In addition, CERCLA provides ATSDR with the authority to prepare toxicological profiles for substances not found on the SPL. CERCLA authorizes ATSDR to establish and maintain inventory of literature, research, and studies on the health effects of toxic substances (CERCLA Section 104(i)(1)(B)); to respond to requests for health consultations (CERCLA Section 104(i)(4)); and to support the site-specific response actions conducted by the agency.

Availability

The Draft Toxicological Profiles are available online at *http://www.atsdr.cdc.gov/ToxProfiles* and at *www.regulations.gov,* Docket No. ATSDR–2015–0001.

Pamela I. Protzel Berman,

Director, Office of Policy, Partnerships and Planning, Agency for Toxic Substances and Disease Registry.

[FR Doc. 2018–16557 Filed 8–1–18; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announce the Intent To Award an Administrative Supplement

ACTION: Announcing the Intent to Award an Administrative Supplement for two (2) Help America Vote Act (HAVA) Training and Technical Assistance (T/TA) grantees, the National Disability Rights Network (NDRN) 90HAVA0001 and the National Federation of the Blind (NFB) 90HAVA0002.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award an administrative supplement to the current Help America Vote Act (HAVA) Training and Technical Assistance (T/TA) grantees held by the National Disability Rights Network (NDRN) and the National Federation of the Blind (NFB). The purpose of the HAVA programs are designed to establish and improve participation in the election process for individuals with a full range of disabilities. In each eligible state and territory, seven percent of HAVA funds are set aside for the Protection and Advocacy Systems (P&As) to ensure that individuals with disabilities have the opportunity to participate in every step of the voting process. After receiving training and technical assistance, P&As may inform others on the availability of accessible voting equipment and its use. The administrative supplement for FY 2018 will be in the amount of $122,721 bringing the total award for FY 2018 to $462,590.

Program Name: Help America Vote Act Training and Technical Assistance.

Recipients: National Disability Rights Network (NDRN) and National Federation of the Blind (NFB).

Period of Performance: The supplement award will be issued for the second year of the two-year project period of September 1, 2018, through August 30, 2019.

Total Award Amount: NDRN $326,274 in FY 2018 NFB $136,316 in FY2018.

Award Type: Administrative Supplement.

Statutory Authority: This program is authorized under Title II, Subtitle D, Part 5 of HAVA 42 U.S.C. 15461–62, Section 102 of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act) (42 U.S.C. 15002).

Basis for Award: The additional funding will not be used to begin new projects. The funding will be used to increase NDRN's capacity building efforts to provide training and technical assistance to the Protection and Advocacy Systems in the electoral process and NFB will be able to attend voting related conferences, conduct voting outreach campaigns and translate materials into Spanish.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Melvenia Wright, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Disabilities, Administration on Intellectual and Developmental Disabilities: telephone (202) 795–7472; email *Melvenia.Wright@acl.hhs.gov.*

Dated: July 26, 2018.

Lance Robertson,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2018–16561 Filed 8–1–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0126]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Ebola Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Zalgen Labs, LLC for the ReEBOV Antigen Rapid Test. FDA revoked this Authorization on May 18, 2018, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as requested by Zalgen Labs, LLC by letter dated March 1, 2018. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of May 18, 2018.

ADDRESSES: Submit written requests for single copies of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4336, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On February 24, 2015, FDA issued an EUA to Corgenix, Inc. for the ReEBOV Antigen Rapid Test, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on June 5, 2015 (80 FR 32140), as required by section 564(h)(1) of the FD&C Act. In response to requests from Zalgen Labs, LLC and Corgenix, Inc. to transfer ownership of the EUA for the ReEBOV Antigen Rapid Test from Corgenix, Inc. to Zalgen Labs, LLC, FDA amended and reissued the EUA to Zalgen Labs, LLC

in its entirety on November 3, 2016. Under section 564(g)(2), the Secretary of Health and Human Services may revoke an EUA if, among other things, the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety.

II. EUA Revocation Request for an In Vitro Diagnostic Device for Detection of the Ebola Virus

Pursuant to a request from Zalgen Labs, LLC on March 1, 2018, FDA revoked the EUA for the ReEBOV Antigen Rapid Test on May 18, 2018, because the criteria for issuance were no longer met and these circumstances made such revocation appropriate to protect the public health or safety.

III. Electronic Access

An electronic version of this document and the full text of the revocation are available on the internet at *https://www.regulations.gov.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for Zalgen Labs, LLC's ReEBOV Antigen Rapid Test. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

May 18, 2018

Matthew L. Boisen, Ph.D.
Director of Diagnostics Development
Zalgen Labs, LLC
20271 Goldenrod Lane, Suite 2083
Germantown, MD 20876

Dear Dr. Boisen:

This letter is in response to your letter dated March 1, 2018, regarding the Food and Drug Administration (FDA)'s Emergency Use Authorization (EUA150001) for emergency use of Zalgen Labs, LLC ("Zalgen") ReEBOV Antigen Rapid Test for the presumptive detection of Zaire Ebola virus (detected in the West Africa outbreak in 2014), Sudan Ebola virus, and Bundibugyo Ebola virus in fingerstick (capillary) whole blood, venous whole blood, and plasma from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection).

In response to requests from Zalgen and Corgenix Inc. ("Corgenix") to transfer ownership of EUA150001 for the ReEBOV Antigen Rapid Test from Corgenix to Zalgen, FDA amended and reissued EUA150001 in its entirety on November 3, 2016. The amended EUA150001 allowed Zalgen and its authorized distributors to distribute the ReEBOV Antigen Rapid Test manufactured by Corgenix. In addition, condition of authorization "N" stated, "*Zalgen Labs, LLC may submit performance validation data (e.g., a method comparison study) to DMD/OIR/CDRH for the ReEBOV™ Antigen Rapid Test manufactured by Zalgen Labs, LLC (or a contract manufacturer). Upon review of this material and DMD/OIR/CDRH's concurrence, Zalgen Labs, LLC (and its authorized distributors) will be authorized to distribute the ReEBOV Antigen Rapid Test manufactured by Zalgen Labs, LLC (or an authorized contract manufacturer), subject to the conditions of authorization set forth in this letter.*"

On June 19, 2017, Zalgen submitted performance validation data to FDA intended to satisfy condition of authorization "N" in FDA's November 3, 2016, Letter of Authorization. FDA concluded that the data did not support that the Zalgen manufactured ReEBOV Antigen Rapid Test would perform as originally labeled in its intended use population, because Zalgen failed to demonstrate comparable performance of the Zalgen manufactured ReEBOV Antigen Rapid Test to the Corgenix manufactured ReEBOV Antigen Rapid Test. Therefore, FDA did not concur that condition of authorization "N" had been satisfied. Consequently, Zalgen remained unable to meet a condition precedent on Zalgen's authorization to distribute the Zalgen manufactured ReEBOV Antigen Rapid Test.

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 E. Sherman

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

Dated: July 27, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16537 Filed 8–1–18; 8:45 am]

BILLING CODE 4164–01–C

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 FDAWhite 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*; or Meshaun Payne, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6668, *meshaun.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.