U.S. FOOD & DRUG ADMINISTRATION

OCT 19 2017

The Honorable Morgan Griffith
Vice Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C, 20515

Dear Mr. Vice Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the May 23, 2017, hearing before the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, entitled "U.S. Public Health Response to the Zika Virus: Continuing Challenges." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

John M. Martin
Principal Associate Commissioner
for Legislation

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We have restated your questions below in bold, followed by our responses.

The Honorable Tim Murphy

1. **Dr. Borio, the FDA revoked the authorization for one of the Zika tests. What would lead the FDA to revoke a test after just being authorized?**

FDA revoked the emergency use authorization (EUA) for the LightMix® Zika rRT-PCR Test — which was initially authorized for emergency use on August 26, 2016 — on March 13, 2017, in response to Roche Molecular Systems Inc.'s request dated March 10, 2017, to withdraw the EUA due to technical performance and business considerations.

The Honorable Frank Pallone

1. **How much funding does FDA have remaining for 2017 Zika preparation and response? Does FDA have sufficient funds remaining to support these efforts for the remainder of fiscal year 2017?**

The Zika Response and Preparedness Act (division B of Public Law 114-223) did not provide any funding to FDA for Zika response activities. To help support these activities at the start of the fiscal year, FDA used base appropriations provided by the Continuing Appropriations Act, 2017 (division C of Public Law 114-223), and reallocated $5 million of the $25 million appropriated for Ebola response activities by the Consolidated and Further Continuing Appropriations Act, 2015 (title VIII of division A of Public Law 113-235). As of May 19, 2017, FDA had obligated $1.8 million of the reallocated Ebola funding, and anticipates obligating the remaining balance by the end of FY 2017.

In May 2017, the Consolidated Appropriations Act, 2017 (title VII of division A of Public Law 115-31) provided an additional $10 million in no-year funding for FDA "to prevent, prepare for, and respond to emerging health threats, including the Ebola and Zika viruses, domestically and internationally and to develop necessary medical countermeasures and vaccines, including the review, regulation, and post market surveillance of vaccines and therapies, and for related administrative activities". This funding—in addition to FDA's base appropriations and the $5 million reallocated from appropriations for Ebola response—should provide FDA with sufficient funding to support continued Zika virus response activities in FY 2017, provided another public health emergency does not occur that would necessitate a reprioritization of funding.

The Honorable Kathy Castor

1. **Please provide an update on vaccine development and clinical trials.**

FDA is actively engaged with the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA), the international community, and product developers to help accelerate vaccine development programs. However, FDA generally

cannot comment on the status of any particular vaccine development program because of confidentiality requirements. We would refer this question to NIH and BARDA.

2. **Please provide the latest information on the Zika vaccine licensing agreement between the U.S. Army and Sanofi and any relevant details.**

Questions related to the licensing agreement between the U.S. Army and Sanofi are best addressed by the Department of Defense (DoD), Department of the Army.

3. **With many members of Congress, states and public health advocates worried that the Zika vaccine being developed at the Walter Reed Army Institute of Research with taxpayer dollars will be priced too high, how is the federal government working to ensure Sanofi, when/if a licensing agreement is made, will sell this taxpayer funded vaccine at an affordable price to federal and state governments and to consumers?**

This question is best addressed by DoD, Department of the Army.

4. **How has public health advice regarding Zika evolved over the past few years for young men and women? What do we know now that we did not before and what new information could be on the horizon?**

This question is best addressed by the Centers for Disease Control and Prevention.

5. **When does each federal agency believe they will run out of money to respond properly to Zika, including vector control, surveillance, vaccine and diagnostics development/improvement and research?**

In May of 2017, the Consolidated Appropriations Act, 2017 (title VII of division A of Public Law 115-31) provided $10 million in no-year funding for FDA "to prevent, prepare for, and respond to emerging health threats, including the Ebola and Zika viruses, domestically and internationally and to develop necessary medical countermeasures and vaccines, including the review, regulation, and post market surveillance of vaccines and therapies, and for related administrative activities". FDA anticipates expending this funding from FY 2017 through FY 2019 to support preparedness and response activities. This additional funding—in addition to FDA's base appropriations—should provide FDA with sufficient funding to support continued Zika virus response activities in that timeframe, provided another public health emergency does not occur that would necessitate a reprioritization of funding.