JOINT EXPLANATORY STATEMENT

1. FSMA Reporting

Given the complexity of FSMA implementation, the agreement directs the FDA to provide quarterly reports to the Committees with a breakdown on how funding has been allocated, as well as projections for future needs. The agreement also directs the FDA to provide a detailed accounting of its food safety resources in the fiscal year 2017 budget request, including which pre-2011 base resources are now repurposed for activities in support of FSMA and which resources are the result of appropriated increases from fiscal years 2011 to 2016, a detailed explanation of what the FDA has accomplished with increased food safety resources since fiscal year 2011, and how the aggregate total of these base resources for food safety will be utilized in fiscal year 2017.

FDA Response:
FDA will provide the requested report.

2. Biosimilars

The agreement acknowledges some progress in FDA's effort to address issues with products that are biosimilar to and interchangeable with FDA-licensed biological drug products. In August of this year, the FDA issued draft guidance and a proposed rule regarding naming of these products. However, the agreement remains concerned that FDA needs to provide the public with a greater opportunity to review and comment on regulatory standards for the approval and oversight of biosimilar drugs. Therefore, FDA is directed to provide the Committees with an estimated timeline by which the agency will finalize all pending draft biosimilars guidance documents and regulations. The Committees expect to receive this report no later than 60 days after enactment.

FDA Response:
FDA will provide the requested report.

3. Drug Shortages

There continue to be shortages of critical drugs following the enactment of the Food and Drug Safety and Innovation Act, including national shortages of drugs to test for and treat tuberculosis (TB). The Commissioner is directed to continue to prioritize the public reporting of manufacturing shortages, and to work with industry to prevent conditions that might lead to drug shortages. Additionally, the Commissioner is directed to report on the work of the FDA's intra-agency Drug Shortages Task Force, including how it works with other government agencies and outside stakeholders to address drug shortages. The report should specify what activities the Task Force has undertaken to prevent drug shortages affecting pediatric patients, including working with outside experts on this issue. The Commissioner is further directed to report on steps the FDA can take to prevent TB drug shortages and help maintain an adequate supply.

FDA Response:
FDA will provide the requested report.

4. Partially Hydrogenated Oils

The agreement provides bill language pertaining to the use of partially hydrogenated oils (PHO) in food products. The language declares that foods with PHOs are neither unsafe nor adulterated during FDA' s three year compliance period and provides businesses legal protection while they phase out the use of PHOs. Simultaneously, FDA is encouraged to provide a timely review of

the Food Additive Petition which addresses minor uses of PHOs for certain baking and processing needs.

FDA Response:
On October 1, 2015, FDA filed a food additive petition submitted by the Grocery Manufacturers Association requesting approval for the use of PHOs in various food applications. FDA is reviewing this petition and intends to complete its scientific safety review in a timely manner. In order for FDA to grant the petition, the petition must establish that the proposed use of the additive is safe, meaning that there is a reasonable certainty that no harm will result under the conditions of use.

5. E-cigarette research

The agreement provides $1,000,000 for the Center for Tobacco Products to enter into a contract with the Institute of Medicine to conduct an in-depth evaluation of available evidence of health effects from e-cigarettes and recommendations for future federally funded research.

FDA Response:
FDA recognizes that the tobacco marketplace is changing rapidly, with new types and brands of tobacco products increasing at a faster pace than ever before. The resulting prospect of consumers exploring and adopting use of new products is prompting tobacco control experts, scientists, and regulators to consider how to best evaluate, monitor, regulate, and communicate to the public about these products in order to protect the public health.

CTP has identified e-cigarettes as an immediate research priority area, and has funded over 50 research projects since 2012 to better understand e-cigarette initiation, use, perceptions, dependence, and toxicity. Research projects to address e-cigarette knowledge gaps is being funded by CTP via grants and contracts administered through the National Institutes of Health and through collaborative research with the Centers for Disease Control and Prevention.

This ongoing funded research will provide characterization of some e-cigarette devices, e-liquids, and aerosols, and a better understanding of e-cigarette users, reasons for use, abuse liability, use perceptions, health effects, and topography. CTP will contract with the Institute of Medicine (IOM) to conduct an in-depth evaluation of available evidence of health effects from e-cigarettes and recommendations for future federally funded research.

6. Seafood guidance

The agreement directs that the FDA ensure that pregnant women receive final guidance on nutrition advice for what seafood is safe and healthy to consume that is consistent, understandable, and based on the FDA's latest scientific review of the net effects of seafood consumption.

FDA Response:
On June 10, 2014, FDA and EPA jointly issued a draft update to the seafood advice they last issued in 2004. The updated joint advice tracks the current recommendation in the Dietary Guidelines for Americans, issued by the Departments of Agriculture and Health and Human Services, in that it advises pregnant women, women who may become pregnant, and nursing women eat at least 8 and up to 12 ounces per week of a variety of fish lower in mercury in order to optimize the developmental benefits that fish could provide.

The two agencies announced that there would be at least one public meeting on the advice, to be held by the FDA Risk Communication Advisory Committee. For that reason, the public

comment period, which opened on June 11, 2014, was indefinite until that meeting, and any other meeting, could be held. Specifically, FDA and EPA announced that the comment period would be open until 30 days after the last transcript from the advisory meeting and any other meetings that the agencies would hold on this subject became available.

The Risk Communication Advisory Committee met on the fish consumer advice on November 3-4, 2014 and the transcript from that meeting was subsequently made available. Since no other public meetings are planned, FDA and EPA closed the comment period by publishing a notice in the Federal Register on February 24, 2015. The agencies have subsequently studied the public comments, made modifications to the advice where appropriate, and expect to publish the updated advice in 2016.

7. Essure

The agreement is concerned about the safety issues raised at the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee meeting on September 24, 2015, and directs the FDA to issue recommendations on how to address these concerns by March 1, 2016.

FDA Response:
This is a high priority for FDA. FDA is working expeditiously to conduct an evidence-based review of the available information and identify appropriate next steps. FDA anticipates communicating our actions publicly by February 2016.

8. Bioequivalence standards and ophthalmological solutions

The agreement remains concerned about the FDA's reliance on the use of draft guidance to make substantive policy decisions. The agreement requests a report documenting FDA's review and solicitation of scientific data impacting bioequivalence standards and patients suffering from ophthalmologic conditions.

FDA Response:
FDA will provide the requested report.

9. White Oak Master Plan

The agreement includes $5,000,000 for FDA to complete a feasibility study to update and issue a revised Master Plan for land inside and contiguous to the White Oak campus in order to address its expanded workforce and the facilities needed to accommodate them. The agreement directs FDA to report on this effort by January 1, 2016.

FDA Response:
FDA will provide the requested report.

FDA will provide the $5,000,000 to the General Services Administration (GSA) via a Reimbursable Work Authorization by January 31, 2016 with a scope of work requesting an update of the Master Plan. It is estimated that it will take GSA 90 to 120 days to award a contract for this work. FDA will request that alternatives to include both additional federal construction on the White Oak Federal Research Center (FRC) and leasing office space in close proximity to the FRC be included in the Master Plan update.

The project schedule will include both alternate paths as well as the need to address National Environmental Policy Act (NEPA) requirements associated with federal construction and the GSA justification process for the acquisition of leased space, if necessary. A project schedule will be provided once finalized by the contractor, GSA and FDA.