comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Alternatively, you may submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to the office that you are ordering from to assist in processing your request.

FOR FURTHER INFORMATION CONTACT: Ribhi Shawar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4604, Silver Spring, MD 20993–0002, 301–796–6698; or Joseph Toerner, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance, when finalized, is intended to assist drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs and AST devices and who seek to coordinate development of these products such that the AST device could be cleared either at the time of new drug approval or shortly thereafter.

Specifically, the guidance intends to describe the interactions between drug sponsors and device manufacturers for coordinated development of a new antimicrobial drug and an AST device; explain the considerations for submitting separate applications to the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) when seeking clearance of an AST device coincident with, or soon following, antimicrobial drug approval; and clarify that the review of the new antimicrobial drug product and AST device(s) will remain independent, and that coordinated development does not influence the review timelines for either product.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on coordinated development of antimicrobial drugs and antimicrobial susceptibility test devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* and a search capability for all Center for Drug Evaluation and Research guidance documents is available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400061 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120, the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078, the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

Dated: September 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22711 Filed 9–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0081]

Armenpharm, Ltd.; Suspension of Approval of an Abbreviated New Drug Application for Chloramphenicol Capsules, 250 Milligrams; Determination That CHLOROMYCETIN (Chloramphenicol) Capsules, 50 Milligrams and 100 Milligrams, and Three Other Products Were 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) is suspending approval of abbreviated new drug application (ANDA) 060851 for chloramphenicol capsules, 250 milligrams (mg), held by Armenpharm, Ltd. (Armenpharm), 49 South Ridge Rd., P.O. Box D1400, Pomona, NY 10970. FDA has also determined that CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg; AMPHICOL (chloramphenicol) Capsules, 100 mg; and CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, 150 mg/5 milliliters (mL), were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve ANDAs for

chloramphenicol capsules, 50 mg and 100 mg, or chloramphenicol palmitate oral suspension, 150 mg/5 mL.

DATES: Effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

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, among other requirements, 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 (FD&C 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. FDA may not approve an ANDA that does not refer to a listed drug.

Section 505(j)(6) of the FD&C Act authorizes FDA to suspend approval of an ANDA if the listed drug relied upon has been withdrawn from sale for what FDA determines are safety or effectiveness reasons. 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 under § 314.153(b) (21 CFR 314.153(b)) that could result in the suspension of approval of the ANDAs that refer to the listed drug.

II. Chloramphenicol Capsules, 250 mg

On February 7, 2011, Armenpharm submitted a citizen petition under § 10.30 (Docket No. FDA–2011–P–0081), requesting that the Agency determine whether CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg (ANDA 060591), was withdrawn from sale for reasons of safety or effectiveness. CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, is the listed drug that was the basis of submission for Armenpharm's ANDA 060851 for chloramphenicol capsules, 250 mg. In the **Federal Register** of July 13, 2012 (77 FR 41412), FDA published a notice stating its determination under § 314.161 that CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, was withdrawn from sale for reasons of safety or effectiveness. FDA also notified Armenpharm of the Agency's decision in a letter dated July 13, 2012.

Pursuant to § 314.153(b)(1), FDA initiated the process to suspend Armenpharm's chloramphenicol ANDA 060851 by sending a letter, dated December 3, 2015, notifying Armenpharm of the Agency's initial determination that CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, was withdrawn for reasons of safety or effectiveness and its initial decision to suspend approval of ANDA 060851 (see Docket No. FDA–2011–P–0081). Under § 314.153(b)(2), Armenpharm had 30 days from that notification in which to present written comments or information bearing on the initial decision. On December 17, 2015, Armenpharm submitted comments requesting an oral hearing under § 314.153(b)(4). However, on March 17, 2016, Armenpharm withdrew its oral hearing request.

Therefore, under section 505(j)(6) of the FD&C Act and § 314.153(b), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of ANDA 060851, and all amendments and supplements thereto, is suspended (see DATES). FDA has removed all chloramphenicol capsules, 250 mg, from the list of drug products published in the Orange Book, and no chloramphenicol capsules, 250 mg, will be listed in the Orange Book. Distribution of chloramphenicol capsules, 250 mg, 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)).

III. Other Discontinued Oral Chloramphenicol Drug Products

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

Application No.	Drug	Applicant
ANDA 060591	CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg.	Parkedale Pharmaceuticals Inc. (formerly Parke Davis Pharmaceutical Research Division of Warner Lambert Co.).
ANDA 062301	CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, Equivalent to (EQ) 150 mg base/5 mL.	Parkedale Pharmaceuticals Inc. (formerly Parke Davis Pharmaceutical Research Division of Warner Lambert Co.).
ANDA 060058	AMPHICOL (chloramphenicol) Capsules, 100 mg	John J. Ferrante.
NDA 050152	CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, EQ 150 mg base/5mL.	Parkedale Pharmaceuticals Inc. (formerly Parke Davis Pharmaceutical Research Division of Warner Lambert Co.).

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this table were withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed Agency records concerning the withdrawal from sale of the drug products listed in the table. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. At the time of the approval of the drug

products listed in the table, there was significant unmet medical need. With the approval of additional therapies with less severe adverse drug effects, FDA has determined that the risks associated with CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg; AMPHICOL (chloramphenicol) Capsules, 100 mg; and CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, 150 mg/5 mL, as currently labeled, outweigh the benefits. Most important, CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg; AMPHICOL (chloramphenicol) Capsules, 100 mg; and CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, 150 mg/5 mL, may cause a number of adverse reactions, the most serious being bone marrow depression (anemia, thrombocytopenia, and granulocytopenia temporally associated with treatment). A boxed warning in the prescribing information for chloramphenicol sodium succinate injection and chloramphenicol capsules and oral suspension states that serious hypoplastic anemia, thrombocytopenia, and granulocytopenia are known to occur after administration of chloramphenicol. The drug product labeling recommends extensive safety monitoring, including baseline blood studies followed by periodic blood studies approximately every 2 days during therapy. The boxed warning also describes fatal aplastic anemia associated with administration of the drug and aplastic anemia attributed to chloramphenicol that later terminated in leukemia. Published literature suggests that the risk of fatal aplastic anemia associated with oral formulations of chloramphenicol may be higher than the risk associated with the intravenous formulation.

FDA has also reviewed approved labeling for the products and has determined that a Risk Evaluation and Mitigation Strategy (REMS) would be required to ensure that the benefits of the drug outweigh its risks. The REMS may include Elements to Assure Safe Use, including restricted distribution, and a Medication Guide could be required as part of the labeling. FDA has determined that additional nonclinical and possibly clinical studies of safety and efficacy would be necessary before CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg; AMPHICOL (chloramphenicol) Capsules, 100 mg; and CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, 150 mg/5 mL, could be considered for reintroduction to the market.

Accordingly, the Agency will remove CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg; AMPHICOL (chloramphenicol) Capsules, 100 mg; and CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, 150 mg/5 mL, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to these drug products.

Dated: September 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22660 Filed 9–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1530]

Reporting of Computational Modeling Studies in Medical Device Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Reporting of Computational Modeling Studies in Medical Device Submissions.'' The purpose of this guidance document is to provide recommendations to industry on the formatting, organization, and content of reports of computational modeling and simulation (CM&S) studies that are used as valid scientific evidence to support medical device submissions, and to assist FDA staff in the review of computational modeling and simulation studies by improving the consistency and predictability of the review of CM&S and facilitating full interpretation and complete review of those studies.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may 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–2013–D–1530] for ''Reporting of Computational Modeling Studies in Medical Device Submissions.'' 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 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