Protecting Public Health Office of Regulatory Affairs (ORA)

Fiscal Year 2018



OFFICE OF REGULATORY AFFAIRS

ORA Facts

ORA Maximizes Compliance of FDA Regulated Products and Minimizes Risks Associated with Those Products







Regulatory and Public Health Partnerships

Expanded our federal, state, local, tribal and territorial regulatory and public health partnership efforts



129 contracts awarded Tor a total of \$27.4 million

Includes contracts with all 50 states & Puerto Rico enabling over 29,000 inspections, site visits, & sample collections



268 cooperative agreements and grants for a total of \$88.9 million

Includes agreements/grants with 49 states, American Samoa, District of Columbia, & 11 associations

Inspections: ORA's Global Reach

ORA's Global Inspections:

Argentina	Estonia
Armenia	Finland
Australia	France
Austria	Georgia
Bahamas	Germany
Barbados	Ghana
Belgium	Greece
Belize	Grenada
Bosnia-Herzegovina	Guatemala
Brazil	Honduras
Bulgaria	Hong Kong SAR
Cambodia	Hungary
Canada	Iceland
Chile	India
China	Indonesia
Colombia	Ireland
Costa Rica	Israel
Croatia	Italy
Cuba	Jamaica
Czech Republic	Japan

Ecuador

Korea (the Republic of)

Andorra

Denmark

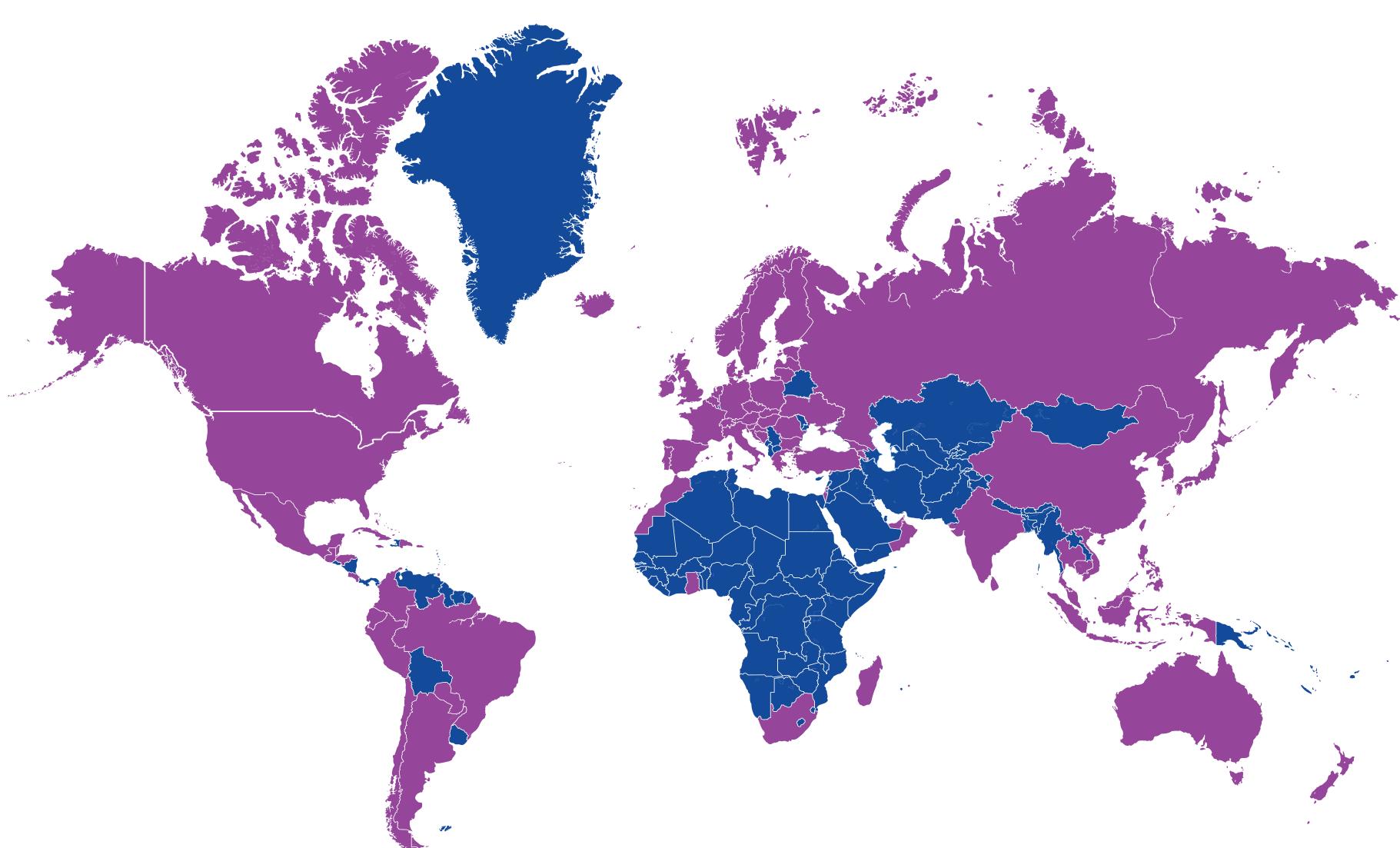
Dominican Republic

Lithuania Macao Madagascar Malaysia Malta

Mauritius Mexico Monaco Morocco **Netherlands** New Zealand Norway Paraguay **Philippines** Poland Portugal Romania Russia Singapore Slovakia Slovenia

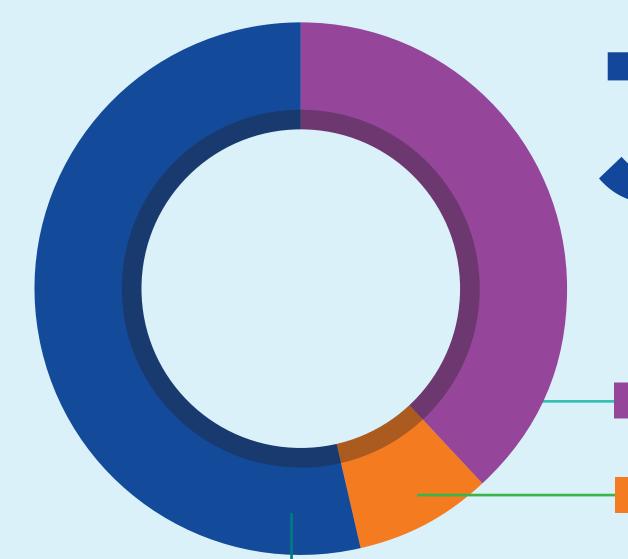
South Africa Sri Lanka Sweden **Switzerland** Taiwan Thailand Trinidad & Tobago Turkey Ukraine **United Arab Emirates United Kingdom United States** Vietnam

Countries Where ORA Performs Inspections



Inspections





38,856 **Total Inspections**

16,336 Domestic Inspections **3,736** Foreign Inspections

18,784 State Inspections



43,099

Samples Collected & Analyzed



A line is a distinct product within a shipment. A single shipment may include multiple lines.

43,606,426

Import Lines

Criminal Investigations

Enforcement





14,285 Warning Letters Issued

*Includes 13,928 warning letters issued by the Center for Tobacco Products



Recalled Products



Injunctions



Seizure



Allow FDA to detain future shipments of potentially violative products without testing or examination





OCI Arrests

\$114,163,550
OCI Assets Forfeited and Seized



OCI Convictions



\$2,182,317,876