Dear Dr. Ostroff:

The US Food and Drug Administration (FDA) has invested over $50 million towards the accreditation of state food testing laboratories to the ISO/IEC 17025:2005 standard (ISO 17025). Accreditation is an integral part of mutual reliance and a critical element of an Integrated Food Safety System (IFSS), both nationally and internationally. A fully functioning IFSS allows for acceptance of state data in federal enforcement actions and means FDA and states can act efficiently and proactively in the prevention of foodborne illnesses.

As of December 2016, twenty-three FDA-funded state laboratories have either achieved ISO 17025 accreditation or expanded their scope of accreditation. Active monitoring of cooperative agreement deliverables shows that all of the original thirty FDA-funded food laboratories are on track to achieve or expand their accreditation by the end of the funding cycle in August 2017. However, continued funding in the amount of $4.5 million annually is needed for these thirty laboratories to sustain their ISO programs and maintain their accreditation.

This investment in accreditation has been critical to protecting the US food supply, largely by strengthening state food testing laboratories’ capacity and capability. The grant-required sampling plans have resulted in several successful food recalls that directly protected public health.

- In February 2015, South Carolina Department of Health and Environmental Control isolated *Listeria monocytogenes* from frozen ice cream products; this discovery was linked to ten human illnesses in Arizona, Kansas, Oklahoma and Texas, including three deaths.
- Due to South Carolina’s discovery, the Nebraska Department of Agriculture Food Laboratory also decided to test frozen dessert products. In April 2015, they discovered a *L. monocytogenes* positive sample that resulted in a recall; no human illnesses were linked to this product.
- In March 2015, the Virginia Division of Consolidated Laboratory Services isolated *L. monocytogenes* samples from soybean sprouts and issued a recall. Subsequent testing following remediation revealed additional positive samples; after the third recall, the manufacturer decided to cease production and closed permanently in November 2015.
- The Ohio Department of Agriculture issued two recalls in 2016 following the discovery of *L. monocytogenes* in frozen vegetable products and in packaged salads. The frozen vegetable products were distributed to retailers in 35 states and four Canadian
provinces. The packaged salads were linked to 19 illnesses in nine states, including one person from Michigan who died as a result of listeriosis.

- In October of 2016, the Connecticut Agricultural Experiment Station (CAES) detected 1.8 mg/kg of the pesticide thiabendazole on imported Malanga (an ethnic root crop). This is a “no tolerance” pesticide violation and is the second time CAES reported violative pesticide residues on this crop in 2016. FDA issued an Import Alert for the violative pesticide sample.

With the first FDA funding cycle set to end in August 2017, currently funded laboratories are seeking ways to maintain their accreditation. The loss of federal funding will devastate some programs established at the state level. Many states will be unable to fully fund their ISO programs without federal funding. Many states are facing budget cuts that will inhibit the retention of positions that are crucial to maintaining accreditation, such as quality managers and sample custodians. State regulations prevent many laboratories from utilizing fee-for-service revenue options, and union rules may prevent the use of unpaid interns to address certain staffing concerns.

The efforts put into achieving accreditation do not cease once the laboratory meets the standard. Accreditation is a process of continuous improvement that requires ongoing training, proficiency testing, and auditing (internal and external) to ensure that the laboratory is always operating at an optimum level. In addition, expansion of the laboratory’s scope of accreditation to address new methods, technologies and analytes is a key component of continuous improvement efforts. Lastly, ISO 17025:2017 is due for release next year and laboratories will have to accommodate changes in the new standard. These activities can be expensive and time-consuming, but they are essential to generating reliable and actionable results in an ISO 17025 environment. Without some level of federal funding to support these activities, there will be a dramatic reduction in the level of maintenance for ISO programs, and some programs will be completely dismantled.

All states are working creatively to maximize their contribution; however, baseline federal funding of $4.5 million will most certainly be needed for the thirty laboratories looking to sustain ISO accreditation, with the focus on retaining qualified staff. Sustaining ISO 17025 demonstrates a commitment to quality and supports the central goal of the Food Safety Modernization Act – the creation of a prevention-based integrated food safety system. By facilitating long-term, permanent improvements to our nation’s laboratory system, FDA’s investment in ISO 17025 accreditation and a leadership structure for state food and feed laboratories is the most efficient and effective path to advance public health initiatives and improve the safety of the US food supply.

Sincerely,

Scott J. Becker, MS
Executive Director