# Protecting Public Health Office of Regulatory Affairs (ORA)

Fiscal Year 2019



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



Cyprus

129 contracts awarded for a total of \$28.17 million

Includes contracts with all 50 states & Puerto Rico enabling ~28,000 inspections, site visits, & sample collections



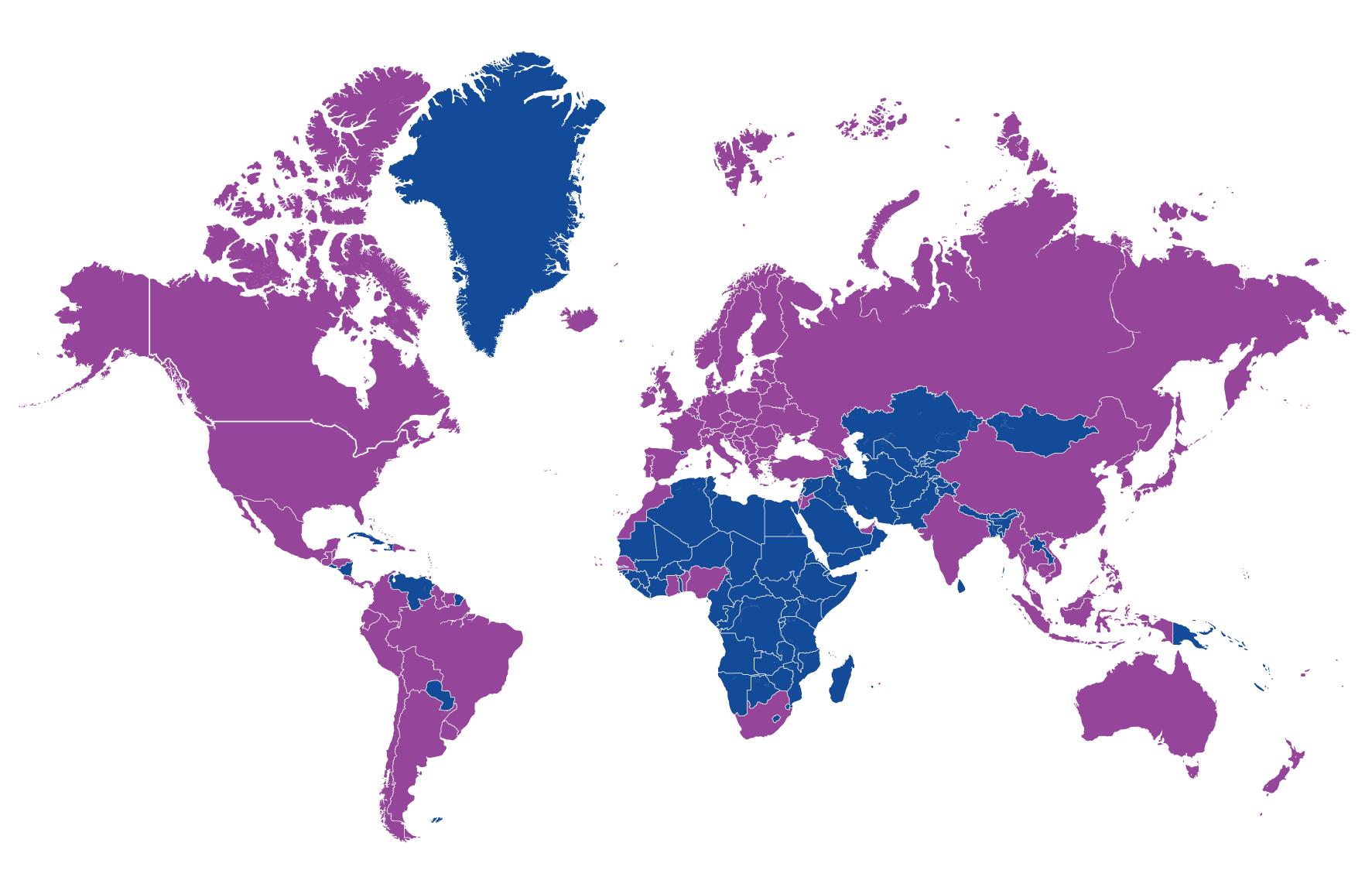
267 cooperative agreements and grants for a total of \$85.7 million

Includes agreements/grants with 49 states, American Samoa, District of Columbia, & 13 regulatory associations

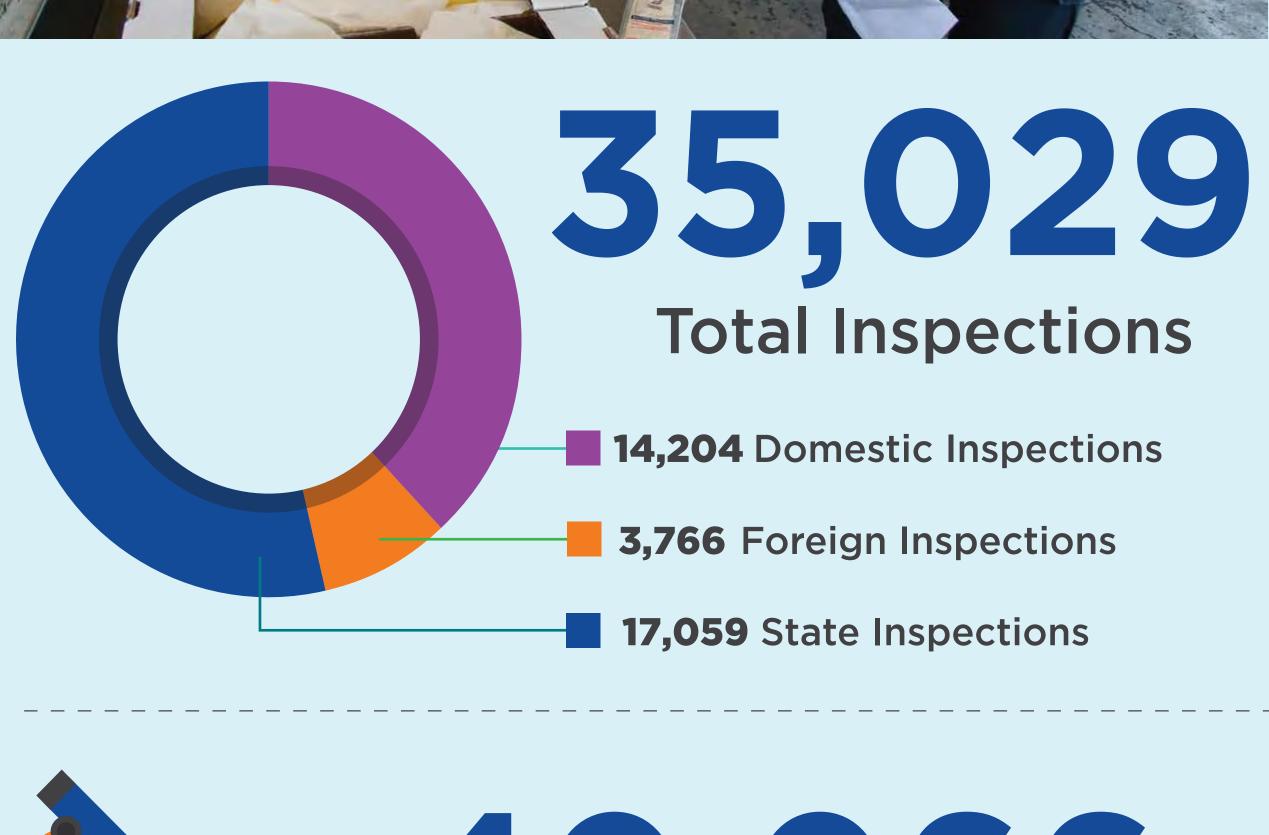
## Inspections: ORA's Global Reach

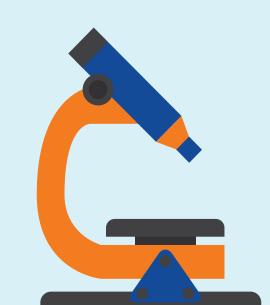
#### **ORA's Global Inspections:**

United States	Czech Republic	Japan	Singapore
Albania	Denmark	Jordan	Slovakia
Argentina	Dominican Republic (the)	Korea (the Republic of)	Slovenia
Armenia	Ecuador	Latvia	South Africa
Australia	Estonia	Lithuania	Spain
Austria	Faroe Islands	Macedonia	Suriname
Bahamas	Fiji	Malaysia	Sweden
Barbados	Finland	Malta	Switzerland
Belarus	France	Marshall Islands	Taiwan
Belgium	Georgia	Mauritius	Thailand
Belize	Germany	Mexico	Tonga
Benin	Ghana	Moldova	Trinidad & Toba
Bolivia	Greece	Morocco	Turkey
Bosnia-Hercegovina	Grenada	Netherlands	Ukraine
Brazil	Guatemala	New Zealand	United Arab Emi
Bulgaria	Guyana	Nigeria	<b>United Kingdom</b>
Burma (Myanmar)	Honduras	Norway	Uruguay
Cambodia	Hong Kong SAR	Panama	Vietnam
Canada	Hungary	Peru	Western Samoa
Cape Verde	Iceland	Philippines	
Chile	India	Poland	Countries W
China	Indonesia	Portugal	ORA Conduc
Colombia	Ireland	Romania	Inspections
Costa Rica	Israel	Russia	
Croatia	Italy	Senegal	



### Inspections





40,066

mples Collected & Analyze

Samples Collected & Analyzed



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

45,194,561

Import Lines

Criminal Investigations

### Enforcement





14,949

Warning Letters Issued
\*Includes 14,607 warning letters issued
by the Center for Tobacco Products



7,893

Possilled Products

Recalled Products





**S**Injunctions

Seizures



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





**OCI Convictions** 



\$1,359,707,049 OCI Assets Forfeited and Seized

\$1,628,507,151
OCI Fines and Restitution