performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. In accordance with this criteria, we consider coverage for CAS reasonable and necessary (section 1862(A)(1)(a) of the Social Security Act). *Form Number:* CMS–10199 (OMB control number: 0938–1011); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,370; *Total Annual Responses:* 4,110; *Total Annual Hours:* 28,998. (For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Conditions of Coverage for Organ Procurement Organizations and Supporting Regulations; Use: Section 1138(b) of the Social Security Act, as added by section 9318 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509), sets forth the statutory qualifications and requirements that organ procurement organizations (OPOs) must meet in order for the costs of their services in procuring organs for transplant centers to be reimbursable under the Medicare and Medicaid programs. An OPO must be certified and designated by the Secretary as an OPO and must meet performance-related standards prescribed by the Secretary. The corresponding regulations are found at 42 CFR part 486 (Conditions for Coverage of Specialized Services Furnished by Suppliers) under subpart G (Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations).

Since each OPO has a monopoly on organ procurement within its designated service area (DSA), we must hold OPOs to high standards. Collection of this information is necessary for us to assess the effectiveness of each OPO and determine whether it should continue to be certified as an OPO and designated for a particular donation service area by the Secretary or replaced by an OPO that can more effectively procure organs within that DSA. *Form Number:* CMS–R–13 (OMB control number: 0938–0688); *Frequency:* Occasionally; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 58; *Total Annual Responses:* 58; *Total Annual Hours:* 13,546. (For policy questions regarding this collection contact Diane Corning at 410–786–8486.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Ambulatory Surgical Center Conditions for Coverage; *Use:* The Ambulatory Surgical Center (ASC) Conditions for Coverage (CfCs) focus on a patient-centered, outcome-oriented, and transparent processes that promote quality patient care. The CfCs are designed to ensure that each facility has properly trained staff to provide the appropriate type and level of care for that facility and provide a safe physical environment for patients. The CfCs are used by Federal or state surveyors as a basis for determining whether an ASC qualifies for approval or re-approval under Medicare. We, along with the healthcare industry, believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. *Form Number:* CMS–10279 (OMB control number: 0938–1071); *Frequency:* Annual; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 5,500; *Total Annual Responses:* 5,500; *Total Annual Hours:* 209,000. (For policy questions regarding this collection contact Jacqueline Leach at 410–786–4282.)

Dated: April 26, 2017.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2017–08738 Filed 4–27–17; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–1551]**

### Determination That DEMEROL (Meperidine Hydrochloride) Injectable and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements. Through this notice, FDA is hoping to stimulate the economy and increase the regulatory certainty with respect to generic versions of these drug products by confirming that generic versions of the subject drug products may continue to be marketed.

**FOR FURTHER INFORMATION CONTACT:** Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or

effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

| Application No. | Drug name | Active ingredient(s) | Strength(s) | Dosage form/route | Applicant |
|---|---|---|---|---|---|
| NDA 005010 | DEMEROL | Meperidine Hydrochloride | 50 milligrams (mg)/5 milliliter (mL). | Syrup; Oral | U.S. Pharmaceutical Holdings II, LLC. |
| NDA 006035 | METHERGINE | Methylergonovine Maleate | 0.2 mg | Tablet; Oral | Edison Therapeutics LLC. |
| NDA 007337 | PERCODAN and PERCODAN–DEMI. | Aspirin, Oxycodone Hydrochloride, Oxycodone Terephthalate. | 325 mg, 4.5 mg, 0.38 mg; and 325 mg, 2.25 mg, 0.19 mg. | Tablet; Oral | Endo Pharmaceuticals Inc. |
| NDA 008720 | LEVO–DROMORAN | Levorphanol Tartrate | 2 mg | Tablet; Oral | Valeant Pharmaceuticals North America LLC. |
| NDA 008848 | PAMINE and PAMINE FORTE. | Methscopolamine Bromide. | 2.5 mg and 5 mg | Tablet; Oral | Fougera Pharmaceuticals Inc. |
| NDA 009470 | XYLOCAINE VISCOUS | Lidocaine Hydrochloride | 2% | Solution; Oral | Fresenius Kabi USA, LLC. |
| NDA 010485 | ATARAX | Hydroxyzine Hydrochloride. | 10 mg/5 mL | Syrup; Oral | Pfizer Inc. |
| NDA 010742 | COMPAZINE | Prochlorperazine Edisylate. | Equivalent to (EQ) 5 mg Base/mL. | Injectable; Injection | GlaxoSmithKline. |
| NDA 012111 | MYDRIACYL | Tropicamide | 0.5%; 1% | Solution/Drops; Ophthalmic. | Alcon Laboratories Inc. |
| NDA 012248 | PLEGINE | Phendimetrazine Tartrate | 35 mg | Tablet; Oral | Wyeth Ayerst Laboratories. |
| NDA 012365 | SOMA COMPOUND | Aspirin; Carisoprodol | 325 mg; 200 mg | Tablet; Oral | Meda Pharmaceuticals Inc. |
| NDA 012366 | SOMA COMPOUND W/ CODEINE. | Aspirin; Carisoprodol; Codeine Phosphate. | 325 mg; 200 mg; 16 mg | Tablet; Oral | Ditto. |
| NDA 016012 | VIVACTIL | Protriptyline Hydrochloride | 5 mg; 10 mg | Tablet; Oral | Teva Women's Health, Inc. |
| NDA 017352 | FASTIN | Phentermine Hydrochloride. | 30 mg | Capsule; Oral | GlaxoSmithKline. |
| NDA 017690 | IMODIUM | Loperamide Hydrochloride | 2 mg | Capsule; Oral | Johnson & Johnson Consumer Inc. |
| NDA 017694 | IMODIUM | Loperamide Hydrochloride | 2 mg | Capsule; Oral | Ditto. |
| NDA 017741 | FLORONE | Diflorasone Diacetate | 0.05% | Cream; Topical | Pharmacia and Upjohn Co. |
| NDA 017802 | LO/OVRAL–28 | Ethinyl Estradiol; Norgestrel. | 0.03 mg; 0.3 mg | Tablet; Oral-28 | Wyeth Pharmaceuticals Inc. |
| NDA 017857 | STADOL | Butorphanol Tartrate | 2 mg/mL | Injectable; Injection | Delcor Asset Corporation. |
| NDA 017857 | STADOL PRESERVATIVE FREE. | Butorphanol Tartrate | 1 mg/mL; 2 mg/mL | Injectable; Injection | Ditto. |
| NDA 018342 | WELLCOVORIN | Leucovorin Calcium | EQ 5 mg Base; EQ 25 mg Base. | Tablet; Oral | GlaxoSmithKline. |
| NDA 018353 | FLAGYL I.V. | Metronidazole Hydrochloride. | EQ 500 mg Base/Vial | Injectable; Injection | G.D. Searle LLC, a subsidiary of Pfizer Inc. |
| NDA 018733 | TALWIN NX | Naloxone Hydrochloride; Pentazocine Hydrochloride. | EQ 0.5 mg Base; EQ 50 mg Base. | Tablet; Oral | Sanofi-Aventis U.S. LLC. |
| NDA 019488 | CARDENE | Nicardipine Hydrochloride | 20 mg; 30 mg | Capsule; Oral | Chiesi USA, Inc. |
| NDA 019578 | MEFLOQUINE HYDROCHLORIDE. | Mefloquine Hydrochloride | 250 mg | Tablet; Oral | U.S. Army Walter Reed Army Institute Research. |
| NDA 019591 | LARIAM | Mefloquine Hydrochloride | 250 mg | Tablet; Oral | Hoffmann-La Roche Inc. |
| NDA 019735 | FLOXIN | Ofloxacin | 200 mg; 300 mg; 400 mg | Tablet; Oral | Janssen Pharmaceuticals, Inc. |
| NDA 019890 | STADOL | Butorphanol Tartrate | 1 mg/Spray | Spray, Metered; Nasal | Bristol-Myers Squibb Co. |
| NDA 020142 | CATAFLAM | Diclofenac Potassium | 50 mg | Tablet; Oral | Novartis Pharmaceuticals Corp. |
| NDA 020254 | VOLTAREN–XR | Diclofenac Sodium | 100 mg | Extended-Release Tablet; Oral. | Ditto. |
| NDA 020312 | UNIVASC | Moexipril Hydrochloride | 7.5 mg; 15 mg | Tablet; Oral | UCB, Inc. |
| NDA 020346 | ZYRTEC | Cetirizine Hydrochloride | 5 mg/5 mL | Syrup; Oral | Johnson & Johnson Consumer Inc. |
| NDA 020584 | LODINE XL | Etodolac | 400 mg; 500 mg; 600 mg | Extended-Release Tablet; Oral. | Wyeth Pharmaceuticals Inc. |
| NDA 020625 | ALLEGRA | Fexofenadine Hydrochloride. | 60 mg | Capsule; Oral | Sanofi-Aventis U.S. LLC. |
| NDA 020729 | UNIRETIC | Hydro chlorothiazide; Moexipril Hydrochloride. | 12.5 mg/7.5 mg; 12.5 mg/15 mg; 25 mg/15 mg. | Tablet; Oral | UCB, Inc. |
| NDA 021066 | ZADITOR | Ketotifen Fumarate | EQ 0.025% Base | Solution/Drops; Ophthalmic. | Alcon Pharmaceuticals, Ltd. |
| NDA 021224 | RAZADYNE | Galantamine Hydrobromide. | 4 mg/mL | Solution; Oral | Janssen Pharmaceuticals, Inc. |
| NDA 021378 | COMBUNO$_X$ | Ibuprofen; Oxycodone Hydrochloride. | 400 mg; 5 mg | Tablet; Oral | Forest Laboratories, Inc. |
| NDA 021473 | CIPRO XR | Ciprofloxacin; Ciprofloxacin Hydrochloride. | 212.6 mg; EQ 287.5 mg Base; 425.2 mg; EQ 574.9 mg Base. | Extended-Release Tablet; Oral. | Bayer HealthCare Pharmaceuticals, Inc. |
| NDA 021606 | ZEMPLAR | Paricalcitol | 4 micrograms (mcg) | Capsule; Oral | AbbVie Inc. |
| NDA 021729 | ABILIFY | Aripiprazole | 10 mg and 15 mg | Tablet, Orally Disintegrating; Oral. | Otsuka Pharmaceutical Co., Ltd. |

| Application No. | Drug name | Active ingredient(s) | Strength(s) | Dosage form/route | Applicant |
|---|---|---|---|---|---|
| NDA 050072 | PENBRITIN–S | Ampicillin Sodium | EQ 125 mg Base/Vial; EQ 250 mg Base/Vial; EQ 500 mg Base/Vial; EQ 1 gram (g) Base/Vial; EQ 2 g Base/Vial; EQ 4 g Base/Vial. | Injectable; Injection | Wyeth Ayerst Laboratories. |
| NDA 050309 | POLYCILLIN–N | Ampicillin Sodium | EQ 125 mg Base/Vial; EQ 250 mg Base/Vial; EQ 500 mg Base/Vial; EQ 1 g Base/Vial; EQ 2 g Base/Vial. | Injectable; Injection | Bristol Laboratories Inc. |
| NDA 050674 | VANTIN | Cefpodoxime Proxetil | EQ 100 mg Base; EQ 200 mg Base. | Tablet; Oral | Pharmacia and Upjohn Co. |
| ANDA 064170 | CEFAZOLIN SODIUM | Cefazolin Sodium | EQ 10 g Base/Vial; EQ 20 g Base/Vial. | Injectable; Injection | Fresenius Kabi USA, LLC. |
| ANDA 075406 | OGESTREL 0.5/50–21 | Ethinyl Estradiol; Norgestrel. | 0.05 mg; 0.5 mg | Tablet; Oral-21 | Watson Laboratories, Inc. |
| ANDA 085106 | PERCOCET | Acetaminophen; Oxycodone Hydrochloride. | 325 mg; 5 mg | Tablet; Oral | Vintage Pharmaceuticals LLC. |
| ANDA 089351 | ROXICET | Acetaminophen; Oxycodone Hydrochloride. | 325 mg/5 mL; 5 mg/5 mL | Solution; Oral | West-Ward Pharmaceuticals International Ltd. |
| ANDA 089456 | PERPHENAZINE | Perphenazine | 8 mg | Tablet; Oral | ANI Pharmaceuticals, Inc. |
| ANDA 089457 | PERPHENAZINE | Perphenazine | 16 mg | Tablet; Oral | Teva Pharmaceuticals USA. |
| ANDA 089707 | PERPHENAZINE | Perphenazine | 2 mg | Tablet; Oral | Ditto. |
| ANDA 089708 | PERPHENAZINE | Perphenazine | 4 mg | Tablet; Oral | Do. |

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

This is not a significant regulatory action subject to Executive Order 12866, and does not impose any additional burden on regulated entities.

Dated: April 24, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–08582 Filed 4–27–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–1114]**

### Pharmaceutical Distribution Supply Chain Pilot Projects; Reopening of Comment Period; Request for Information

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

**ACTION:** Notice; reopening of comment period; request for information.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening the comment period for the Request for Information that appeared in the **Federal Register** of April 15, 2016. In the Request for Information, FDA requested comments regarding issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, and identifying system attributes that are necessary to implement the requirements established under the Drug Supply Chain Security Act (DSCSA). The information gathered from additional public comments will further inform the design and development of the pilot project(s) that FDA establishes under the DSCSA. FDA is reopening the comment period to receive updated comments and any new information.

**DATES:** FDA is reopening the comment period on the Request for Information published April 15, 2016 (81 FR 22279). Submit either electronic or written comments by April 30, 2018. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 30, 2018. The *https://www.regulations.gov/* electronic filing system will accept comments until midnight Eastern Time at the end of April 30, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov/.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://www.regulations.gov/.*