

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.

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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

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 guidance document entitled "Reporting of Computational Modeling Studies in Medical Device Submissions" 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. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Tina Morrison, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2204, Silver Spring, MD 20993-0002, 301-796-6310.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled "Reporting of Computational Modeling Studies in Medical Device

Submissions." This guidance is intended to provide recommendations to industry on the formatting, organization, and content of reports for CM&S studies that are used as valid scientific evidence to support medical device submissions.

In the **Federal Register** on January 17, 2014 (79 FR 3211), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by April 17, 2014.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Reporting of Computational Modeling Studies in Medical Device Submissions". 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 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>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Reporting of Computational Modeling Studies in Medical Device Submissions" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1807 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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 814, subparts A through E have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 814, subpart

H have been approved under OMB control number 0910-0332.

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-2004-N-0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 045

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 045" (Recognition List Number: 045), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit electronic or written comments concerning this document at any time. These modifications to the list of recognized standards are effective September 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