of an explanatory statement before the domestic address or telephone number. The guidance document provides the Agency's interpretation of the labeling requirements for section 403(y) of the FD&C Act and the Agency's views on the information that should be included on the label. The Agency believes that the guidance will enable persons to meet the criteria for labeling that are established in section 403(y) of the FD&C Act.

In the **Federal Register** of June 14, 2012 (77 FR 35687), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received no comments in response to the notice.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent [2]	Total annual disclosures	Average burden per disclosure	Total hours
Domestic address or phone number labeling requirement (21 U.S.C. 343(y))	1,460	3.8	5,560	0.2	1,112
FDA recommendation for label statement explaining purpose of domestic address or phone number	1,460	3.8	5,560	0.2	1,112
Total					2,224

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Number has been rounded to the nearest tenth.

The labeling requirements of section 403(y) of the FD&C Act became effective on December 22, 2007, although FDA exercised enforcement discretion until September 30, 2010, to enable all firms to meet the labeling requirements for dietary supplements. FDA estimates that all labels required to include the domestic address or telephone number pursuant to section 403(y) of the FD&C Act have been revised by the effective date. Thus, in succeeding years, the Agency estimates that the burden hours associated with the labeling requirements of section 403(y) of the FD&C Act and the Agency's recommendations on the use of an explanatory statement will apply only to new product labels. Based on the A.C. Nielsen Sales Scanner Data, FDA estimated that the number of dietary supplement stock keeping units for which sales of the products are greater than zero is 55,600. Assuming that the flow of new products is 10 percent per year, then 5,560 new dietary supplement products will come on the market each year. FDA also estimates that there are about 1,460 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements. Assuming the approximately 5,560 new products are split equally among the firms, then each firm would prepare labels for close to four new products per year (5,560 new products/1,460 firms is approximately 3.8 labels per firm. Thus, the estimated total annual disclosures are 5,560 (1,460 firms × 3.8 labels per year = 5,560).

The Agency expects that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed on their product labels. Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 0.2 hours per product to comply with the requirement to include the domestic address or telephone number pursuant to section 403(y) of the FD&C Act. The total hour burden of this task is shown in row 1 of table 1.

FDA estimates that all firms will include an explanatory statement on the label, which lets consumers know the purpose of the domestic address or telephone number on the label of the dietary supplement product. Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 0.2 hour per product to comply with the Agency's recommendations on the use

of an explanatory statement. The total hour burden of this task is shown in row 2 of table 1.

The total reporting hour burden is 2,224 hours, which equals the burden for the required domestic address or telephone (1,112 hours) plus the burden for the explanatory statement before the domestic address or telephone number (1,112 hours). This estimate is 3,336 hours lower than the 5,560 hours reported in the 60-day notice published June 14, 2012, due to an Agency reassessment that 0.2 hours per disclosure more accurately reflects the burden. This reassessment is based on the Agency's expectation that firms, estimated to design four new labels per year, are familiar with the requirement to include the domestic address or telephone number in their product labels. It is also based on FDA's recommendations on the use of an explanatory statement and our expectation that the disclosed information (domestic address or telephone number and explanatory statement) would not change from product label to product label. Thus, FDA estimates that firms would not need a full hour per label, but rather, approximately 24 minutes per label to include this information.

Dated: August 16, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20602 Filed 8–21–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Gastrointestinal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 16, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *GIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 203441, with the proposed trade name GATTEX (teduglutide) for subcutaneous injection, by NPS Pharmaceuticals, Inc, for the proposed indication of treatment of adult patients with short bowel syndrome.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 28, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 20, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 21, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 17, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–20612 Filed 8–21–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.