heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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: Kristen Hardin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5443, Silver Spring, MD 20993–0002, 240–402–4246.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations.'' This guidance represents FDA's current thinking on the conduct of in vivo absorption trials for topically applied active ingredients that are under consideration for inclusion in an OTC monograph. A maximal usage trial (MUsT) is a standard approach to assessing the in vivo bioavailability of topical drug products. The methodology described in this guidance adapts MUsT principles for active ingredients being considered for inclusion in an OTC monograph. Because information from a MUsT can help identify the potential for systemic exposure to a topically applied active ingredient, such information can help inform an FDA determination of whether additional safety data are needed to support a finding that a topical OTC drug containing that active ingredient is generally recognized as safe and effective for its intended use.

This guidance was written, in part, in response to comments submitted to Docket No. FDA–2015–D–4021 for the draft guidance entitled ''Over-the-Counter Sunscreens: Safety and Effectiveness Data'' (80 FR 72975, November 23, 2015) and the final guidance that replaced it, entitled ''Nonprescription Sunscreen Drug Products—Safety and Effectiveness Data,'' (81 FR 84594, November 23, 2016), requesting that FDA provide further guidance and details on the MUsT recommended in that document. FDA has also recommended a MUsT to address data gaps regarding active ingredients under consideration for inclusion in the OTC monograph for topical antimicrobial drug products, and in the OTC sunscreen monograph rulemaking (see proposed rules ''Safety and Effectiveness of Consumer Antiseptics, Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record'' (81 FR 42912, June 30, 2016) and ''Sunscreen Drug Products for Over-the-Counter Human Use'' (84 FR 6204, February 26, 2019)). This guidance provides additional information on the study elements, data analysis, and considerations when designing a MUsT for a topically applied active ingredient being considered for inclusion in an OTC monograph.

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 ''Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations.'' 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: May 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09692 Filed 5–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2165]

Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations; 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 final guidance for industry entitled ''Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations.'' The purpose of this guidance is to assist sponsors in evaluating reproductive toxicity (mainly related to embryo-fetal development (EFD)) for anticancer pharmaceuticals and to provide recommendations to applicants for pharmaceutical labeling on duration of contraception following cessation of therapy to minimize potential risk to a developing embryo or fetus. The guidance also clarifies FDA's current thinking on when nonclinical studies for reproductive toxicology assessment may not be needed (*e.g.,* for pharmaceuticals intended for use in postmenopausal women only). The intended outcome of this guidance is to facilitate the development of oncology pharmaceuticals while avoiding unnecessary use of animals, in accordance with the 3R (reduce, refine, replace) principles, and to provide a consistent approach to labeling recommendations for the duration of contraception after completion of therapy. This guidance finalizes the guidance of the same name issued September 29, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on May 10, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–2017–D–2165 for ''Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 Dockets Management Staff. 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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: John Leighton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2204, Silver Spring, MD 20993–0002, 301–796–7550; or Haleh Saber, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2117, Silver Spring, MD 20993–0002, 301–796–7550.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations.'' This guidance represents FDA's current approach to assessing potential risk to a developing embryo or fetus associated with the use of anticancer pharmaceuticals in male and female patients. The term oncology pharmaceutical in this guidance refers to small molecules, biotechnology-derived products, and related compounds such as conjugated products. This guidance describes: (1) How to evaluate EFD toxicity for various types of pharmaceuticals, such as for genotoxic, biological, conjugated, and combination products; (2) whether reproductive toxicity assessment is warranted for specific patient populations, such as pharmaceuticals being developed for use in male patients only or in postmenopausal women only; and (3) recommendations for the duration of contraception after completion of therapy to minimize risk to a developing embryo or fetus.

Although, current regulatory guidances exist regarding the need to assess the EFD toxicity potential of pharmaceuticals and the overall design of the studies, this guidance provides additional recommendations for evaluation of EFD toxicity for specific types of pharmaceuticals and for specific populations, which are not covered under other guidances. This guidance also expands on the weight of evidence approaches that could be utilized to substitute for dedicated EFD toxicology studies and hence facilitate the development of oncology pharmaceuticals while avoiding unnecessary use of animals, in accordance with the 3R principles. Moreover, this guidance provides labeling recommendations on the duration of contraception after completion of therapy, not previously addressed in other guidance documents. This guidance finalizes the guidance of the same name issued on September 29, 2017 (82 FR 45593).

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 ''Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations.'' 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. This guidance is not subject to Executive Order 12866.

II. 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 in 21 CFR 201.56 and 201.57 and the final rule ''Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling'' have been approved under OMB control numbers 0910–0572 and 0910–0624.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: May 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09691 Filed 5–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2478]

Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration is announcing the availability of a final guidance entitled ''Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis.'' The final guidance document notifies blood establishments that collect blood and blood components that we have determined babesiosis to be a relevant transfusion-transmitted infection (RTTI) and provides recommendations for donor screening, donation testing, donor deferral, and product management to reduce the risk of transfusion-transmitted babesiosis (TTB). The recommendations contained in the guidance apply to the collection of blood and blood components, except Source Plasma. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on May 10, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–D–2478 for ''Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 Dockets Management Staff. 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jenifer Stach, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: