

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Community Services Block Grant (CSBG) Model State Plan.
OMB No.: 0970-0382.

Description: Section 676 of the Community Services Block Grant (CSBG) Act requires States, including the District of Columbia and the

Commonwealth of Puerto Rico, and U.S. territories applying for CSBG funds to submit an application and plan (Model State Plan). The Model State Plan must meet statutory requirements prior to being funded with CSBG funds.

Applicants have the option to submit a detailed plan annually or biannually. Entities that submit a biannual plan must provide an abbreviated plan the following year if substantial changes to the initial plan will occur.

This request is to revise the Model State Plan format for States by automating the form, streamlining the

information, and incorporating accountability measures. The revised and automated form may impose an added first-use burden; however, this burden will diminish substantially in subsequent years. Copies of the proposed collection of information/ Model State Plan can be obtained by visiting <http://www.acf.hhs.gov/programs/ocs/programs/csbg>.

Respondents: State Governments, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Model State Plan	56	1	33	1,848

Estimated Total Annual Burden Hours: 1,848.

Additional Information

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1152]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

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 June 22, 2015.

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 0910-0608. Also include the FDA docket number found

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road, COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@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.

Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR 111.75(a)(1)(ii) (OMB Control Number 0910-0608)—Reinstatement

The Dietary Supplement Health and Education Act (DSHEA) (Pub. L. 103-417) added section 402(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(g)), which provides, in part, that the Secretary of Health and Human Services (the Secretary) may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if “it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.” Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

Part 111 (21 CFR part 111) establishes the minimum Current Good Manufacturing Practice (CGMP) necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. Section 111.75(a)(1) (21 CFR 111.75(a)(1)) establishes a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. Under § 111.75(a)(1)(ii), manufacturers may request an exemption from the requirements set forth in § 111.75(a)(1)(i) when the dietary ingredient is obtained from one or more suppliers identified in the petition. The regulation clarifies that we are willing to consider, on a case-by-case basis, a manufacturer's conclusion, supported by appropriate data and information in the petition submission, that it has developed a system that it would implement as a sound, consistent means of establishing, with no material diminution of assurance compared to the assurance provided by 100 percent identity testing, the identity of the dietary ingredient before use.

Section 111.75(a)(1) reflects our determination that manufacturers that

test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we added to § 111.75(a)(1) an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the Agency for such an exemption to 100 percent identity testing under § 10.30 (21 CFR 10.30) and the Agency grants such exemption. Such a procedure would be consistent with our stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements. Section 111.75(a)(1)(ii)

sets forth the information a manufacturer is required to submit in such a petition. The regulation also contains a requirement to ensure that the manufacturer keeps our response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95. The collection of information in § 111.95 has been approved under OMB control number 0910-0606.

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, importers, large businesses, and small businesses.

In the **Federal Register** of March 9, 2015 (80 FR 12491), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, but was not responsive to the four collection of information topics solicited in the notice and, therefore, is not discussed in this document.

We estimate the annual burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section; CGMP requirements for dietary supplements	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
111.75(a)(1)(ii)	1	1	1	8	8

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

In the last 3 years, we have not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients; therefore, the Agency estimates that one or fewer petitions will be submitted annually. Based on our experience with petition processes, we estimate it will take a requestor about 8 hours to prepare the factual and legal information necessary to support a petition for exemption and to prepare the petition. Although we have not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients in the last 3 years, we believe that OMB approval of these information collection provisions should be extended to provide for the potential future need of a firm in the dietary supplement industry to petition for an exemption from 100 percent identity testing of dietary ingredients.

Dated: May 18, 2015.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA-2015-N-0001]
Pharmacy Compounding 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: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

Date and Time: The meeting will be held on June 17, 2015, from 8:30 a.m. to 5 p.m., and on June 18, 2015, from 8:30 a.m. to 11:30 a.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/>