

| 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has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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/>.

• 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-1114 for “Pharmaceutical Distribution Supply Chain Pilot Projects; Reopening of Comment Period; Request for Information.” Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov/> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. 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 comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov/>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other

applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov/> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Daniel Bellingham, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, DSCSAPilotProjects@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 15, 2016, FDA published a Request for Information with a 30-day comment period to request comments relating to FDA implementation of the DSCSA. To permit additional and update submissions, we are reopening this comment period and extending it for April 30, 2018. We are particularly interested in comments regarding past or present pilot projects related to enhancing the safety and security of the pharmaceutical distribution supply chain. Stakeholders that may be interested in responding to this request for information include manufacturers, repackagers, wholesale distributors, dispensers, State and Federal authorities, solution providers, and standards organizations, and other interested persons. FDA is particularly interested in learning about the practices, processes, and systems that supply chain stakeholders have used or considered using in such pilot projects. This includes, but is not limited to, information about the following:

- Utilizing the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;
- Technical capabilities each sector of the supply chain to comply with systems and processes needed to utilize the product identifier to enhance the tracing of a product; or
- System attributes that are necessary to implement the requirements established under the DSCSA.

Interested persons are requested to provide any other relevant information that may inform FDA’s development of a pilot project under the DSCSA.

FDA is reopening the comment period for the Request for Information for 1 year, until April 30, 2018. The Agency believes that an additional comment period of 1 year will allow time for interested persons to submit new, additional, or updated comments on these important issues.

Dated: April 19, 2017.

Anna K. Abram,

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

[FR Doc. 2017-08583 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-2017-N-1393]

Government-Owned Inventions; Availability for Licensing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The invention listed in this document is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed in this document may be obtained by writing to the indicated licensing contact at the Food and Drug Administration (FDA) Technology Transfer Program, 10903 New Hampshire Ave., Bldg. 1, Rm. 4213, Silver Spring, MD 20993, telephone: 240-402-2561, FAX: 301-847-3539. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Title of Abstract: Solid-Phase Purification of Synthetic DNA Sequences.

Description of Technology: Scientists at FDA have developed a high-throughput method for purifying full-length phosphorothioate and native DNA sequences. This method comprises a modified silica gel that enables capture of DNA sequences functionalized with a novel linker specifically designed for exclusive capture of full-length sequences. This