JOINT EXPLANATORY STATEMENT SIGNIFICANT ITEMS

1. Organizational Chart

The agreement directs the Office of Budget and Program Analysis (OBPA) of the U.S. Department of Agriculture (USDA) to provide an organizational chart for each agency funded by this Act to the division and subdivision level, as appropriate, by June 1, 2017. The agreement also directs the Food and Drug Administration (FDA) and the Farm Credit Administration (FCA) to provide an organizational chart of each agency respectively to the division and subdivision level, as appropriate, by June 1, 2017.

FDA Response:
FDA will provide the requested charts.

2. Food Safety Modernization Act (FSMA)

As part of the increases, the agreement provides an additional $35,675,000 to support the implementation of the Food Safety Modernization Act (FSMA). Of this amount, $18,672,000 is provided for the National Integrated Food Safety System and $16,913,000 is provided for Import Safety. Funds for import safety should help FDA ensure an even playing field in the application

Of FSMA regulations as it relates to both domestic and imported producers, processors, and manufacturers of food and animal feed. The agreement notes that FSMA implementation places additional requirements on state governments and private stakeholders, and therefore urges the

FDA to provide sufficient resources to State education and inspection programs to address these needs. The agreement continues to require quarterly reports to the Committees with a breakdown on funding allocations, as well as projections for future needs.

FDA Response:
FDA will provide the requested reports.

3. Foreign High-Risk Inspections

The $2,500,000 increase above the amount provided in fiscal year 2016 for foreign high-risk inspections will allow FDA's Office of the Global Regulatory Operations Policy to continue efforts to develop and utilize a targeted, risk-based, and efficient inspection model that incorporates commercially available information on high-risk establishments for onsite verifications. FDA is directed to provide the Committees with an update on these efforts, including estimated efficiencies and concerns, and plans to continue or expand this effort in the future.

FDA Response:
FDA will provide the requested update.

4. Employee Conduct

Employees charged with implementing federal programs are expected to carry out their duties in a legal and ethical manner, free from conflicts of interest, without seeking private gain or advancing a private agenda, and without giving preferential treatment to any outside organization or individual. The agency is reminded of its responsibility to ensure that federal employees handle information, including information received from the employees, offices, or Committees of the Congress, in a professional and confidential manner according to the federal government's code of conduct, standards, regulations, and statutes.

FDA Response:
The agency continues to strengthen its ethics and integrity program to help employees avoid conflicts of interest. The agency is committed to preventive activities, such as continuing awareness campaigns of ethics standards for employees and in depth training to supervisors and managers to avoid conflicts. Additionally, the agency has established recommended actions when behavior in violation of these principles has been confirmed.

5. Laboratory Developed Tests

The agreement strongly urges the FDA to continue to work with Congress to address the issues and concerns regarding the regulation of Laboratory Developed Tests.

FDA Response:
FDA will work with Congress to address any issues or concerns related to Laboratory Developed Tests.

6. Compounding

The agreement remains concerned with the draft MOU that the FDA proposed under Section 503A of the FDCA. Section 503A distinguishes between "distribution" and "dispensing" for the purposes of the MOU. In the DQSA, Congress only allowed the FDA to regulate "distribution." The MOU appears to exceed the authority granted in the statute by redefining "distribution" in a manner that includes dispensing. Congress did not intend to include dispensing of compounded drugs over state lines within the scope of the MOU. The MOU should not address dispensing of compounded drugs to a patient over state lines if all other requirements of 503A are met.

FDA Response:
Section 503A of the FD&C Act describes the conditions that must be satisfied for a drug compounded by a licensed pharmacist in a State licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from section 505 (concerning pre-market approval requirements), section 502(f)(1) (concerning labeling with adequate directions for use), and section 501(a)(2)(B)(concerning current good manufacturing practice requirements).

When Congress enacted the DQSA, it left intact as one of the conditions necessary to qualify for the exemptions listed in section 503A of the FD&C Act that:

(1) the drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State

(2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (see section 503A(b)(3)(B)(i) and (b)(3)(B)(ii) of the FD&C Act).

Even though the statute did not direct FDA to obtain public input on the draft standard MOU, other than the consultation with the National Association of Boards of Pharmacy (NABP), FDA has engaged in a public process to obtain comments on the draft standard MOU. FDA has solicited public input from the public generally through written comments to the docket, and has also discussed the proposed MOU with representatives from the 50 states.

FDA discussed the concepts it was considering for the MOU at an Intergovernmental Working Meeting with representatives of the 50 States and NABP in March, 2014. After the draft standard MOU was published for comment, FDA discussed the published draft at Intergovernmental Working Meetings with representatives of the 50 States in March, 2015, and again in November, 2015, after the comment period closed. FDA received over 3,000 comments to the docket on the draft MOU. FDA is considering all of the comments, including comments on the definition of “distribution,” as we work to finalize the MOU.

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