Inspections in a COVID-19 World

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Perspectives

• Common mission and goals that U.S. patients have access to a secure and consistent supply of pharmaceuticals
• Our nation needs a diverse and resilient pharmaceutical supply chain
• Industry has the primary responsibility to reliably produce safe quality products
Pandemic

- Onset of the COVID-19 pandemic and travel restrictions
- On March 10 and 18, respectively, FDA postponed conducting routine foreign and domestic inspections
- ORA continued mission-critical on-site work, such as for-cause inspections on a case-by-case basis, import review, laboratory analysis of samples
- On July 10, FDA announced plans to resume prioritized domestic inspections
- Resumed prioritized surveillance inspections
Pandemic, cont.

• On July 10, FDA announced a plan to resume prioritized domestic inspections
• ORA stands ready to resume any postponed inspections as soon as feasible, applying a strategic benefit versus risk calculus to our inspectional work
Foreign Pharmaceutical Inspection

Inspections: ORA's Global Reach

ORA's Global Inspections:

- United States
- Australia
- Austria
- Bahamas
- Barbados
- Belgium
- Benin
- Bolivia
- Bosnia and Herzegovina
- Brazil
- Bulgaria
- Burundi
- Cambodia
- Canada
- Cape Verde
- Chile
- China
- Colombia
- Costa Rica
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Dominican Republic
- Ecuador
- Estonia
- Fiji
- France
- Georgia
- Germany
- Ghana
- Greece
- Grenada
- Guatemala
- Guyana
- Honduras
- Hong Kong SAR
- Hungary
- Iceland
- India
- Indonesia
- Ireland
- Israel
- Italy
- Jamaica
- Japan
- Jordan
- Kazakhstan
- Korea
- Kuwait
- Lebanon
- Lithuania
- Luxembourg
- Macau
- Macedonia
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Mauritania
- Mauritius
- Mexico
- Micronesia
- Moldova
- Monaco
- Morocco
- Netherlands
- New Zealand
- Nicaragua
- Nigeria
- Norway
- Oman
- Pakistan
- Panama
- Peru
- Philippines
- Poland
- Portugal
- Puerto Rico
- Qatar
- Romania
- Russia
- Samoa
- Senegal
- Serbia
- Singapore
- Slovakia
- Slovenia
- South Africa
- Spain
- Sri Lanka
- Sweden
- Switzerland
- Taiwan
- Thailand
- Timor-Leste
- Turkey
- Ukraine
- United Arab Emirates
- United Kingdom
- Uruguay
- Vietnam
- Western Sahara

Countries Where ORA Conducts Inspections
# FY19 Statistics

<table>
<thead>
<tr>
<th></th>
<th>Biologics</th>
<th>BIMO</th>
<th>Devices (MQSA)</th>
<th>Pharma</th>
<th>Tobacco</th>
<th>Human &amp; Animal Food</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FDA Domestic</strong></td>
<td>1,641</td>
<td>1,016</td>
<td>2,144 (785)*</td>
<td>941</td>
<td>131</td>
<td>8,522</td>
<td>14,395</td>
</tr>
<tr>
<td><strong>State Domestic</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>7,449 (7,402)*</td>
<td>N/A</td>
<td>N/A</td>
<td>9,613</td>
<td>17,062</td>
</tr>
<tr>
<td><strong>FDA Foreign</strong></td>
<td>57</td>
<td>315</td>
<td>581 (12)*</td>
<td>1,045</td>
<td>0</td>
<td>1,784</td>
<td>3,782</td>
</tr>
<tr>
<td><strong>Total FDA and State Domestic Inspections</strong></td>
<td>1,641</td>
<td>1,016</td>
<td>9,593</td>
<td>941</td>
<td>131</td>
<td>18,135</td>
<td>31,457</td>
</tr>
<tr>
<td><strong>Total FDA Domestic, State Domestic, and Foreign Inspections</strong></td>
<td>1,698</td>
<td>1,331</td>
<td>10,174</td>
<td>1,986</td>
<td>131</td>
<td>19,919</td>
<td>35,239</td>
</tr>
</tbody>
</table>

* MQSA count are in parenthesis. The MQSA counts re a sub-set of the Devices count.
Lessons from Crisis: A Changed World

• Ability to conduct on-site facility inspections is important to carrying out our mission.

• Implemented alternative ways to conduct inspectional work that do not jeopardize public safety and that protect firms as well as FDA staff.
Innovation and Alternative Approaches

• Using our authority to request records and other information in advance of or in lieu of inspections
• Relying on global partnerships in requesting establishment inspection reports from capable foreign regulatory authorities under the MRA
• Looking critically at ways to innovate and optimize use of these tools to better serve the American public in the future
Facilitating New Approaches

• To create efficiencies and regulatory predictability we will need to engage on new approaches and new tools

• Leveraging technologies, such as secure data platforms to share, assess and exchange records

• Further enhancing relationships with capable regulatory partners to reduce redundant and duplicative work and disperse critical resources more effectively
Facilitating New Approaches, cont.

• Benchmarking operations against other inspectorates to identify new and improved strategies

• An open and honest dialogue about a true partnership to advance medical product quality and accessibility

• Expanded cooperation with industry, working collaboratively to evaluate facility processes and ways to achieve inspectional operations in innovative and creative ways
Future Opportunities

• Understand how the pandemic has changed pharmaceutical industry
• Identify how we work together toward achieving outcomes in the best interest of patients
• Engaging on ideas for strengthening partnerships particularly in the area of inspection operations
Thank You - Questions?