

decision about whether to require a REMS:

- The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug
- The expected benefit of the drug with respect to the disease or condition
- The seriousness of the disease or condition that is to be treated with the drug
- Whether the drug is a new molecular entity
- The expected or actual duration of treatment with the drug
- The estimated size of the population likely to use the drug

These six factors influence FDA's decisions with respect to both whether a REMS is required for a particular drug and what type of REMS might be necessary (*i.e.*, what specific elements/tools should be included as part of the REMS). FDA makes decisions about requiring a REMS as part of a benefit-risk determination for a drug after an evaluation that includes integrated consideration of each of the statutory factors. No single factor, by itself, is determinative as to whether a REMS is necessary to ensure that the benefits of a drug outweigh its risks. This guidance describes how FDA considers each of these factors in conducting its REMS analysis.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on how the Agency applies statutory factors in determining when a REMS is necessary. 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.

## II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: September 15, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-D-2561]

#### Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled "Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices." This draft guidance is intended to assist drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs and antimicrobial susceptibility test (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. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 21, 2016.

**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-2016-D-2561 for "Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices." 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 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 <http://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: <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](mailto: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.*

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## **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