

the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC Web site at: <http://www.cdc.gov/vaccines/hcp/vis/index.html>.

HHS/CDC is proposing updated versions of the MMR (measles, mumps, and rubella) and MMRV (measles, mumps, rubella, and varicella) vaccine information statements.

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug

Administration, and parent and health care provider groups.

We invite written comment on the proposed revised vaccine information materials entitled “MMR Vaccine (Measles, Mumps, and Rubella): What You Need to Know” and “MMRV Vaccine (Measles, Mumps, Rubella, and Varicella): What You Need to Know.” Copies of the proposed vaccine information materials are available at <http://www.regulations.gov> (see Docket Number CDC–2016–0094). Comments submitted will be considered in finalizing these materials. When the final materials are published in the **Federal Register**, the notice will include an effective date for their mandatory use.

Dated: October 13, 2016.

**Sandra Cashman,**

*Executive Secretary, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:*

*Title:* Renewal of Office of Community Services (OCS) Community Economic Development (CED) Standard Reporting Format.

*OMB No.:* 0970–0386.

*Description:* The Office of Community Services (OCS) will continue collecting key information about projects funded through the Community Economic Development (CED) program. The legislative requirement for this program is in Title IV of the Community Opportunities, Accountability and Training and Educational Services Act (COATS Human Services

Reauthorization Act) of October 27, 1998, Public Law 105–285, section 680(b) as amended. The reporting format, Performance Progress Report (PPR), collects information concerning the outcomes and management of CED projects. OCS will use the data to critically review the overall design and effectiveness of the program.

The PPR will continue to be administered to all active grantees of the CED program. Grantees will be required to use this reporting tool for their semi-annual reports to be submitted twice a year. The current PPR replaced both the annual questionnaire and other semi-annual reporting formats, which resulted in an overall reduction in burden for the grantees while significantly improving the quality of the data collected by OCS. OCS seeks to renew this PPR to continue to collect quality data from grantees. To ensure the burden on grantees is not increased, but that the information collected demonstrates the full impact of the program, OCS has conducted an in-depth review to remove indicators that are not being used; add indicators that will allow OCS to better demonstrate the impact of the program; and clarify language of some indicators to reduce grantee confusion. Based on this review, proposed changes to the CED PPR are minimal and focused on clarifying language, removing outdated indicators, and gathering minimal additional data that will not increase the burden on grantees. These measures will result in a stronger and streamlined CED PPR that will allow for the following:

- More clarity for grantees and ability to avoid confusion around what data should be provided.
- Increased consistency across data.
- Ability for OCS and grantees to better demonstrate the impact of these projects.

A summary of all proposed changes can be provided upon request.

*Respondents:* Active CED Grantees

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
PPR for Current OCS–CED Grantees .....	170	2	1.5	510

*Estimated Total Annual Burden Hours:*

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), 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, 330 C Street SW., Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto: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 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.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-3118]

#### **Mallinckrodt Pharmaceuticals; Proposal To Withdraw Approval of an Abbreviated New Drug Application for Extended-Release Methylphenidate Tablets; Opportunity for a Hearing**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of an abbreviated new drug application (ANDA) for methylphenidate hydrochloride (HCl) extended-release (ER) tablets and is announcing an opportunity for the holder of the ANDA to request a hearing on this proposal.

**DATES:** Mallinckrodt Pharmaceuticals may submit a request for a hearing by November 17, 2016. Submit all data, information, and analyses upon which the request for a hearing relies by December 19, 2016. Submit written or electronic comments by December 19, 2016.

**ADDRESSES:** The request for a hearing may be submitted by Mallinckrodt Pharmaceuticals by either 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 to submit your request for a hearing. Comments submitted electronically to <http://www.regulations.gov>, including any attachments to the request for hearing, will be posted to the docket unchanged.

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

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

- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request does not include any confidential information that you may not wish to be publicly posted, such as confidential business information, *e.g.*, a manufacturing process. The request for a hearing must include the Docket No. FDA-2016-N-3118 for "Mallinckrodt Pharmaceuticals; Proposal to Withdraw Approval of an Abbreviated New Drug Application for Extended-Release Methylphenidate Tablets; Opportunity for a Hearing." The request for a hearing will be placed in the docket and publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Mallinckrodt Pharmaceuticals may submit all data and analysis upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- *Confidential Submissions*—To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of any decisions on this matter. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov> or available at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Submit both copies to the Division of Dockets Management. Any information marked as "confidential" will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law.

*Comments Submitted by Other Interested Parties:* For all comments submitted by other interested parties, submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

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

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2016-N-3118 for "Mallinckrodt Pharmaceuticals; Proposal to Withdraw Approval of an Abbreviated New Drug Application for Extended-Release Methylphenidate Tablets; Opportunity for a Hearing." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management