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–2010–D–0509 for ''Enforcement Policy—Over-the-Counter Sunscreen Drug Products Marketed Without an Approved Application; Guidance for Industry; Availability.'' 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: 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 ''Enforcement Policy—OTC Sunscreen Drug Products Marketed Without an Approved Application.'' This guidance applies to OTC sunscreen products marketed without approved applications and describes FDA's approach to enforcement for these products until a final OTC sunscreen monograph becomes effective. This guidance finalizes a draft guidance that was issued under the same title on June 17, 2011 (76 FR 35665) and reflects FDA's consideration of public comments on 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 the enforcement policy for OTC sunscreen drug products marketed without an approved application. 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 found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) and under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.327 and 201.66, and 21 CFR part 330 have been approved under OMB control numbers 0910–0717, 0910–0340, and 0910–0688, respectively.

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 *https://www.regulations.gov.*

Dated: May 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10994 Filed 5–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1456]

Maximal Usage Trials for Topical Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations; Draft 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 draft guidance for industry entitled ''Maximal Usage Trials for Topical Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations.'' This draft guidance addresses FDA's current thinking on the conduct of in vivo absorption trials for topical active ingredients that are under

consideration for inclusion in an over-the-counter (OTC) monograph.

DATES: Submit either electronic or written comments on the draft guidance by July 23, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–1456 for ''Maximal Usage Trials for Topical Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations; Draft Guidance for Industry.'' 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 draft 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 draft 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 draft guidance for industry entitled ''Maximal Usage Trials for Topical Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations.'' This draft guidance addresses the current thinking of FDA on the conduct of in vivo absorption trials for topical 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 draft 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 an OTC drug containing that active ingredient is generally recognized as safe and effective for its intended use.

This draft guidance was written 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. It provides additional information on the study elements, data analysis, and considerations when designing a MUsT for a topical active ingredient being considered for inclusion in an OTC monograph.

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 ''Maximal Usage Trials for Topical 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. Paperwork Reduction Act of 1995

This draft guidance contains collections of information that are exempt from the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). Section 586D(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–4(a)(1)(C)) as amended by the Sunscreen Innovation Act states that the PRA shall not apply to collections of information made for purposes of guidance under that subsection.

III. Electronic Access

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

Dated: May 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10993 Filed 5–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Enhancement and Update of the National HIV Curriculum e-Learning Platform

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of a single source award.

SUMMARY: HRSA's HIV/AIDS Bureau (HAB) intends to issue a single source award to the University of Washington for $300,000 for activities authorized under Section 2692(a) of the Public Health Service (PHS) Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009. This notice is subject to the appropriation of funds and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can award funds in a timely manner.

Subject to the availability of funds and the University of Washington's satisfactory performance, HAB will also issue non-competitive, single source awards of $300,000 each in fiscal years (FYs) 2019 to 2022. This will allow the University of Washington to update and enhance the National HIV Curriculum (NHC) and the electronic platform that supports it, and to keep pace with the latest HIV science, federal guidelines, and treatment protocols and practices for educating health professionals on the optimal care and treatment of people living with HIV over its four-year project period.

FOR FURTHER INFORMATION CONTACT: Sherrillyn Crooks, Chief, HIV Education Branch, Office of Training and Capacity Development, HAB/HRSA, 5600 Fishers Lane, Room 9N110, Rockville, MD 20857, by email at *scrooks@hrsa.gov* or by phone at (301) 443–7662.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: The University of Washington.

Period of Supplemental Funding: September 1, 2018–August 31, 2022.

Funding Amount: Subject to the availability of appropriated funds, $300,000 each in FY 2018 to FY 2022.

Authority: Section 2692(a) of the Public Health Service (PHS) Act (42 U.S.C. 300ff–111(a)) and section 2693 of the PHS Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111–87).

CFDA Number: 93.145.

Justification: The *Enhancement and Update of the National HIV Curriculum e-Learning Platform* project responds to the need to update and enhance the NHC and the electronic platform that supports it, and to keep pace with the latest HIV science, federal guidelines, treatment protocols, and practices for educating health professionals on the optimal care and treatment of people living with HIV (PLWH). With the ultimate goal of addressing the shortage of health professionals who care for people living with or who are at risk for HIV (PLWH), the University of Washington convened a multidisciplinary panel of clinical and learning technology experts under the auspices of the AIDS Education and Training Centers Program network, to create the national HIV curriculum. Released in July 2017, this free, online curriculum targets multidisciplinary novice-to-expert health professionals, students, and faculty who treat or aspire to treat PLWH. As the developer and proprietor of the NHC, the University of Washington is the only entity suitable for receiving a single source award to accomplish the critical task of ensuring that the NHC remains a relevant and important tool to educate HIV care providers in the United States.

Throughout the period of performance, the University of Washington will work in close coordination with recipients of awards under Notice of Funding Opportunity HRSA–18–045, *Integrating the National HIV Curriculum e-Learning Platform into Health Care Provider Professional Education.* Recipients under HRSA–18–045 will be collaborating with multiple health professions' academic and training institutions to incorporate the NHC into their curricula, including activities to train and orient faculty on effective methods to integrate the NHC. Though the University of Washington will gather feedback on the NHC from a wide variety of users, a collaboration with recipients under HRSA–18–045 will facilitate consistent collection, in real time, of integration practices that are proving most effective, and discussion of recommendations for disseminating those practices. This collaboration will influence and inform enhancements to the NHC e-Learning platform and further HRSA's goal to ensure that health professions academic and training institutions routinely use this state-of-the-art curriculum thus increasing the number of competent HIV treatment providers.

Dated: May 17, 2018.

George Sigounas,

Administrator.

[FR Doc. 2018–11033 Filed 5–22–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Correction

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: HRSA is correcting a notice published in the September 26, 2017 issue of the **Federal Register** entitled Improving Care for Children and Youth—Incentive Prize. This correction amends the subject of the challenge and the timeline. Please note, however, that this correction notice, along with future updates, as needed and pursuant to recent changes to the applicable law, will be posted on *challenge.gov* and *mchbgrandchallenges.hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Jessie Buerlein, Public Health Analyst, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20852, *jbuerlein@hrsa.gov,* 301–443–8931.

Correction

In the **Federal Register** at 82 FR 44812 (September 26, 2017) please make the