4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4790]

Self-Collection Devices for Pap Test; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Self-Collection Devices for Pap Test." The purpose of the public workshop is to obtain feedback about the feasibility, benefits, risks, impact on current standard of care, and least burdensome validation approaches for self-collection devices for cervical samples for the purpose of cervical cancer screening by Pap testing. Comments and suggestions generated through this workshop will guide the development of an appropriate least burdensome regulatory framework for the evaluation of cervical sample self-collection devices to be used for cervical cancer screening of patients.

DATES: The public workshop will be held on January 11, 2018, from 9 a.m. to 4 p.m. Submit either electronic or written comments on this public workshop by February 14, 2018.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public workshop 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. See the SUPPLEMENTARY INFORMATION section for registration date and information.

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 February 14, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of February 14, 2018. 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-2017-N-4790 for "Self-Collection Devices for Pap Test." 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 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.

FOR FURTHER INFORMATION CONTACT: Shyam Kalavar (Rm. 5660, 301-796-6807, Shyam.Kalavar@fda.hhs.gov) or Cheng Cui (Rm. 5543, 240-402-5028, Cheng.Cui@fda.hhs.gov), Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993-0002.

SUPPLEMENTARY INFORMATION:

I. Background

Cervical cancer is a disease that results from uncontrolled, or abnormal, growth of cells in the cervix. Cervical cancer is generally considered as a consequence of a long-term infection

with human papillomavirus (HPV), especially with high-risk strains such as HPV16 and 18. Through regular screening and early detection, cervical cancer can often be prevented. According to the National Cancer Institute, routine screening with Pap Test (or Pap smear) and HPV Test in the United States has decreased the incidence of cervical cancer, based on an estimated 12,820 new cases and 4,210 deaths (0.7 percent of all cancer deaths) in 2017 (Ref. 1).

The standard of care for cervical cancer screening has been well-established in the United States over the past several decades. Automated liquid-based Pap Test has largely replaced conventional Pap smear method. Liquid-based cervical specimens can be used for both Pap Test and HPV Test. By using specimen collection devices such as a cervical broom or cervical spatula and brush combination, cervical specimens are collected by healthcare professionals and sent to a Clinical Laboratory Improvement Amendments certified laboratory for processing for Pap Test and HPV Test. The results of these tests are then returned to the ordering clinician who conveys the results to the patient and initiates appropriate treatment.

Despite the established standard of care for cervical cancer screening in the United States, gaps in cervical cancer screening exist. Barriers to cervical cancer screening may include limited access to such services in rural areas, socioeconomic status, etc. As a result, in certain populations and geographic areas of the United States, cervical cancer incidence and death rate are still high, due in large part to limited access to cervical cancer screening (Refs. 2-3).

The role of self-sampling in overcoming these barriers is unclear. Careful evaluation of risks and benefits, and impact to current standard of care is needed to better understand issues concerning how such devices should be dispensed to end users for self-collection, proper use of the device to ensure patient safety, the collection of adequate samples for testing, the use of these test results in patient care, and the impact on the current regulatory framework. FDA is holding

this public workshop to solicit input from stakeholders about the self-collection of cervical specimens for cancer screening, including its feasibility, benefits, risks, current attitudes, and impact on current standard of care.

II. Topics for Discussion at the Public Workshop

This public workshop will consist of both morning and afternoon sessions. Each session will include brief presentations followed by an interactive panel discussion. The presentations will provide information to outline the goals of the workshop and help promote interactive discussions. Following the presentations, there will be a moderated discussion where speakers and additional panelists will be asked to provide their individual perspectives.

The presentations and discussions will focus on several related topics. The morning session will involve scientific considerations, focusing on the current status of cervical cancer screening and the feasibility, benefits, and risks of self-collection of cervical specimens for Pap Test. The afternoon session will involve validation and regulatory considerations, focusing on the impact of self-collection of cervical samples on the current standard of care and the regulatory environment for supporting self-collection for Pap Test. A detailed agenda will be posted on the following website in advance of the workshop: https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar (https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm) and select this event from the list of items provided. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by January 3, 2018, 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, 301-796-5661 or email Susan.Monahan@fda.hhs.gov, no later than December 28, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our 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, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we 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 prior to the workshop. All requests to make oral presentations must be received by the close of registration on January 3, 2018, 4 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Shyam Kalavar and Cheng Cui (see FOR FURTHER INFORMATION CONTACT) in advance of the workshop. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming webcast of the public workshop: This public workshop will also be webcast. The webcast link will be available on the registration web page after January 3, 2018. Organizations are requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the Internet at https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.

IV. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. National Cancer Institute, "Cancer Stat Facts: Cervix Uteri Cancer," (http://seer.cancer.gov/statfacts/html/cervix.html).

2. Horner, M.J., S.F. Altekruse, Z. Zou, L. Wideroff, et al. "U.S. Geographic Distribution of Pre-Vaccine Era Cervical Cancer Screening, Incidence, Stage, and Mortality." *Cancer Epidemiology, Biomarkers & Prevention*. 2011 Jan.; 20(4):591-9. doi: 10.1158/1055-9965. EPI-10-1183.

3. Freeman, H.W.B. "Excess Cervical Cancer Mortality: A Marker for Low Access to Health Care in Poor Communities." Rockville (MD): National Cancer Institute, Center to Reduce Cancer Health Disparities; 2005.

Dated: September 1, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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