



Alliance for a Stronger FDA Budget Priorities Webinar Series  
Summary of Webinar with Dr. Judith McMeekin, Associate Commissioner  
for Regulatory Affairs  
April 6, 2022 | Moderated by Nancy Myers and Rachel Sher

FDA’s Office of Regulatory Affairs (ORA), led by Associate Commissioner Judy McMeekin, reaches across all of FDA. In an information-filled webinar on April 6, Commissioner McMeekin said that ORA has one-third of FDA’s workforce, with a currently budget of \$1.2 billion. Their activities include inspections around the world, looking at produce, tobacco, data from vaccine trials, testing product samples, analyzing cosmetics, following up on adverse events, and conducting import investigations and inspections at all nine import mail facilities.

ORA conducts three types of inspections: 1) for cause; 2) pre-approval premarket as part of the application process (with 20% of applications requiring inspections before approval); and 3) surveillance inspections that may result in “no official action”, “voluntary action indicated”, or “official action indicated. Surveillance inspections are based on risk. Inspections and alternative tools allowed for keeping up with requirements during the pandemic, with the goal for domestic surveillance inspections exceeded by the end of FY 21, significant progress made in catching up on postponed inspections, and exceeding follow up goals on those where official action was indicated.

ORA works with federal, state, local, tribal, and foreign partners. States conduct approximately 80% of animal feed inspection. ORA has mutual recognition agreements with the European Union and others to facilitate international work.

Opioid funds provided during FY 22 allowed for the inspection and destruction of fraudulent drugs, and work on e-commerce. The mobile laboratory at the Chicago International Mail Facility allowed for testing to be done so that hold determinations could be done quickly.

ORA routinely works with FDA Center Directors, and this past year created the FDA Inspectional Affairs Council to plan and coordinate inspectional activities and look at the use of new technology to optimize agency resources.

For FY 23, ORA is seeing \$1.36 billion, with 91% of this amount coming from budget authority appropriations and just 9% from user fees. A key effort in this budget request is the need to optimize inspection approaches with support for the recruitment and training of new inspectors.

Associate Commissioner McMeekin emphasized the importance of further investment in data modernization and enhanced technology. She hoped Congress will support funding for the development of new IT systems which will both gain operational efficiency and meet customer expectations. She did say that ORA's budget has not kept up with the demands placed on it.

She went on to respond to multiple questions from the Alliance and those participating in the webinar:

- *Dealing with inspection backlogs* - Associate Commissioner McMeekin expects to continue to use enhanced alternative systems to do the work. There is a need to balance domestic and foreign requirements, with the need to deploy resources to deal with the global supply chain. ORA will be focused on products having the highest risk. The food safety side will use a full range of tools.
- *Remote inspections* – She said that ORA will continue to use alternate tools and prioritize resources to maintain flexibility. They will prioritize domestic and foreign inspections that could not be done during the pandemic, based on public health needs, complexity, follow up, and other factors.
- *Mutual Recognition Agreements* – These agreements with the EU and others have helped to avoid duplication and allowed the priority use of resources. They leveraged third party inspections for drug approvals and are now incorporating third party efforts into the annual work plan. Surveillance work continued, and critical assessment was provided with written reports. There have been some minor challenges with just 22 of the 28 EU countries having third party reports available, and in some cases the reports are 18 months old. She expects these efforts to expand to include veterinary medicine.
- *ORA staffing challenges* – She said it can be a challenge to maintain staffing levels. The goal is to have a diverse and highly capable work force. They use direct hiring, veteran recruitment, and an expanded use of CURES authority. However, CURES is intended only for medical products, so the hiring capability creates a disparity for food safety. Foreign travel is demanding and challenging for personnel, with 18 weeks of travel per year.
- *ORA's role in international harmonization* – The effort is particularly important, and she cited the Pharmaceutical Inspection Co-operation Scheme (PIC/S) as an example of the effort. A coalition can provide tools to preserve finite inspection resources. ORA supports bilateral information sharing activities.
- *Resumption of foreign inspections* – They have continued foreign mission critical inspections. Certain inspections that were not mission critical have been prioritized. They have been able to resume domestic inspections across all commodities and are starting some foreign inspections. While she could not say when all inspections will be back on track, she did say that ORA will use all available tools.
- *Challenges in China and India* – She said that different countries pose different challenges, noting travel restrictions in China. Congress does want a resumption of unannounced inspections, which will start in India but are on hold in China. The safety of FDA's inspectors is top priority. When going into special economic zones, an escort is required.
- *ORA's partners* - Associate Commissioner McMeekin said they have many stakeholders. FDA is participating in an interagency executive council with 40 other agencies for dealing with imported products. They have partnerships with states to conduct

inspections. She also referenced the National Association of State Departments of Agriculture (NASDA) and the Association of Food and Drug Officials. She also mentioned CDC, USDA, Customs and Border Patrol, and foreign regulatory counterparts.

When asked about the most demanding part of her job and what prepared her to take it on, she suggested the variety and depth of work, hitting every commodity FDA regulates, is fascinating. She started this job at the outset of the pandemic, so has had multiple challenges for which her career experience with a variety of skill sets prepared her.