

and volume of solvent used for extraction?

- How can FDA standardize in vitro testing to help substantiate appropriate and consistent product manufacture that assures abuse deterrence at release and through a drug product's shelf life?
- How can performance attributes measured by in vitro testing be quantified and linked to their impact on abuse deterrence? For example, discuss what amount of time delay in defeating an abuse-deterrent property should be considered significant and the basis for the recommendation.
- How can FDA build flexibility into standardized testing so that it may be suitable for application to emerging technologies? Are there any specific emerging technologies that might require new types of testing?

II. Registration and Accommodations

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public meeting must register by close of business on October 17, 2016.

If you need special accommodations because of a disability, please contact La'Shaune Morant, 240-316-3206, email: lashaune@tepgevents.com no later than October 12, 2016.

To register for the public meeting, please visit <http://www.cvent.com/d/wvq0sm/4W> (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**) by October 17, 2016. Those without Internet access may register by contacting La'Shaune Morant, 240-316-3206. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. You will receive confirmation after you have registered and been accepted or you will be notified if you are on a waiting list. FDA may allow onsite registration if space is available. If registration reaches maximum capacity, FDA will post a notice closing registration at <http://www.fda.gov/Drugs/NewsEvents/ucm509853.htm>.

Streaming Webcast of the Public Meeting: The meeting will also be Webcast. Persons interested in viewing the Webcast must register online by October 17, 2016. Early registration is recommended because Webcast connections may be limited. Organizations are requested to register all participants, but to view using one connection per location. A link to the live Webcast will be available at <http://www.fda.gov/Drugs/NewsEvents/ucm509853.htm> on the day of the public meeting. A video record of the public

meeting will be available at <http://www.fda.gov/Drugs/NewsEvents/ucm509853.htm> following the meeting. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Requests for Oral Presentations: If you wish to present at the public meeting, you must register and indicate which topic(s) you wish to address: approach to testing FDA recommended in its draft guidance "General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products," new technologies for deterring abuse of oral opioid drug products, or standardization of in vitro testing methodologies for evaluating purportedly abuse-deterrent formulations of opioid drug products. This will help FDA organize the presentations. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of the registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 24, 2016. All requests to make oral presentations must be received by the close of registration, October 17, 2016. If you are selected, any presentation materials must be emailed to Michelle Eby (see **FOR FURTHER INFORMATION CONTACT**) no later than October 27, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

FDA is holding this public meeting to obtain information on scientific and technical issues relating to formulation development and pre-market evaluation of opioid drug products with abuse-deterrent properties. In order to permit the widest possible opportunity for public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. The deadline for submitting comments related to this public meeting is December 1, 2016.

Accommodations: Attendees are responsible for their own hotel accommodations. Attendees making reservations at the College Park Marriott Hotel and Conference Center, 3501 University Blvd. East, Hyattsville, MD 20783, are eligible for a reduced rate of \$231/night, not including applicable taxes. To receive the reduced rate, please reference "FDA Opioid Drug

Meeting" if you make your reservation by calling 1-800-676-6137, or book your reservation at http://www.marriott.com/meeting-event-hotels/group-corporate-travel/groupCorp.mi?resLinkData=FDA%20Opioid%20Drug%20Meeting%5Ewasum%60FDGFDGA%60231.00%60USD%60false%602%6010/30/16%6011/16%6010/12/16&app=resvlink&stop_mobi=yes.

If you need special accommodations because of a disability, please contact La'Shaune Morant, 240-316-3206, lashaune@tepgevents.com no later than October 12, 2016.

III. Transcript Request

Transcripts of the meeting will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20850, and on the Internet at <http://www.regulations.gov> approximately 30 days after the meeting. A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>.

Dated: September 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-24234 Filed 10-5-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4561]

Head Lice Infestation: Developing Drugs for Topical Treatment; Guidance for Industry; 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 guidance for industry entitled "Head Lice Infestation: Developing Drugs for Topical Treatment." The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of head lice infestation. This guidance addresses the Agency's current thinking regarding the overall development program and clinical trial designs of drugs to support approval of an indication for topical treatment of head lice infestation. The information

presented will help sponsors plan clinical trials, design clinical protocols, and conduct and appropriately monitor clinical trials. This guidance finalizes the draft guidance of the same name issued on December 15, 2015.

DATES: Submit either electronic or written comments on Agency guidances 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-2015-D-4561 for "Head Lice infestation: Developing Drugs for Topical Treatment." 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.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Strother D. Dixon, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 22, Rm. 5168, Silver Spring, MD 20993-0002, 301-796-1015.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Head Lice Infestation: Developing Drugs for Topical Treatment." The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of head lice infestation. This guidance addresses the Agency's current thinking regarding the overall development program and clinical trial designs of drugs to support approval of an indication for topical treatment of head lice infestation. The information presented will help sponsors plan clinical trials, design clinical protocols, and conduct and appropriately monitor clinical trials. This guidance finalizes the draft guidance of the same name issued on December 15, 2015 (80 FR 77636). No changes were made from the draft 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 developing drugs for topical treatment of head lice infestation. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively. The collections of information for prescription drug product labeling in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572.

III. Electronic Access

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

Dated: September 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0530]

Tropical Disease Priority Review Vouchers; Guidance for Industry; 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 guidance for industry entitled “Tropical Disease Priority Review Vouchers.” There has been significant outside interest in FDA’s interpretation of the priority review voucher section in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) added by the Food and Drug Administration Amendments Act (FDAAA). This section makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease product applications that meet the criteria specified by the FD&C Act. This guidance explains to internal and external stakeholders how FDA is implementing the provisions of this section. This guidance finalizes the draft guidance of the same name issued October 2008.

DATES: Submit either electronic or written comments on Agency guidances 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-2008-D-0530 for Tropical Disease Priority Review Vouchers; Guidance for Industry; Availability. 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.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6360, Silver Spring, MD 20993-0002, 301-796-1182; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Tropical Disease Priority Review Vouchers.” Section 1102 of FDAAA added section 524 to the FD&C Act. Section 524 is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world. By enacting section 524, Congress intended to stimulate new drug development for drug products to treat certain tropical diseases by offering additional incentives for obtaining FDA