

Page 2 – Dr. Boisen, Zalgen Labs, LLC

Pursuant to continued discussions with FDA, Zalgen requested in a letter dated March 1, 2018, that the request for transfer of EUA150001 from Corgenix be withdrawn. We interpret this request to mean that Zalgen is no longer pursuing FDA consent to permit Zalgen to manufacture the Corgenix developed ReEBOV Antigen Rapid Test. We understand that there is no longer viable Corgenix manufactured ReEBOV Antigen Rapid Test inventory remaining and therefore this product will no longer be made available. Accordingly, under section 564(g)(2) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. 360bbb-3(g)(2), FDA has determined that the criteria for authorization under section 564(c) of the Act are no longer met. These circumstances make revocation appropriate to protect the public health or safety.

Accordingly, FDA revokes EUA150001 for emergency use of the ReEBOV Antigen Rapid Test, under section 564(g) of the Act. As of the date of this letter, the ReEBOV Antigen Rapid Test that was authorized by FDA for use by clinical laboratories for the qualitative detection of RNA from Ebola virus is no longer authorized by FDA.

FDA encourages Zalgen to instruct its customers to discontinue use of and discard any remaining ReEBOV Antigen Rapid Test inventory immediately.

Notice of this revocation will be published in the Federal Register, pursuant to section 564 of the Act, 21 U.S.C. 360bbb-3.

Sincerely,



Rachel Sherman, M.D., M.P.H.  
Principal Deputy Commissioner

Dated: July 27, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-2657]

#### Advancing the Development of Pediatric Therapeutics 5: Advancing Pediatric Pharmacovigilance; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Division of Pediatric and Maternal Health, Office of Surveillance and Epidemiology, and Office of Pediatric Therapeutics, Food and Drug Administration (FDA or the Agency) are announcing a public workshop entitled “Advancing the Development of Pediatric Therapeutics 5: Advancing Pediatric Pharmacovigilance.” The purpose of this 1-day workshop is to provide a forum to gather information

on the latest developments in pediatric pharmacovigilance from the perspective of various stakeholders and to expand the conversation to include the utility and challenges of emerging pharmacovigilance tools, including specific challenges associated with pediatric data tools.

**DATES:** The public workshop will be held on Friday, September 14, 2018, from 8 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave. Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993. 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>.

**FOR FURTHER INFORMATION CONTACT:** For questions regarding the workshop, contact Denise Pica-Branco, Center for

Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1732, [denise.picabranco@fda.hhs.gov](mailto:denise.picabranco@fda.hhs.gov); or Meshawn Payne, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6668, [meshawn.payne@fda.hhs.gov](mailto:meshawn.payne@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Drugs and biologics (products) receive marketing approval only after undergoing premarket review and upon establishment of safety and efficacy through adequate and well-controlled clinical trials. Because all safety issues related to a product may not be detected in the premarket phase, FDA receives and analyzes postmarket safety information to determine if events reported in the postmarketing period are likely to be related to exposure to a product. When FDA determines that reported postmarketing events are likely related to a product, FDA can introduce labeling changes and other activities to inform the professional and lay public.

FDA receives reports through the MedWatch website (<https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>), which are then entered into the FDA Adverse Event Reporting System for subsequent analysis. Because the volume of reports is large and because reporting entities (product manufacturers and the professional or lay public) need only suspect a possible link between product exposure and an adverse event, FDA employs specific tools and strategies to assess postmarket safety reports and potential signals that arise from review of these reports. The process for receipt and assessment of such postmarket safety information is referred to as pharmacovigilance.

FDA has a specific regulatory mandate to perform pediatric pharmacovigilance and to present or make available the results of such pediatric pharmacovigilance to the Pediatric Advisory Committee.

## II. Topics for Discussion at the Public Workshop

In this workshop, FDA will gather information on the latest developments in pediatric pharmacovigilance from the perspective of various stakeholders and expand the conversation to include the utility and challenges of emerging pharmacovigilance tools, including specific challenges associated with pediatric data tools.

## III. Participation in the Public Workshop

**Registration:** Persons interested in attending this public workshop must register online at <https://www.eventbrite.com/e/advancing-the-development-of-pediatric-therapeutics-5-adept5-tickets-46654530958> by Thursday, September 6, 2018, midnight Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Onsite registration will not be available.

Registration for onsite participation or via webcast is free and based on space availability, with priority given to early registrants. 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 you need special accommodations due to a disability, please contact Denise Pica-Branco ([denise.picabranco@fda.hhs.gov](mailto:denise.picabranco@fda.hhs.gov)) or Meshawn Payne ([meshawn.payne@fda.hhs.gov](mailto:meshawn.payne@fda.hhs.gov)) no later than Thursday, September 6, 2018.

**Streaming Webcast of the Public Workshop:** Webcast information will be provided after participants have registered for the workshop. 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](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](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.

Dated: July 27, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-2126]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration's Research and Evaluation Survey for the Public Education Campaign on Tobacco Among the Lesbian Gay Bisexual Transgender Community**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's Research and Evaluation Survey for the Public Education Campaign on Tobacco (RESPECT) among the Lesbian Gay Bisexual Transgender (LGBT).

**DATES:** Submit either electronic or written comments on the collection of information by October 1, 2018.

**ADDRESSES:** 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 October 1, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 1, 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-2015-N-2126 for "Food and Drug Administration's (FDA's) Research and Evaluation Survey for the Public Education Campaign on Tobacco (RESPECT) among LGBT." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those