



The Small Business Representative

David Arvelo
FDA ORA SWR SBR

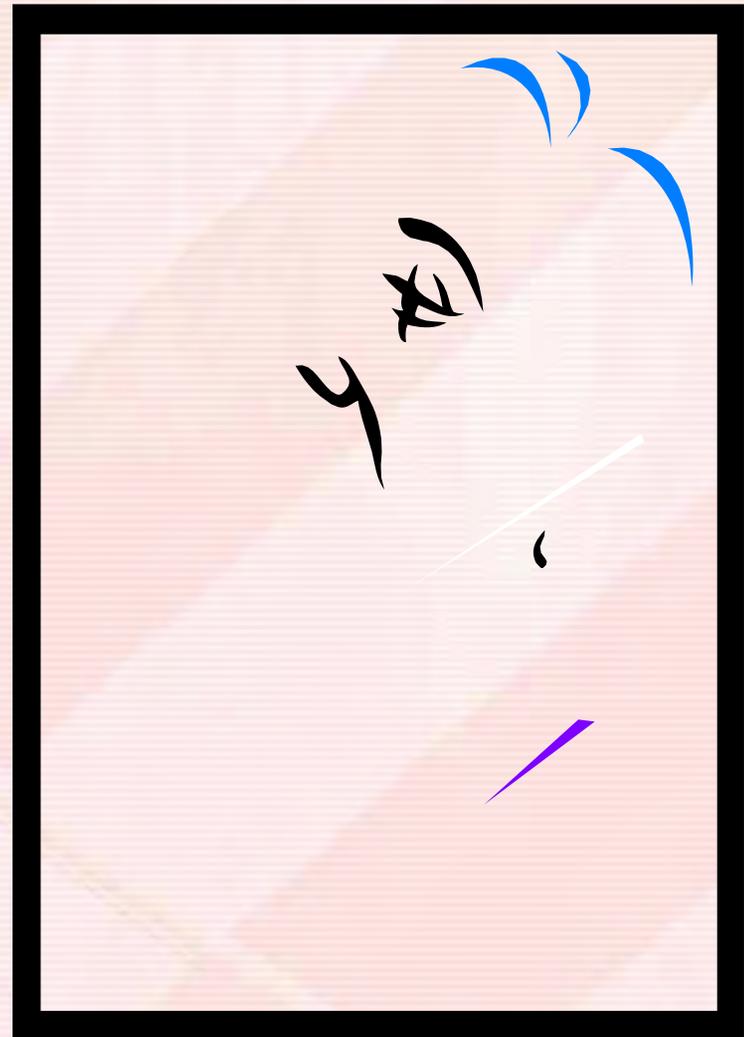
ORA SBR Mission

- Assist industry and entrepreneurs
 - Facilitate access to guidance, policies, regulations and laws enforced by FDA
 - Provide technical assistance
 - Act as liaison



ORA SBR Customers

- Small Businesses
- Entrepreneurs
- Start-ups
- Professional Associations
- Trade Associations
- Consultants
- Corporations



Agency Jurisdiction

- Foods
- Drugs
- Biologics
- Cosmetics
- Medical Devices
- Radiation-Emitting Products
- Veterinary Products



ORA SBR Services

- Inquiries
- Training
- On-Site Visits



Small Business
Representative
Program



US Food and Drug
Administration



Office of Regulatory Affairs

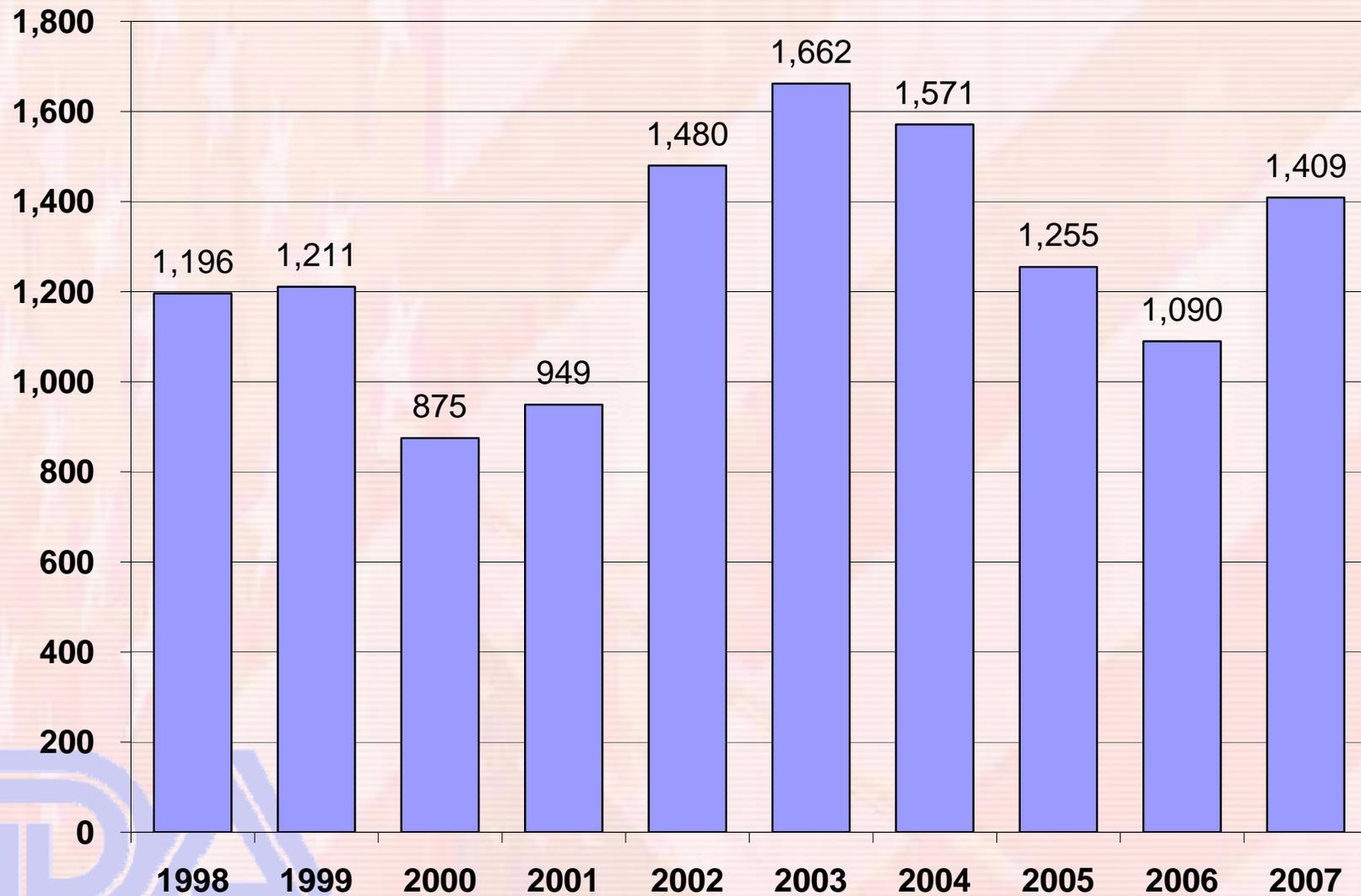


ORA SBR Inquiries

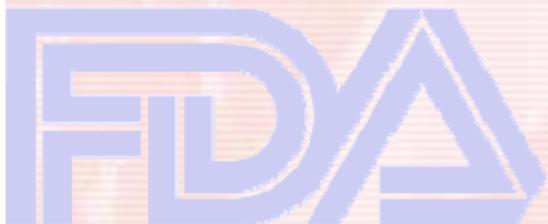
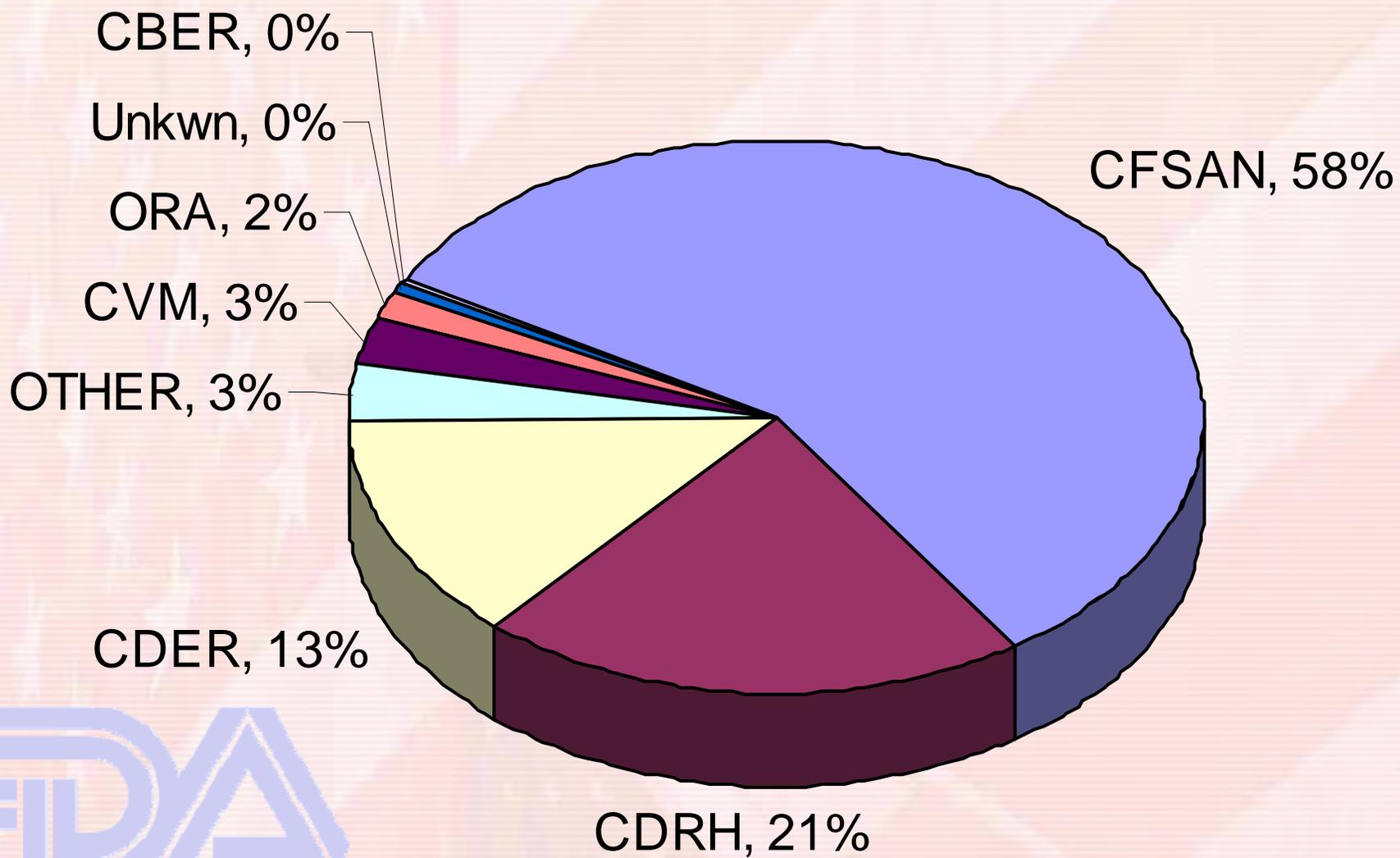
- Received and responded via
 - Telephone
 - e-Mail
 - Fax
 - Snail-Mail
- 10-day deadline
- 2-day average turnaround



ORA SWR SBR Inquiries

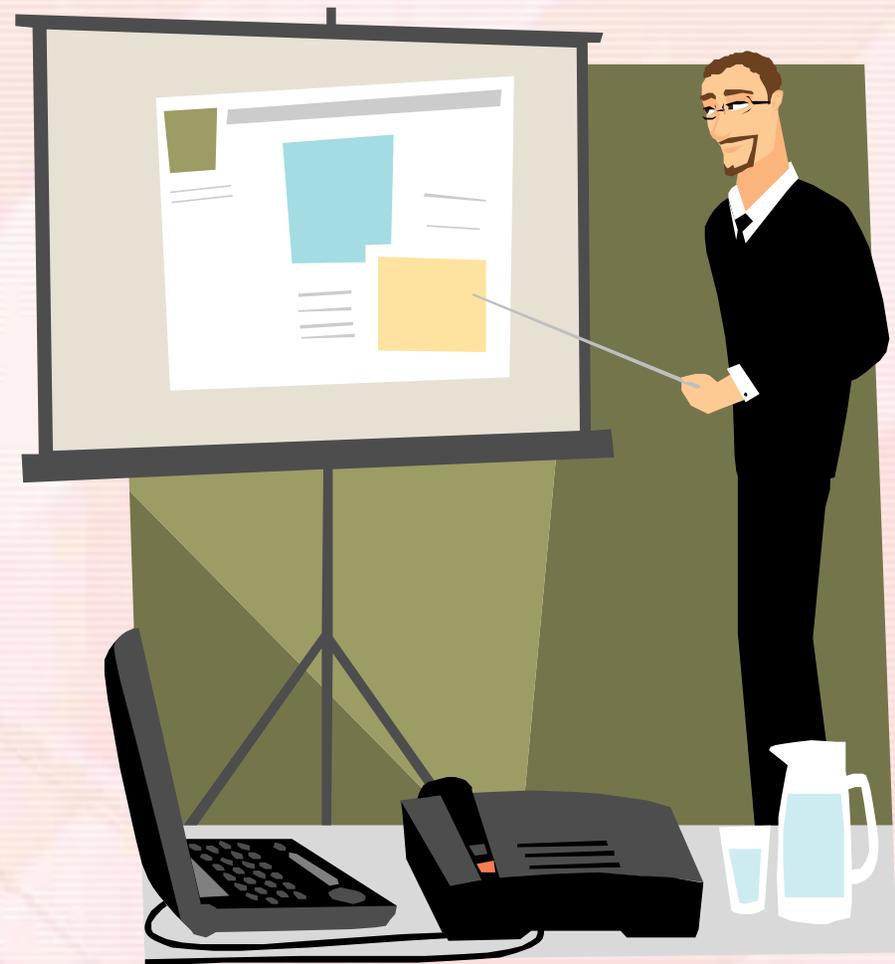


ORA SWR SBR FY-2007 Inquiries



ORA SBR Training

- Deliver presentations
 - To industry and professional associations
- Organize and publicize workshops
 - Co-sponsor with industry and professional associations



SWR SBR Upcoming Training

- FDA Clinical Trial Requirements Regulations, Compliance, and GCP Conference
 - November 19 and 20, 2008
 - Westin Crown Center, Kansas City
 - http://www.socra.org/html/FDA_Conference.htm
- Food Allergen Workshop
- Food Labeling Workshop



ORA SBR On-Site Visits

- Voluntary review
- At industry's request
- Confidential
- cursory, brief
- Limited by schedule and budget



ORA SBR Confidentiality

- FDA employees are prohibited by law from divulging proprietary or confidential information
- SBR's do not discuss industry inquiries with inspectors unless it is life threatening



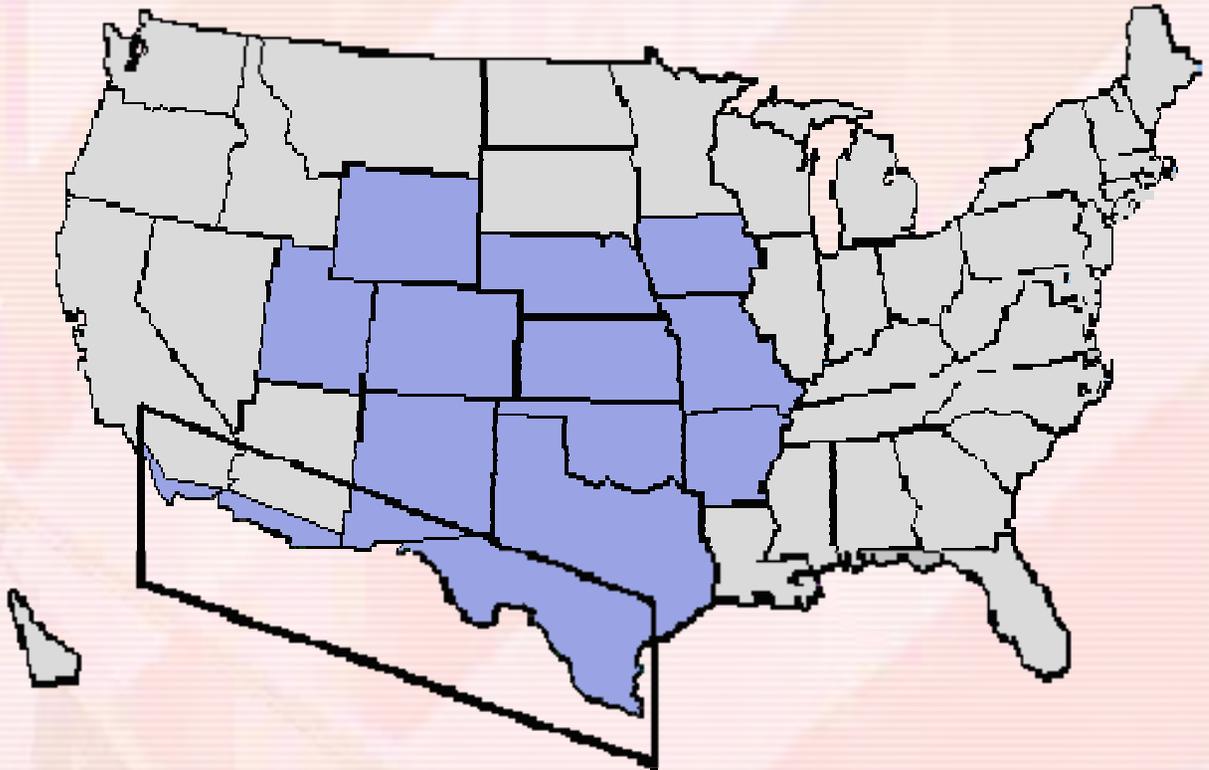
ORA SBR Limitations

- Cannot intervene when a current investigation reveals violative conditions that warrant regulatory action
 - 483 observations
 - Warning letters
 - Import detentions



ORA SWR SBR Geographical Limits

- Arkansas
- Colorado
- Iowa
- Kansas
- Missouri
- Nebraska
- New Mexico
- Oklahoma
- Texas
- Utah
- Wyoming
- US-Mexico Border





Search go

- Food ▶
- Drugs ▶
- Medical Devices ▶
- Biologics, Blood & Vaccines ▶
- Animal & Veterinary ▶
- Cosmetics ▶
- Radiation-Emitting Products ▶
- Combination Products ▶



http://www.fda.gov/

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- ▶ Qualified Health Claims
- ▶ Vaccines

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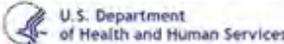
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- How to use the Federal Register
- How to comment on proposed regulations
- How to petition the FDA
- What to do when marketing a new product, undergoing FDA inspection, recalling violative products, etc.



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Small Business Guide to FDA

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We Want You



To Voluntarily Comply!

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