accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 25, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Diane Goyette at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 1, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–19036 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–0779]

Retrospective Review of Draft Guidance Documents Issued Before 2010; Withdrawal of Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an initiative in the Center for Drug Evaluation and Research (CDER) involving the review of draft guidance documents issued before 2010 to determine their status, and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. Guidances that are no longer up to date, and for which more current information is available, will be withdrawn. Guidances that reflect CDER's current thinking, CDER will decide whether to revise or finalize. This notice describes CDER's initiative, announces the first group of guidances to be withdrawn, describes in general terms draft guidances under consideration for revision or finalization, and explains how CDER is making this process as transparent as possible.

DATES: General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit electronic comments on Agency guidance documents 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to Agency guidance documents.

FOR FURTHER INFORMATION CONTACT: Kimberly K. Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993–0002, 301–796–2357, *kimberly.k.thomas@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In September 2000, FDA issued the final rule ''Administrative Practices and Procedures; Good Guidance Practices'' (GGP) (65 FR 56468; September 19, 2000). The GGP regulation describes FDA policies and procedures for the development, issuance, and use of guidance documents and makes these Agency policies and procedures clear to the public. The GGP regulation provides for developing and issuing guidances that set forth initial interpretations of statutory or regulatory requirements, explain changes in interpretation of policies that are of other than minor in nature, or discuss complex scientific issues or highly controversial issues. The GGP regulation also requires that such guidances be issued in draft for public comment before they are finalized (Level 1 guidances). In addition, the GGP regulation explains that FDA will periodically review existing guidance documents to determine whether they need to be changed or withdrawn.

A key component of the GGP regulation is ensuring transparency during guidance development and issuance. Since finalization of the GGP regulation in September 2000, CDER has issued an average of approximately 20 draft guidances each year, seeking public input and carefully considering that input before issuing final versions of the guidances. In many cases, guidances were not finalized most often because of higher staff priorities. However, over the years, because of new information, scientific developments, and emerging technologies, draft guidances were also revised, and reissued or withdrawn.[1]

Recently, CDER launched an initiative to review draft guidance documents published before 2010 to decide which guidances to withdraw, revise, or finalize with only minor changes. CDER is withdrawing draft guidances that are no longer up to date. CDER is also actively reviewing the draft guidances to determine which ones to either revise or finalize. This notice lists the first group of guidances CDER has identified for withdrawal, describes generally what guidances are being reviewed, and describes how CDER will keep the public informed of the guidances that are available with the goal of making the initiative transparent and consistent with the GGP regulation (21 CFR 10.115).

II. Withdrawal of Guidances

CDER has reviewed many draft guidances published before 2010. As a result of this review, CDER identified 23 draft guidances for withdrawal. The guidances are being withdrawn because they are out of date, thus of little use to the pharmaceutical industry. In most cases, FDA has developed other guidances and resources to assist industry with clinical evaluation and requirements for drug approval. The guidances identified for withdrawal relate to these topics:

- Current good manufacturing practice (cGMP) compliance specific to manufacturing, processing, and dose unit sampling and assessment;
- Development of antimicrobial drugs for the treatment of acute bronchitis, bacterial meningitis, bacterial prostatitis, bacterial vaginosis, catheter-related bloodstream infections, febrile neutropenia, gonorrhea, Lyme disease, streptococcal pharyngitis and tonsillitis, uncomplicated urinary tract infections, and vuvlovaginal candidiasis;
- Clinical trials for developing antimicrobial drugs and packaging of

[1] When Level 1 guidances are revised, they are usually issued as draft, version 2s, for public input before being issued in final form. When a guidance needs to be withdrawn, a notice is sometimes published in the **Federal Register** announcing that the guidance has been withdrawn. If no withdrawal announcement is made, CDER maintains a current list of new/revised/withdrawn guidances on the CDER guidance Web page at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

inhalation products in semipermeable container systems;

- Approval of abbreviated new drug applications (ANDAs) and 505(b)(2) applications under the Drug Price Competition and Patent Term Restoration Act of 1984 (i.e., the Hatch-Waxman Act);
- Procedures relating to submission of patent information, submission of marketing applications, and forms for registration and disclosure of information;
- Labeling in ANDAs; and
- Qualifying for pediatric exclusivity under the Best Pharmaceuticals for Children Act.

CDER is withdrawing the following guidances:

1. ''Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients''—issued April 1998.
2. ''Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment''—issued November 2003.
3. ''Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution''—issued May 2001.
4. ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by CDER, Beginning on January 1, 2000''—issued December 1999.

For information on the four preceding guidances, contact the Office of Compliance in CDER.

5. ''Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products''—issued February 1997.
6. ''Empiric Therapy of Febrile Neutropenia—Developing Antimicrobial Drugs for Treatment''—issued July 1998.
7. ''Lyme Disease—Developing Antimicrobial Drugs for Treatment''—issued July 1998.
8. ''Secondary Bacterial Infections of Acute Bronchitis—Developing Antimicrobial Drugs for Treatment''—issued July 1998.
9. ''Streptococcal Pharyngitis and Tonsillitis—Developing Antimicrobial Drugs for Treatment''—issued July 1998.
10. ''Uncomplicated Gonorrhea—Developing Antimicrobial Drugs for Treatment''—issued July 1998.
11. ''Uncomplicated Urinary Tract Infections—Developing Antimicrobial Drugs for Treatment''—issued July 1998.
12. ''Vulvovaginal Candidiasis—Developing Antimicrobial Drugs for Treatment''—issued July 1998.
13. ''Bacterial Vaginosis—Developing Antimicrobial Drugs for Treatment''—issued July 1998.
14. ''Acute Bacterial Meningitis—Developing Antimicrobial Drugs for Treatment''—issued July 1998.
15. ''Acute or Chronic Bacterial Prostatitis—Developing Antimicrobial Drugs for Treatment''—issued July 1998.
16. ''Developing Antimicrobial Drugs—General Considerations for Clinical Trials''—issued July 1998.
17. ''Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment''—issued October 1999.

For information on the preceding 13 guidances (number 5 through 17), contact the Office of Antimicrobial Products in the Office of New Drugs in CDER.

18. ''Labeling Over-the-Counter (OTC) Human Drug Products—Updating Labeling in ANDAs''—issued February 2001.

For information on the preceding guidance (number 18), contact the Office of Drug Evaluation IV in the Office of New Drugs in CDER.

19. ''Inhalation Drug Products Packaged in Semipermeable Container Closure Systems''—issued July 2002.
20. ''Listed Drugs, 30-Month Stays, and ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers''—issued November 2004.
21. ''Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications''—issued October 2000.
22. ''Submission of Patent Information for Certain Old Antibiotics''—issued December 2008.

For information on the preceding four guidances (number 19 through 22), contact the Office of Pharmaceutical Science in CDER.

23. ''Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act''—issued September 1999.

For information on the preceding guidance (number 23), contact the Pediatric and Maternal Health Staff in the Office of New Drugs in CDER.

III. Revision or Finalization of Guidances

In addition to identifying the first set of guidances for withdrawal, CDER also identified guidances for revision or finalization. CDER is in the process of developing a plan for their completion. Guidances for revision or finalization are specific to the following topics:

- Biopharmaceutics;
- Chemistry, manufacturing, and controls;
- Clinical pharmacology;
- Combination products;
- cGMP compliance;
- Development of antimicrobial drugs;
- Drug advertisements;
- Drug safety;
- Electronic submissions;
- Labeling;
- OTC products;
- Pharmacology and toxicology;
- Procedural guidances; and
- Radiopharmaceuticals.

IV. Maintaining Transparency

CDER would like to make this process as transparent as possible, consistent with the GGP regulation. As a result, CDER is issuing this notice announcing the initiative for draft guidance review, and listing the first group of guidances for withdrawal. CDER also maintains and regularly updates on its guidance Web site a list of new, revised, and withdrawn guidances (at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*). Each year CDER also publishes on its guidance Web site a Guidance Agenda, which lists new draft and revised draft guidances planned for issuance in the given calendar year.

V. Comments

Interested persons may submit either electronic comments regarding Agency guidance documents 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.*

VI. Electronic Access

Persons with access to the Internet may obtain CDER guidance documents at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

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