

all persons who receive a copy. Section VII requires DesignerWare to submit compliance reports to the Commission within sixty (60) days, and periodically thereafter as requested. It also requires the company to notify the Commission of changes in DesignerWare's corporate status.

Section VI of the proposed order with the DesignerWare principals requires respondents to distribute it to all current and future principals, officers, directors, and managers of any company that either respondent controls that engages in any covered RTO transaction as well as to all current and future employees, agents, and representatives having responsibilities relating to the subject matter of this order. It also requires the respondents to secure a signed and dated statement acknowledging receipt of the order from all persons who receive a copy. Section VII of the proposed order with the DesignerWare principals requires them to submit compliance reports to the Commission within sixty (60) days, and periodically thereafter as requested. In addition, this section requires them to notify the Commission of changes in their business or employment for three (3) years.

Under Section VIII of the proposed orders with both DesignerWare and its principals, respondents must retain documents relating to their compliance with the order for a five (5) year period. Finally, Section IX of both proposed orders is a provision "sunsetting" the orders after twenty (20) years, with certain exceptions.

The proposed orders against the RTO stores (which are identical to each other) contain similar injunctive provisions to those in the proposed orders with DesignerWare and its principals. Section I of each of the proposed orders bans the RTO stores from using monitoring technology in connection with any covered RTO transaction. Section II prohibits the stores from using geophysical location tracking technology to gather information from any computer without providing clear and prominent notice to the computer's renter and obtaining affirmative express consent from the computer's renter at the time the computer is rented. This section also requires clear and prominent notice to a computer user immediately prior to each time such technology is activated. The proposed RTO store orders also suspend the notice requirement if (1) there is a reasonable basis to believe that the computer has been stolen and (2) a police report has been filed. Section III of each of the proposed orders prohibits the deceptive collection of consumer

information via fake software registration notices.

Section IV bars the stores from collecting or attempting to collect a debt, money, or property pursuant to a consumer rental contract by using any information or data that was improperly obtained from a computer by monitoring technology. Section V requires that any data collected through any monitoring or tracking software without the requisite notice and consent be destroyed, and that any properly collected data be encrypted when transmitted. As fencing in, Section VI bars misrepresentations about the privacy or security of any personal information gathered from or about consumers.

Sections VII through X of the proposed RTO store orders contain reporting and compliance provisions. Section VII requires distribution of the order now and in the future to all current and future principals, officers, directors, and managers, and to persons with responsibilities relating to the subject matter of the order. It also requires the RTO stores to secure signed and dated statements acknowledging receipt of the order from all persons who receive a copy of the order. Section VIII requires the RTO stores to submit compliance reports to the Commission within sixty (60) days, and periodically thereafter as requested, and ensures notification to the Commission of changes in corporate status. Under Section IX, the RTO stores must retain documents relating to order compliance for a five (5) year period. Finally, Section X is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed orders. It is not intended to constitute an official interpretation of the proposed complaints or orders or to modify the terms of the orders in any way.

By direction of the Commission,
Commissioner Rosch abstaining.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting Notice for the President's Advisory Council on Faith-Based and Neighborhood Partnerships

In accordance with section 10(a)(2) of the Federal Advisory Committee Act

(Pub. L. 92-463), the President's Advisory Council on Faith-based and Neighborhood Partnerships announces the following three conference calls:

Name: President's Advisory Council on Faith-based and Neighborhood Partnerships Council Conference Calls

Time and Date: Thursday, October 18th 4 p.m.-5:30 p.m. (EDT); Thursday, November 15th 4 p.m.-5:30 p.m. (EST); December 13th 4 p.m.-5:30 p.m. (EST)

Place: All meetings announced herein will be held by conference call. The call-in line is: 1-866-823-5144; Passcode: 1375705. Space is limited so please RSVP to partnerships@hhs.gov to participate.

Status: Open to the public, limited only by lines available.

Purpose: The Council brings together leaders and experts in fields related to the work of faith-based and neighborhood organizations in order to: Identify best practices and successful modes of delivering social services; evaluate the need for improvements in the implementation and coordination of public policies relating to faith-based and other neighborhood organizations; and make recommendations for changes in policies, programs, and practices.

Contact Person for Additional Information: Please contact Ben O'Dell for any additional information about the President's Advisory Council meeting at partnerships@hhs.gov.

Agenda: Please visit <http://www.whitehouse.gov/partnerships> for further updates on the Agenda for the meeting.

Public Comment: There will be an opportunity for public comment at the conclusion of the meeting. Comments and questions can be asked over the conference call line, or sent in advance to partnerships@hhs.gov.

Dated: September 26, 2012.

Ben O'Dell,

Designated Federal Officer and Associate Director, HHS Center for Faith-Based and Neighborhood Partnerships.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Developmental Disabilities Protection & Advocacy Program Statement of Goals and Priorities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration Intellectual and Developmental Disabilities (AIDD), Administration for Community Living (ACL) is announcing that the proposed collection of

information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. This notice originally had a submission deadline of September 19, 2012. We are republishing the notice to due to incorrect contact information for OMB. Comments already successfully submitted will be given consideration and in the event an individual or organization resubmits comments, there most recent submission will be considered.

DATES: Submit written comments on the collection of information by November 1, 2012.

ADDRESSES: Submit written comments on the collection of information to OIRA_submission@omb.eop.gov or by

fax to 202.395.5806. Attn: OMB Desk Officer for ACL, Office of Information and Regulatory Affairs, OMB.

FOR FURTHER INFORMATION CONTACT: Brianne Burger, 202.618.5525.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. Federal statute and regulation require each State Protection and Advocacy (P&A) System to prepare and solicit public comment on a Statement of Goals and Priorities (SGP) for the P&A for Developmental Disabilities (PADD) program for each coming fiscal year. While the P&A is mandated to protect and advocate under a range of different federally authorized disabilities programs, only the PADD program requires an SGP. Following the

required public input for the coming fiscal year, the P&As submit the final version of this SGP to the Administration on Intellectual and Developmental Disabilities (AIDD). AIDD will aggregate the information in the SGPs into a national profile of programmatic emphasis for P&A Systems in the coming year. This aggregation will provide AIDD with a tool for monitoring of the public input requirement. Furthermore, it will provide an overview of program direction, and permit AIDD to track accomplishments against goals/targets, permitting the formulation of technical assistance and compliance with the Government Performance and Results Act of 1993. ACL estimates the burden of this collection of information as follows:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
P&A SGP	57	1	44	2,508

Estimated Total Annual Burden Hours: 2,508.

Dated: September 27, 2012.

Kathy Greenlee,

Administrator & Assistant Secretary for Aging.

[FR Doc. 2012-24236 Filed 10-1-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1010]

Draft Guidance for Industry on Initial Completeness Assessments for Type II Active Pharmaceutical Ingredient Drug Master Files Under the Generic Drug User Fee Amendments of 2012

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled "Initial Completeness Assessments for Type II API DMFs Under GDUFA." Under the Generic Drug User Fee Amendments of 2012 (GDUFA), holders of certain drug master files, namely, Type II active pharmaceutical ingredient (API) drug master files (DMFs) that are referenced in generic drug applications, or in

amendments or prior approval supplements to these applications, will be required to undergo an initial completeness assessment in accordance with FDA criteria. This guidance is intended to clarify the criteria FDA will use in the initial completeness assessment.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 3, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Jaewon Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-866-405-5367 or 301-796-6707.

SUPPLEMENTARY INFORMATION:

I. Background

Section 744B(a)(2)(D)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-42(a)(2)(D)(ii)) (FD&C Act), which was added by GDUFA, Title III, Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), states that, on or after October 1, 2012, a Type II API DMF will be deemed available for reference in an abbreviated new drug application (ANDA), ANDA amendment, or ANDA prior approval supplement (PAS), if the required fee has been paid *and* if the DMF has not failed an initial completeness assessment "in accordance with criteria to be published by" FDA. Any Type II API DMF intended for reference in a generic drug submission for which the fee is paid will undergo an initial completeness assessment. Section 744B(a)(2)(D)(iii) of the FD&C Act requires FDA to make publicly available on its Web site a list of DMF numbers that correspond to DMFs that have successfully undergone an initial completeness assessment in accordance with criteria to be published by FDA and are available for reference.