PDA Metro Chapter Meeting
September 28, 2011
Somerset, NJ

FDA Enforcement Update

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New Jersey District

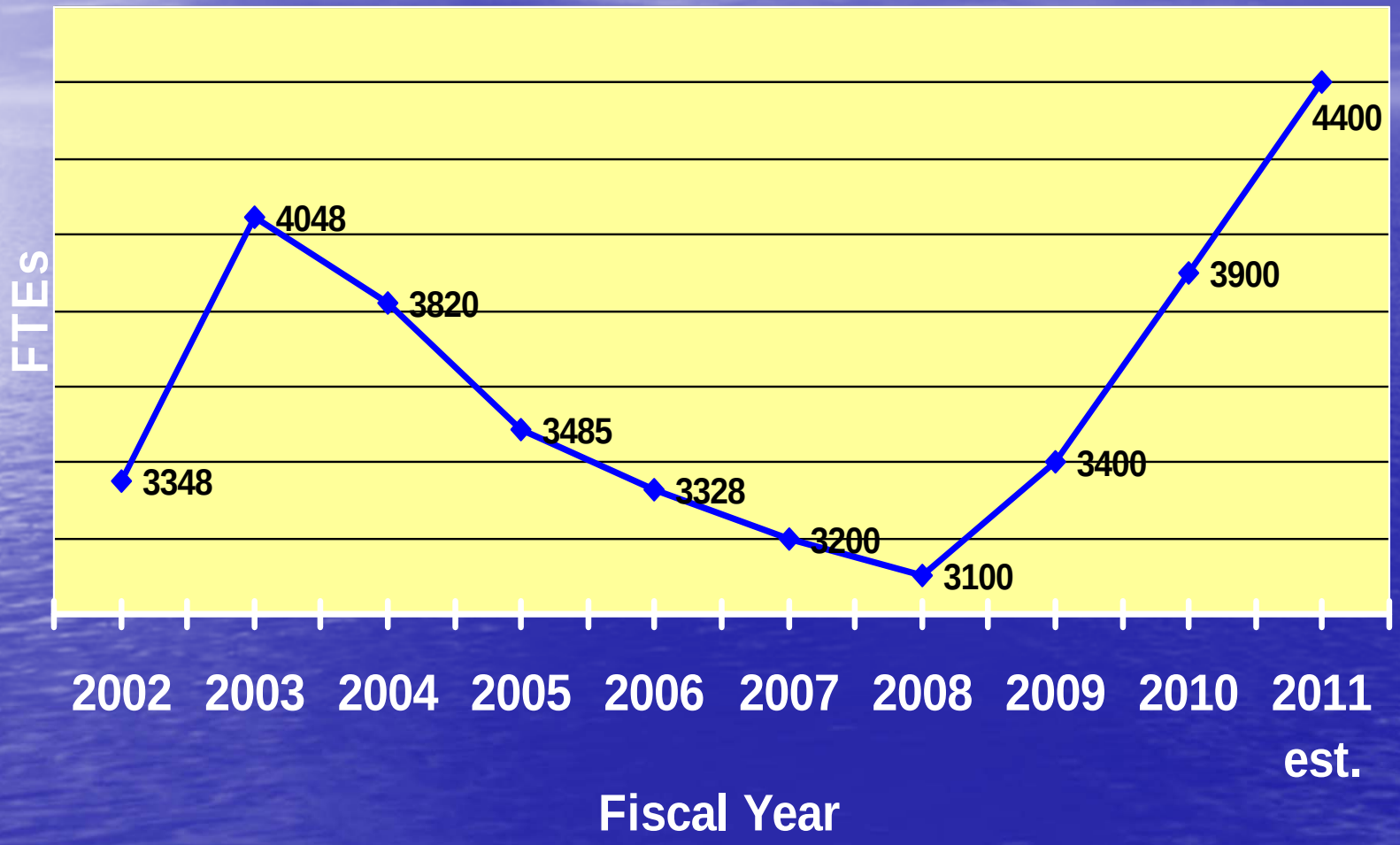
FDA/ORA Update

- Consent Decrees
- Seizures
- Warning Letters
- FDA-483 Trends

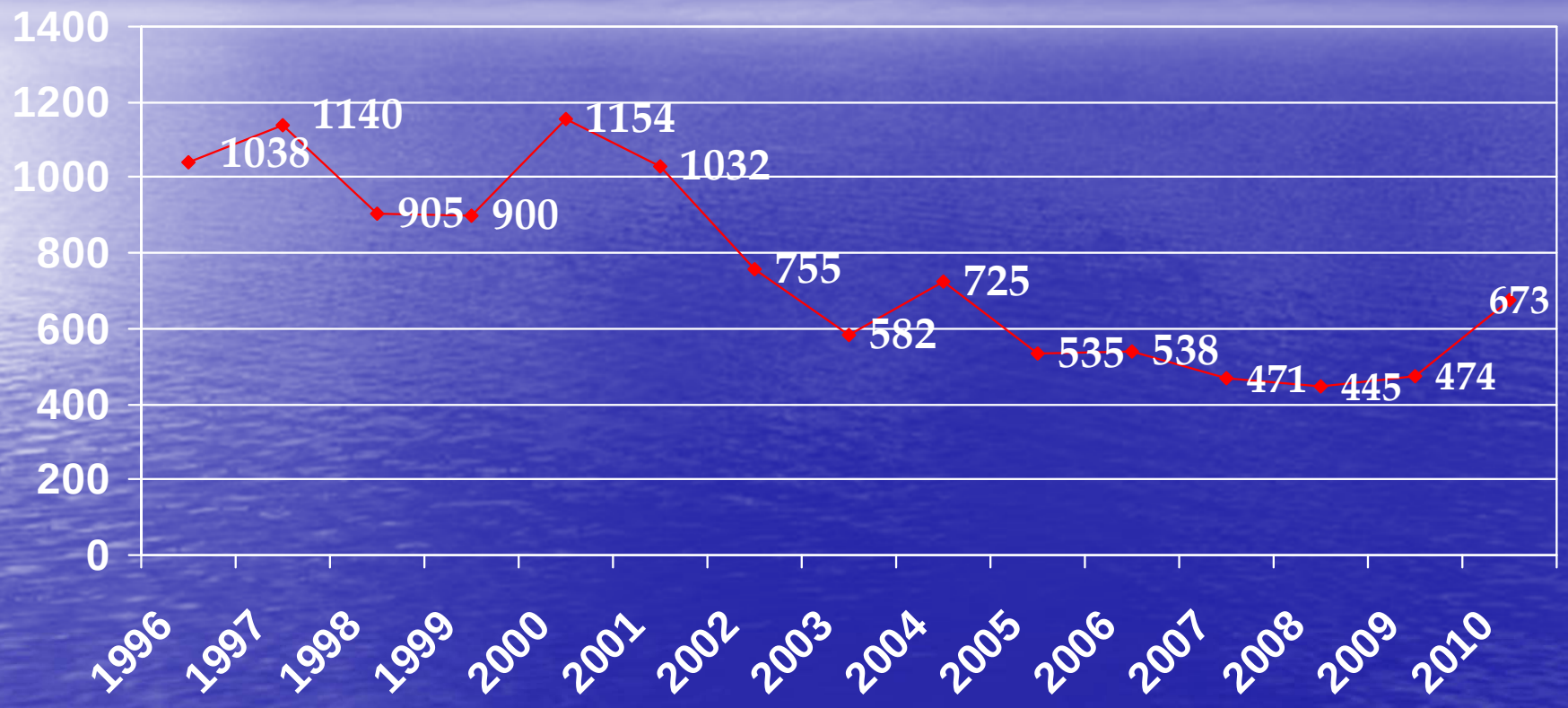
District Level Responsibilities

- Workplan
- Assignments from Centers
- Pre-Approval Inspections
- Consumer Complaints
- Trade Complaints
- Recalls
- Referrals from State, OCI

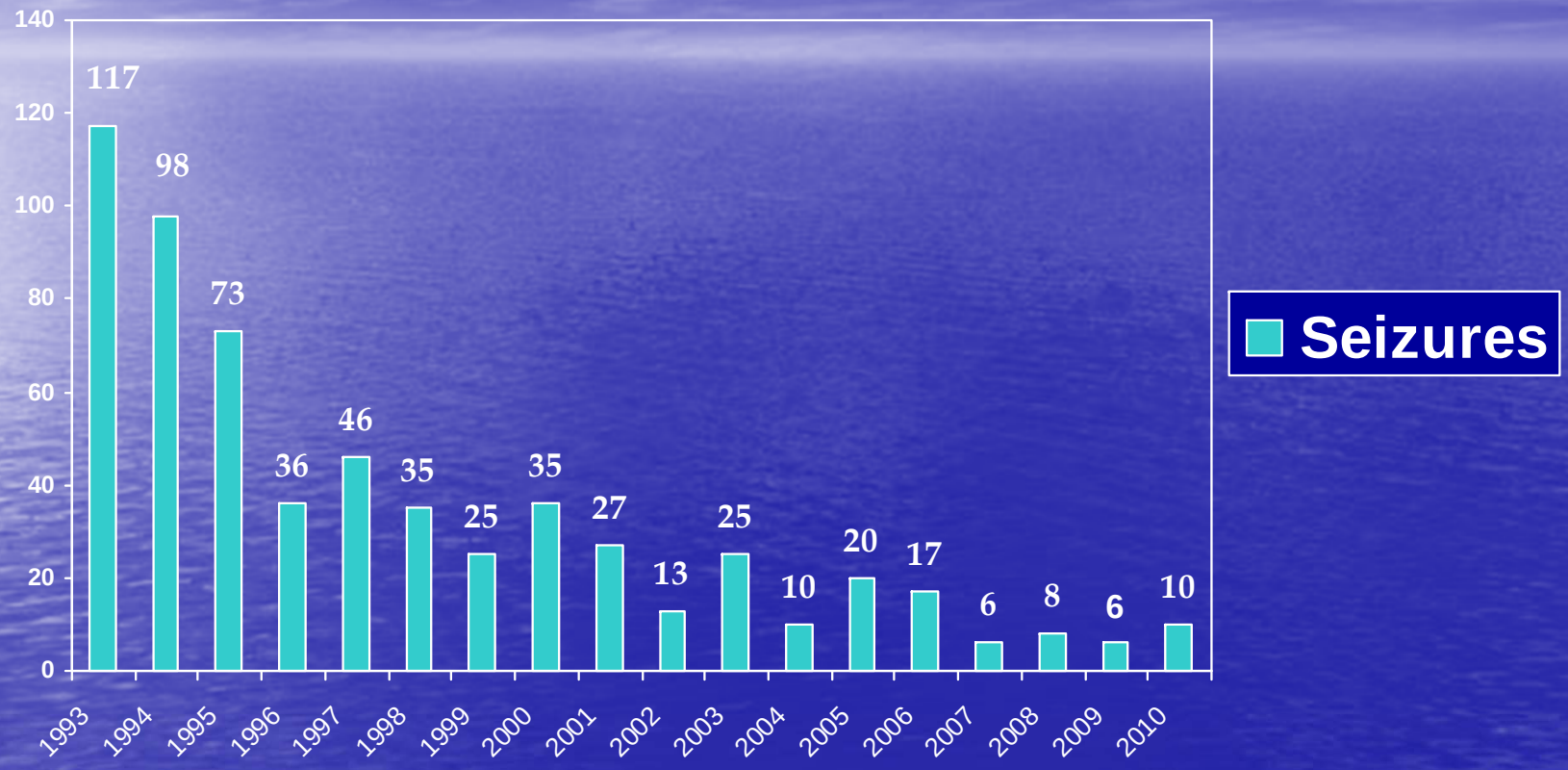
ORA FTE History



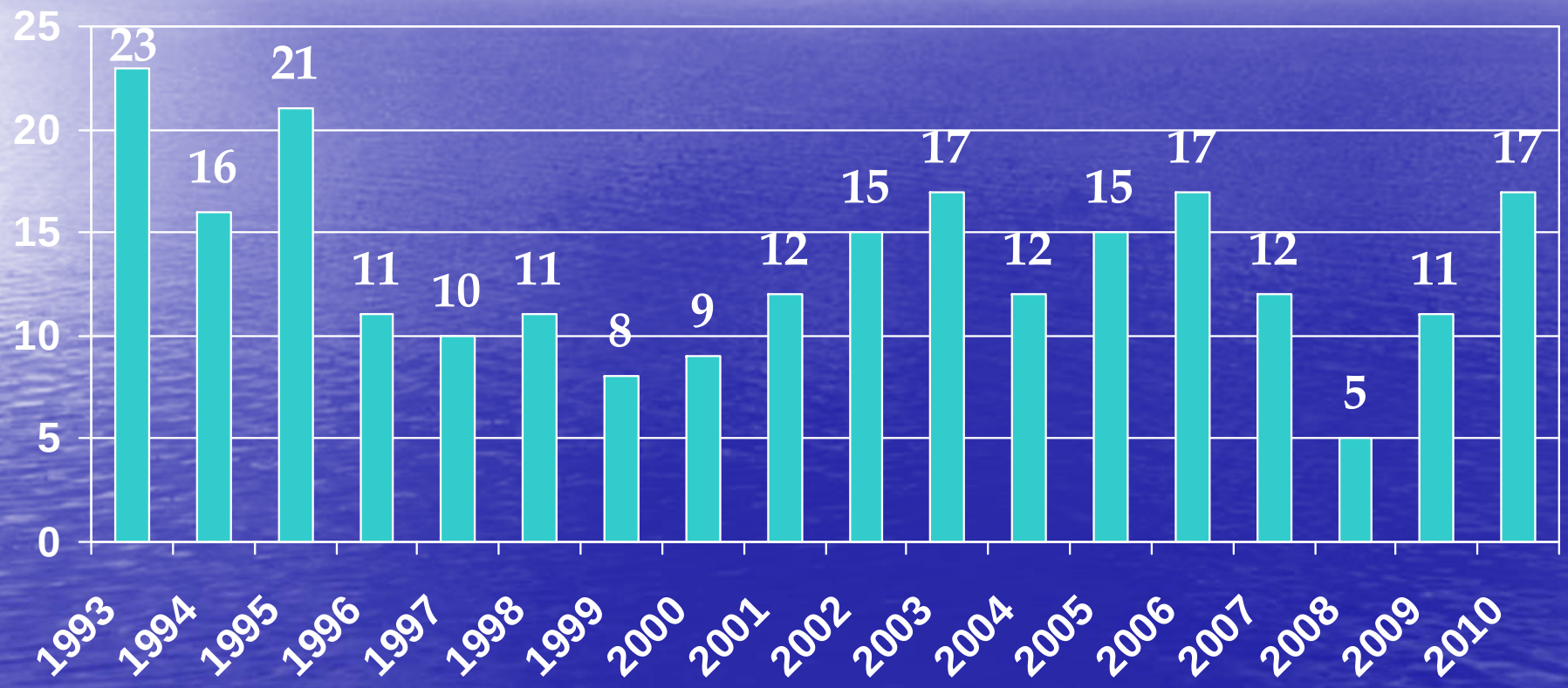
Warning Letters
Fiscal Years 1996 – 2010



Seizures
Fiscals Years 1993 – 2010



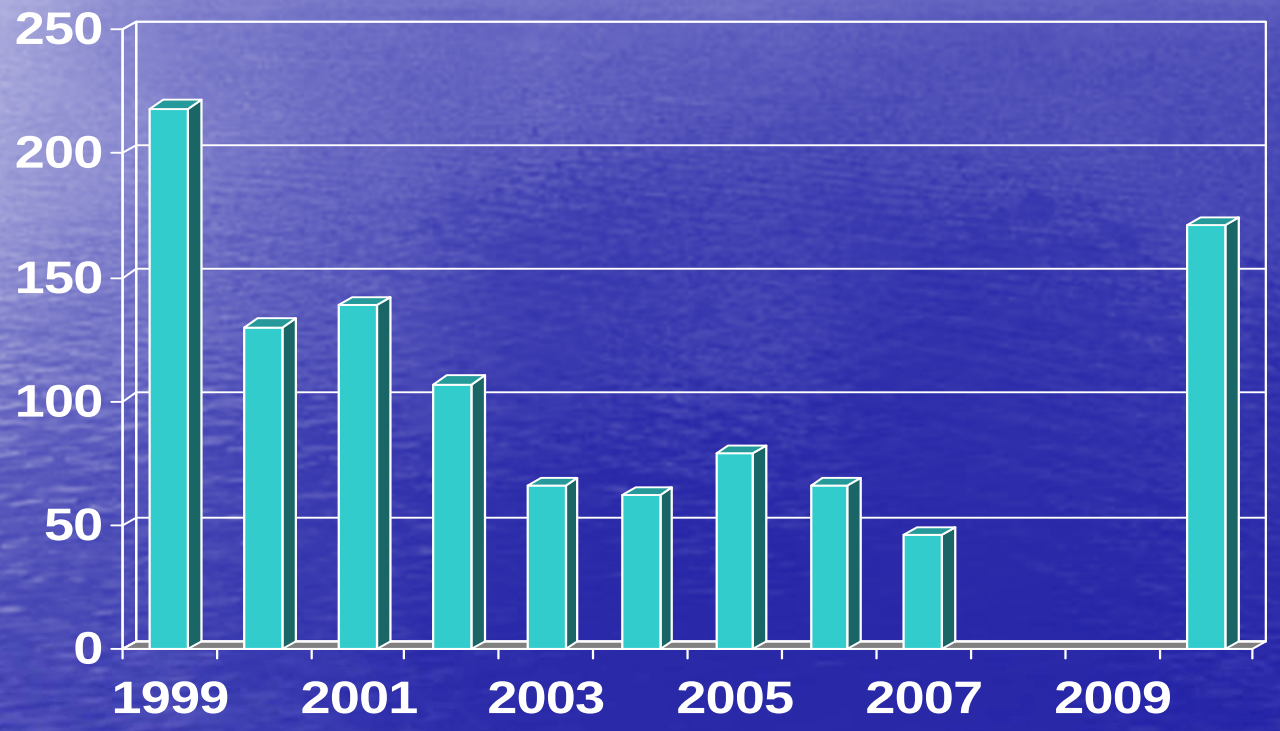
Injunctions
Fiscals Years 1993 – 2010



WL

- 2010 673
- 2009 474
- 2008 445
- 2007 471
- 2005 535
- 2000 1154

CDER WARNING LETTERS



Trending by Fiscal Year

	2007	2008	2009	2010	YTD
Warning Letters	471	445	474	673	
Seizures	6	8	6	10	
Injunctions	12	5	11	17	
ORA FTE's	3200	3100	3400	3900	

NWJ-DO Drug vs. Total

WARNING LETTERS

FY	'04	05	06	07	08	09	10	ytd
Drug=	9	2	4	4	1	1	8	
Total=	19	13	13	14	7	6	18	

Trends for Top 10 Turbo Citations

2009 – 8/8/11

- 211.22(d)
- 211.192
- 211.160(b)
- 211.100(b)
- 211.100(a)
- 211.110(a)
- 211.25(a)
- 211.67(b)
- **211.67(a)**
- 211.165(a)

2004 – 2008

- 211.22(d)
- 211.110(a)
- 211.100(b)
- 211.160(b)
- 211.192
- 211.100(a)
- 211.165(a)
- 211.25(a)
- **211.188**
- 211.67(b)

FDA-483 example

FDA-483 example

FDA-483 example

FDA-483 example

FDA-483 example

RESPONSE TO FDA-483

- Executive summary including time frames for corrective actions.
- Original FDA-483 comment with your response and attachments.
- List of corrections already made by date.
- Sent within 15 day's to NWJ-DO Director of Compliance.

WARNING LETTER'S (WHAT TRIGGERS THEM)

- Re-occurring violations
- Significant violations showing adulteration or misbranding.
- No response to FDA-483 or response was inadequate

CONCLUSION

- BE READY FOR INSPECTION
- DAILY WRAP UP/DISCUSSION
- FINAL DISCUSSION
- HANDLING OF FDA 483
- PREPARING A RESPONSE

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