to uninfected sexual partners; this is also called treatment as prevention or TasP. PrEP is 99% effective at reducing the risk of HIV through sexual contact when taken daily. PrEP is also 74%–84% effective at reducing the risk of HIV infection through injection drug use when taken daily. Persons living with HIV who are taking ARVs as prescribed as well as achieving viral suppression effectively have no risk for transmitting the virus to an HIV-negative partner through sexual contact. CDC is working with various jurisdictions with high HIV prevalence to increase capacity of ARV provision, build collaborative efforts between health departments and community-based organizations, and engage multi-sector provider systems to reach individuals with high risk of HIV infection as part of the End the HIV Epidemic Initiative. CBOs will play a crucial role in the End the HIV Epidemic Initiative. In a previous survey conducted by CDC's Division of HIV/AIDS Prevention, CBOs reported high awareness of nPEP, PrEP, and TasP, but their ability to meet client need was low. Although clinical CBOs were more prepared to support the expansion of biomedical HIV prevention interventions, the likelihood that all CBOs would incorporate these interventions if they had additional resources was somewhat high.

Research is needed to better understand the capacity of CBOs to incorporate biomedical HIV prevention interventions into their existing infrastructure. It is unclear whether the provision of and capacity to provide nPEP, PrEP, and TasP has increased among CBOs since the original survey was conducted. Furthermore, it is unclear whether non-clinical CBOs have achieved parity in linking clients to biomedical HIV prevention interventions with their clinical counterparts. This new survey will assess current capacity and provision of nPEP, PrEP, and TasP among CBOs providing HIV services to populations with increased risk for HIV acquisition. In addition, the results of this survey will be compared to the results of the 2015 survey to assess differences in awareness, capacity, and provision of biomedical HIV prevention interventions. Respondents will include organizations engaged in HIV prevention and outreach. Up to 330 respondents (N=330; 175 funded CBOs and 155 CBOs that did not receive funding) will be recruited to complete the survey. This project will employ a cross-sectional survey design. All CBOs within each of the two strata (1. Clinical and non-clinical CBOs directly funded by CDC, and 2. Clinical and non-clinical CBOs that did not receive CDC funding) will receive phone calls to elicit interest in participating in the survey and to receive the contact information of an organization's representative to complete the survey on behalf of the organization. Potential respondents will be contacted from a list of CBOs that completed the 2015 survey. In addition, CBOs that received DHAP funding through PS15–1502 and PS17–1704 will also be contacted to determine their interest in participating in the data collection effort and to nominate a staff member to complete the survey. Each organization's representative will receive an email with a link to the survey website (created with Survey Monkey). The email will instruct the representative on how to complete the survey. Three email reminders will be sent to organizations for those that do not complete the survey. Where possible, data from the 2015 survey will be combined with data from the 2020 survey. Analyses will include completeness (non-response rates per item) as well as frequency of item responses for awareness, intentions, and provision of PrEP, nPEP, and TasP will be assessed for all respondents combined. Frequency and differences in item responses will be analyzed for relationship to CBO characteristics (*e.g.,* clinical CBOs vs non-clinical CBOs). Frequency and differences in item responses will be analyzed across survey years. We will perform multivariable analysis as needed (to assess interactions between time and type of CBO). The total annualized burden hours is 165 hours. There are no other costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Community Based Organization	Community Based Organization HIV Prevention Needs Assessment Survey.	330	1	30/60	165
Total	.....	.....	.....	.....	165

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–04721 Filed 3–6–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0043]

Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment; 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 ''Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment.'' This draft guidance provides recommendations for the characterization, during product development, of local safety of topical drug products regarding the risk for contact dermatitis. These recommendations are specifically directed to development of topical new drug products intended for cutaneous application.

DATES: Submit either electronic or written comments on the draft guidance

by May 8, 2020 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–2020–D–0043 for ''Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment.'' 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.govinfo.gov/content/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: Jennifer Harmon, Center for Drug Evaluation and Research (HFD–540), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5239, Silver Spring, MD 20993; 240–402–4880.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment.''

Historically, FDA requested sponsors of new topical drug products to characterize local safety with regard to cutaneous irritation, sensitization, phototoxicity, and photoallergy (the latter two only for products that absorb ultraviolet radiation at relevant wavelengths) through the conduct of dedicated ''dermal safety studies.'' These studies were conducted in healthy volunteers by repeated application of the drug product under occlusion on the skin of the back or upper arm. The studies are considered provocative in that the test condition of occlusion is used to evoke the adverse reaction at a greater rate than might be observed under labeled conditions of use.

The Division of Dermatology and Dental Products (DDDP) became concerned that these provocative studies, conducted under augmented conditions, were not informative for drug development, did not provide information that was useful for labeling, and induced adverse reactions in study subjects that might result in permanent harm. DDDP convened a scientific workshop in September 2018 during which outside experts provided input on the utility of these studies for development of new topical drugs. The consensus of the workshop was that the dedicated dermal safety studies, previously requested by FDA, were not needed to evaluate local cutaneous safety of topical new drug products.

DDDP intends to publish this draft guidance to inform sponsors of new topical drug products intended for cutaneous application of our recommendations for evaluating local (cutaneous) safety of topical drug products with regard to contact dermatitis. These recommendations will be specifically directed to developing topical new drug products; the draft guidance will not address over-the-counter drugs under monograph, generic drugs, or nondrug cosmetic products or ingredients.

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 ''Contact Dermatitis From Topical Drug Products for Cutaneous Application: Human Safety Assessment.'' 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. Paperwork Reduction Act of 1995

This draft 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 parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: March 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04753 Filed 3–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0256]

United States Food and Drug Administration and Health Canada Joint Regional Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a regional public meeting entitled ''U.S. Food and Drug Administration and Health Canada Joint Regional Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).'' The purpose of the public meeting is to provide information and solicit public input on the current activities of the ICH, as well as the upcoming ICH Assembly Meeting and the Expert Working Group Meetings in Vancouver, Canada, scheduled for May 23 through 27, 2020. The topics to be addressed at the public meeting are the current ICH guideline topics under development that will be discussed at the forthcoming ICH Assembly Meeting in Vancouver.

DATES: The public meeting will be held on Friday, April 3, 2020, from 10 a.m. to 1 p.m. Submit either electronic or written comments on this public meeting by Thursday, April 30, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503 (the Great Room), Silver Spring, MD 20993–0002. The meeting will also be broadcast on the web, allowing participants to join in person or via the web. For those who will attend in person, the entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* For those who register to attend the public meeting remotely via the webcast, a link to access the webcast will be emailed 1 week in advance of the meeting.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 20, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on Thursday, April 30, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2020–N–0256 for ''U.S. Food and Drug Administration and Health Canada Joint Regional Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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