Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to Title III and VII State Program Report.

DATES: Submit written or electronic comments on the collection of information by April 15, 2013.

ADDRESSES: Submit electronic comments on the collection of information to: *Elena.Fazio@acl.hhs.gov* Submit written comments on the collection of information to: U.S. Department of Health and Human Services: Administration for Community Living, Washington, DC 20201, Attention: Elena Fazio.

FOR FURTHER INFORMATION CONTACT: Elena Fazio by telephone: (202)357–3583 or by email: *Elena.Fazio@acl.hhs.gov.*

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 request 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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility; (2) the accuracy of ACL'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.

The Older Americans Act (OAA) requires annual program performance reports from States. In compliance with this OAA provision, ACL developed a State Program Report (SPR) in 1996 as part of its National Aging Program Information System (NAPIS). The SPR collects information about how State Agencies on Aging expend their OAA funds as well as funding from other sources for OAA authorized supportive services. The SPR also collects information on the demographic and functional status of the recipients, and is a key source for ACL performance measurement. This collection includes minor revisions of the format from the 2010 approved version. The proposed revised version will be in effect for the FY 2014 reporting year and thereafter, while the current reporting, OMB Approval Number 0985–0008, will be extended to the end of the FY 2013 reporting cycle. The proposed FY 2014 version may be found on the ACL Web site link entitled Proposed SPR for Review available at *http://www.aoa.gov/AoARoot/Program_Results/OAA_Performance.aspx#national.*

ACL estimates the burden of this collection of information as follows: 2,828 hours.

Dated: February 6, 2013.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2013–03139 Filed 2–11–13; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0124]

Food and Drug Administration Drug Shortages Task Force and Strategic Plan; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: To assist the Food and Drug Administration (FDA or Agency) in drafting a strategic plan on drug shortages as required by the Food and Drug Administration Safety and Innovation Act, the Agency is seeking public comment from interested persons on certain questions related to drug and biological product shortages.

DATES: Submit either electronic or written comments by March 14, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0124, by any of the following methods:

Electronic Submissions:

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions:

Submit written submissions in the following way:

- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0124. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kalah Auchincloss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6208; Silver Spring, MD 20993, 301–796–0659.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). Section 1003 of FDASIA adds section 506D to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require the formation of a task force to develop and implement a strategic plan for enhancing the Agency's response to preventing and mitigating drug shortages. Section 506D of the FD&C Act (21 U.S.C. 356D) requires that the drug shortages strategic plan include the following:

- Plans for enhanced interagency and intra-agency coordination, communication, and decisionmaking;
- Plans for ensuring that drug shortages are considered when the

Secretary initiates a regulatory action that could precipitate a drug shortage or exacerbate an existing drug shortage;

- Plans for effective communication with outside stakeholders, including who the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared;
- Plans for considering the impact of drug shortages on research and clinical trials; and
- An examination of whether to establish a ''qualified manufacturing partner program'' as described in section 506D(a)(1)(C) of the FD&C Act.

II. Scope of Public Input Requested

Per the directive in section 506D, FDA has formed an internal Drug Shortages Task Force (Task Force) to develop and implement the drug shortages strategic plan. The Task Force is seeking comments from the public on issues related to the development of this strategic plan. Importantly, although FDASIA refers only to a drug shortages strategic plan, we anticipate that the strategic plan will consider prevention and mitigation of both drug and biological product shortages. Accordingly, we are interested in receiving comments on these questions from all parties, including those with an interest in biological products. The Task Force is specifically interested in seeking public input on the following questions:

1. In an effort to address the major underlying causes of drug and biological product shortages, FDA is seeking new ideas to encourage high-quality manufacturing and to facilitate expansion of manufacturing capacity.

a. To assist in the evaluation of product manufacturing quality, FDA is exploring the broader use of manufacturing quality metrics. With that in mind, FDA would like input on the following issues: What metrics do manufacturers currently use to monitor production quality? To what extent do purchasers and prescribers use information about manufacturing quality when deciding how to purchase or utilize products? What kinds of manufacturing quality metrics might be valuable for purchasers and prescribers when determining which manufacturers to purchase from or which manufacturers' products to prescribe? What kinds of manufacturing quality metrics might be valuable for manufacturers when choosing a contract manufacturer? How frequently would such metrics need to be updated to be meaningful?

b. The use of a qualified manufacturing partner program similar to one used under the Biomedical Advanced Research and Development Authority (BARDA) has been suggested as a potentially useful approach to expanding manufacturing capacity and preventing shortages. FDA recognizes that there are important potential differences between the BARDA program and the use of a parallel program to address shortages. For example, the BARDA program covers a relatively stable and limited number of products, but drugs at risk of shortage are many, may change rapidly over time, and are difficult to predict in advance. In addition, FDA does not have funding to pay manufacturers to participate in a drug shortages qualified manufacturing partner program or to guarantee purchase of the end product. With these differences in mind, is it possible to design a qualified manufacturing partner program that would have a positive impact on shortages?

c. Are there incentives that FDA can provide to encourage manufacturers to establish and maintain high-quality manufacturing practices, to develop redundancy in manufacturing operations, to expand capacity, and/or to create other conditions to prevent or mitigate shortages?

2. In our work to prevent shortages of drugs and biological products, FDA regularly engages with other U.S. Government Agencies. Are there incentives these Agencies can provide, separately or in partnership with FDA, to prevent shortages?

3. When notified of a potential or actual drug or biological product shortage, FDA may take certain actions to mitigate the impact of the shortage, including expediting review of regulatory submissions, expediting inspections, exercising enforcement discretion, identifying alternative manufacturing sources, extending expiration dates based on stability data, and working with the manufacturer to resolve the underlying cause of the shortage. Are there changes to these existing tools that FDA can make to improve their utility in managing shortages? Are there other actions that FDA can take under its existing authority to address impending shortages?

4. To manage communications to help alleviate potential or actual shortages, FDA uses a variety of tools, including posting information on our public shortages Web sites and sending targeted notifications to specialty groups. Are there other communication tools that FDA should use or additional information the Agency should share to help health care professionals, manufacturers, distributors, patients, and others manage shortages more effectively? Are there changes to our public shortage Web sites that would help enhance their utility for patients, prescribers, and others in managing shortages?

5. What impact do drug and biological product shortages have on research and clinical trials? What actions can FDA take to mitigate any negative impact of shortages on research and clinical trials?

6. What other actions or activities should FDA consider including in the strategic plan to help prevent or mitigate shortages?

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov*.

Dated: February 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03198 Filed 2–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Current Traumatic Brain Injury State Implementation Partnership Grantees; Non-Competitive One-Year Extension Funds

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Non-Competitive One-Year Extension Funds for Current Traumatic Brain Injury (TBI) State Implementation Partnership (H21) Grantees.

SUMMARY: The Health Resources and Services Administration (HRSA) will issue funding for a non-competitive one-year extension for the State Implementation Partnerships (H21) awards to current grantees whose awards are scheduled to end in fiscal year (FY) 2013. Up to $250,000 per