Dated: August 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–19051 Filed 8–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0883]

Purdue Pharma L.P.; Withdrawal of Approval of a New Drug Application for Oxycontin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for OXYCONTIN (oxycodone hydrochloride) Extended-Release Tablets, held by Purdue Pharma L.P. (Purdue), One Stamford Forum, Stamford, CT 06901–3431. Purdue has voluntarily requested that approval of this application (NDA 20–553) be withdrawn and has waived its opportunity for a hearing.

DATES: Effective August 7, 2013.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522.

SUPPLEMENTARY INFORMATION: FDA approved NDA 20–553 for OXYCONTIN (oxycodone hydrochloride) Extended-Release Tablets, 10 milligrams (mg), 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg, (original OxyContin), on December 12, 1995. A reformulated version of these products, OXYCONTIN (oxycodone hydrochloride) Extended-Release Tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg (reformulated OxyContin), is the subject of NDA 22–272, also held by Purdue and initially approved on April 5, 2010. Reformulated OxyContin was developed with physicochemical properties that are intended to make the tablet more difficult to manipulate for purposes of abuse or misuse. Both original and reformulated OxyContin are opioid agonist products. Original OxyContin was indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

In correspondence dated August 10, 2010, Purdue notified FDA that it had ceased shipment of original OxyContin, and FDA subsequently moved original OxyContin to the ''Discontinued Drug Product List'' section of the Orange Book. In a letter to FDA dated March 19, 2013, Purdue requested that FDA withdraw approval of NDA 20–553 for original OxyContin, noting that the original formulation of OxyContin was subject to abuse and misuse, and that it was ''not possible to develop labeling or REMS provisions that would create a positive risk/benefit ratio for the original formulation of OxyContin.'' In that letter, Purdue waived its right to a hearing.

On April 18, 2013, FDA published notice of its determination that original OxyContin, NDA 20–553, was withdrawn from sale for reasons of safety or effectiveness (78 FR 23273). The notice concluded that ''[o]riginal OxyContin . . . poses an increased potential for abuse by certain routes of administration, when compared to reformulated OxyContin. Based on the totality of the data and information available to the Agency at this time, FDA concludes that the benefits of original OxyContin no longer outweigh its risks.''

Under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 20–553, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: July 30, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2013–18694 Filed 8–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request: National Institute of Mental Health Data Access Request and Use Certification

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Mental Health (NIMH), the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 28, 2013, Volume 78, Number 102, Pages 31947–31948 and allowed 60-days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301–443–4335 or email your request, including your address to: *kshropsh@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The National Institute of Mental Health Data Access Request and Use Certification (previously National Database for Autism Research Data Access Request), 0925–0667, Revision, Expiration Date: 01/31/2016; National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

Need and Use of Information Collection: NIMH recently received OMB approval for use of the National Database for Autism Research (NDAR) Data Use Certification (DUC) Form. NIMH is interested in renaming this form the ''NIMH Data Access Request and Use Certification (DUC) Form'' and using it to meet the unique data access

needs of all NIMH data repositories. The NIMH DUC form is necessary for ''Recipient'' Principal Investigators and their organization or corporations with approved assurance from the DHHS Office of Human Research Protections to access data or images from NIMH repositories and datasets for research purposes. The primary use of this information is to document, track, monitor, and evaluate the use of the NIMH repositories/datasets, as well as to notify interested recipients of updates, corrections or other changes to the database. There are currently three data repositories/sets positioned to use the NIMH DUC form: NDAR, the NIH Pediatric MRI Data Repository (PedsMRI), and the NIMH Clinical Research Datasets (NCRD).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 380.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Type of respondent	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
NIMH Data Access Request and Use Certification.	Principal Investigators/Research Assistant.	240	1	95/60	380

Dated: July 25, 2013.

Sue Murrin,

Executive Officer, NIMH, NIH.

[FR Doc. 2013–19072 Filed 8–6–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request: Autism Spectrum Disorder Research Portfolio Analysis

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Mental Health (NIMH), the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 24, 2013, Volume 78, Number 101, Pages 31568–31569 and allowed 60-days for public comment. One public comment was received; in this comment, a request was made for access to any data that is collected on autism projects that are funded. This comment was considered, but it did not result in alteration to the data collection or data management process because steps are already in place to make the data publicly accessible via an online *Web Tool* on the IACC Web site. No comments that specifically addressed cost and hour burden were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: The Office of Autism Research Coordination, NIMH, NIH, Neuroscience Center, 6001 Executive Blvd., MSC 9663, Room 6184, Bethesda, MD 20892 or Email your request, including your address to: *iaccpublicinquiries@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Autism Spectrum Disorder (ASD) Research Portfolio Analysis, 0925—NEW-National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of the ASD portfolio analysis is to collect research funding data from U.S. and international ASD research funders, to assist the Interagency Autism Coordinating Committee (IACC) in fulfilling the requirements of the Combating Autism Act, and to inform the committee and interested stakeholders of the funding landscape and current directions for ASD research. Specifically, these analyses will examine the extent to which current funding and research topics align with the *IACC Strategic Plan for ASD Research.* The findings will help guide future funding priorities by outlining current gaps and opportunities in ASD research as well as serving to highlight annual activities and research progress.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 419.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents (funders)	Number of respondents	Number of response per respondent	Average time per response (in hours)	Total burden hours
U.S. Federal	26	36	15/60	234
U.S. Private	12	54	15/60	162
International Government	4	14	15/60	14
International Private	4	9	15/60	9