October 1, 2009

PDA Metro Meeting

“The State of the Pharmaceutical Industry”

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TOPICS

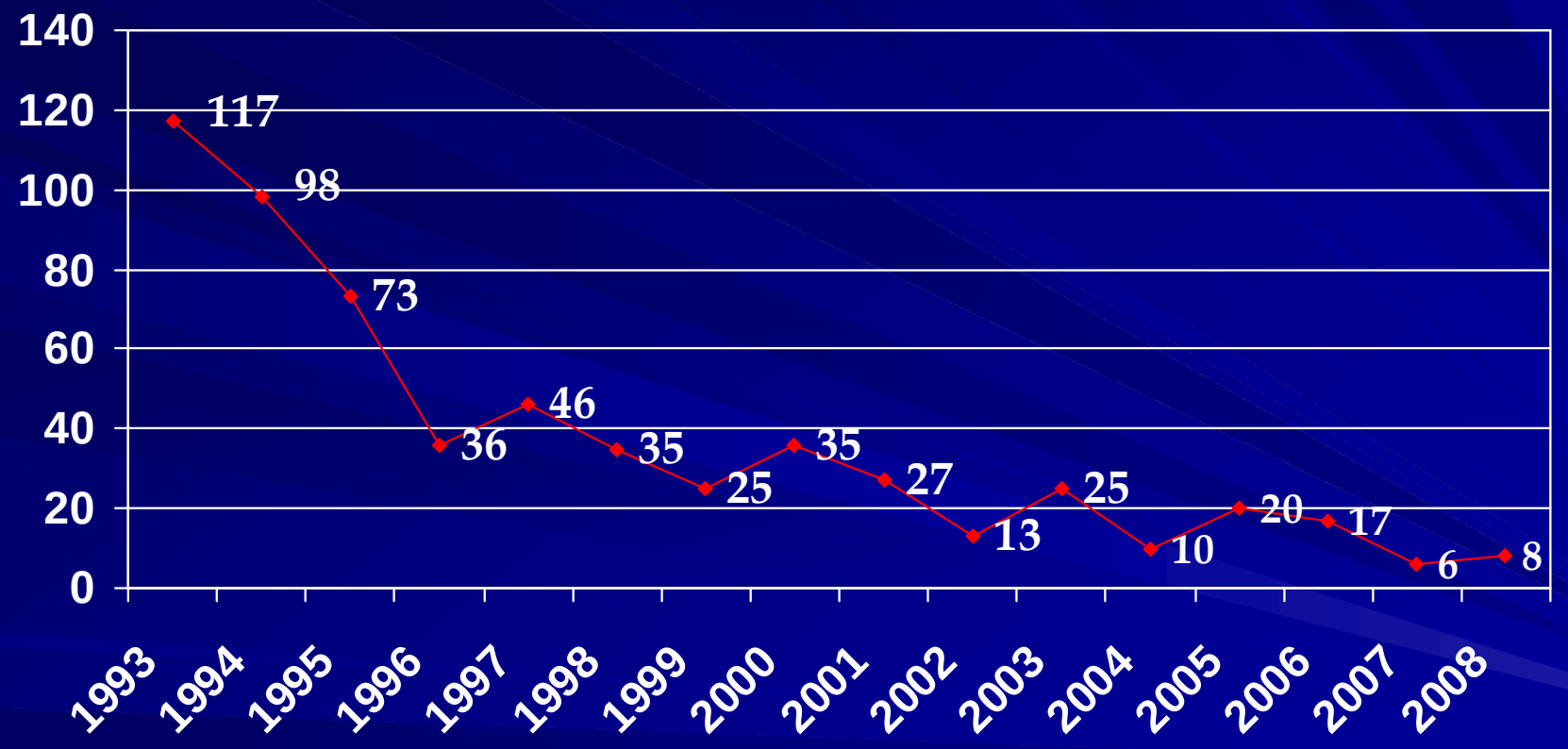
- New Consent Decrees
- Warning Letters
- Seizures
- Criminal Actions
- FDA-483 Trends
- Misc.

- Globalization
- Increase in imported products
- Opened foreign Offices
- Dedicated Foreign Inspection cadre
- Hired new investigators
- Risk based approach

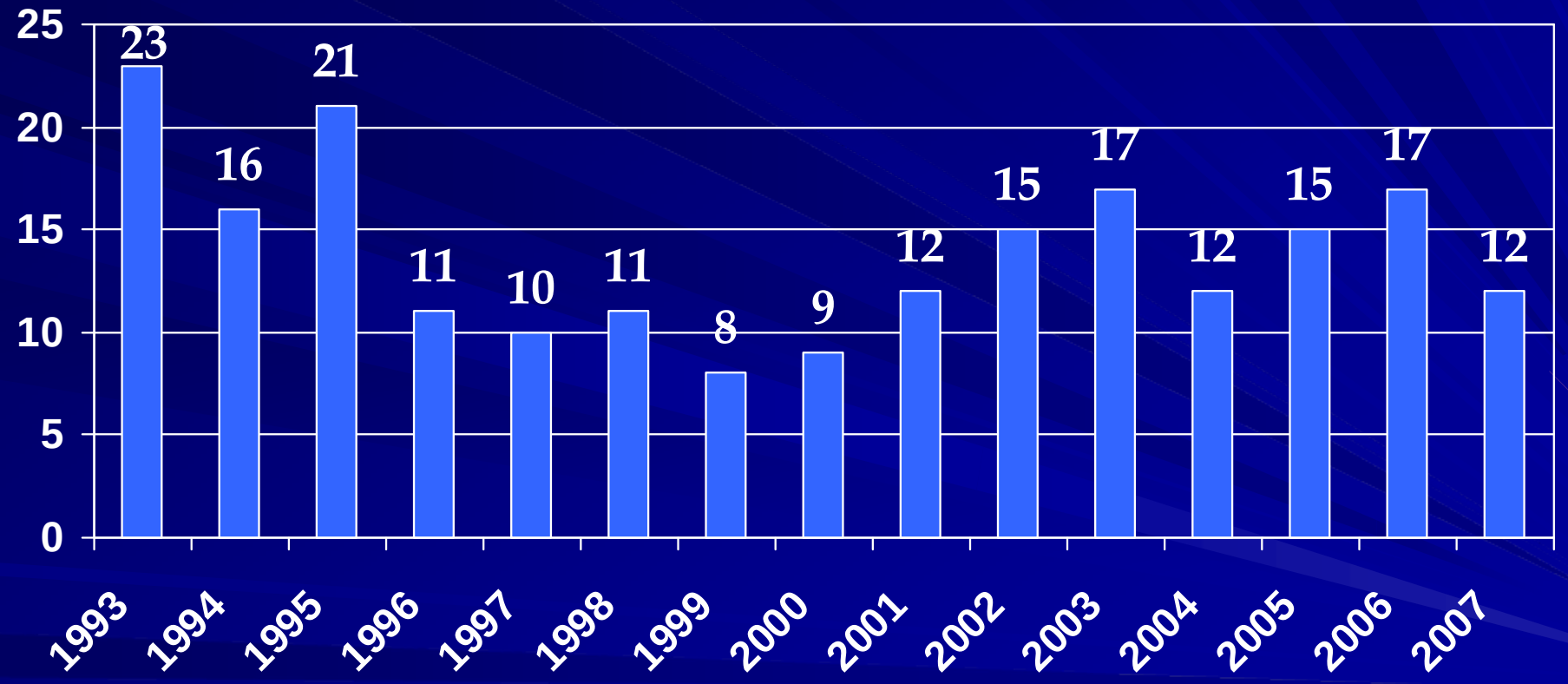
FY'08 #'s

	FDA	NWJ	FY'07
– WL	445	7	471
– Seizures	8	0	6
– Injunctions	5	0	12
– # EI (Dom)	15245		15581
(For)	947		1003

Seizures
Fiscals Years 1993 – 2008



Injunctions
Fiscals Years 1993 – 2007

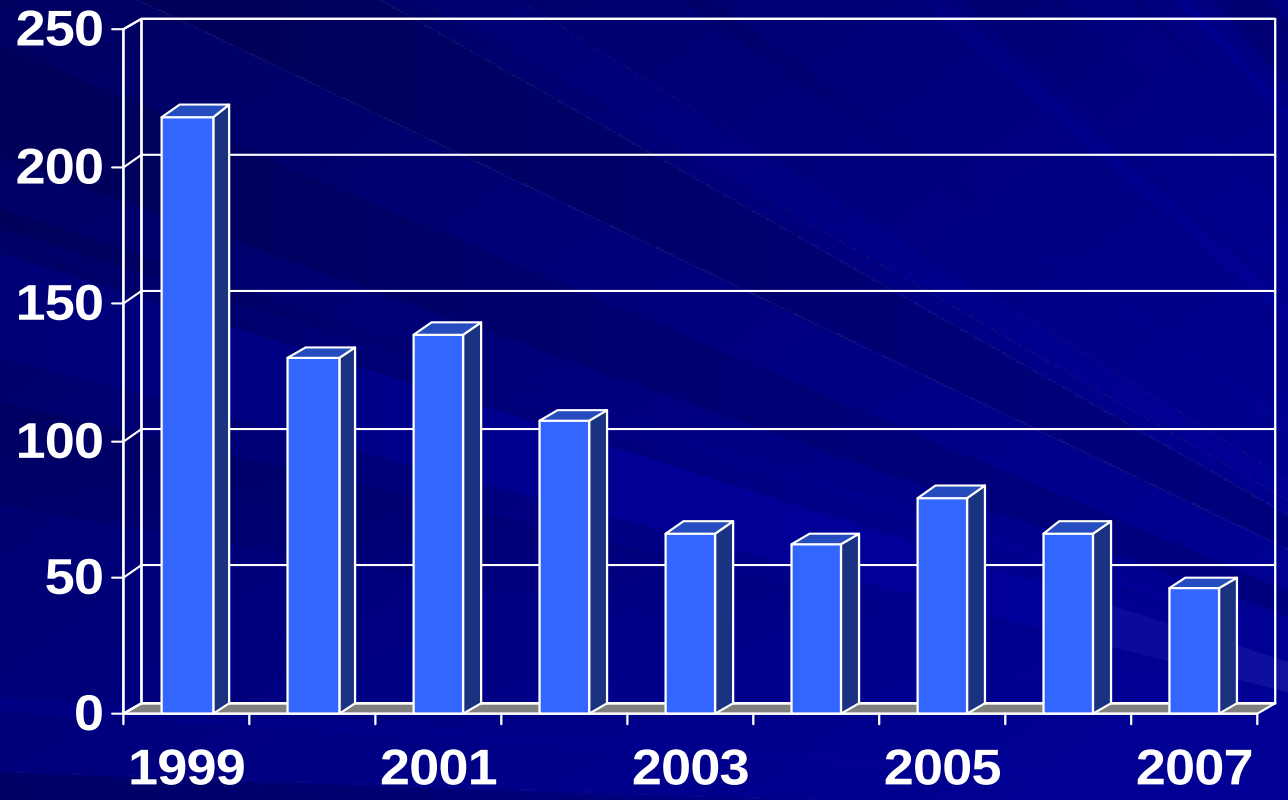


Warning Letters
Fiscal Years 1996 – 2007

WL

- FY
- 2008 445
- 2007 471
- 2006 538
- 2005 535
- 2004 725
- 2000 1154

CDER WARNING LETTERS



FY ’08 Actions
NEW JERSEY

SEIZURE’S

INJUNCTION’S

TOTAL WARNING LETTERS

FY- 04	FY- 05	FY-06	FY-07	FY-08
9 Drug	2	4	4	1
19 Total	13	13	14	7

TOP GMP CITES
for
FY ‘08
FDA-483 (Drugs)

#1) 211.22
#2) 211.100(b)
#3) 211.110(a)
#4) 211.160(b)
#5) 211.100(a)

Examples of recent FDA-483 Observations

- The aseptic filling of drug products on the ____filling line at the speed of____has not been validated.
- Your firm does not conduct adequate monitoring of bioburden after hold times of intermediates or pooled buffers during purification.
- Your firm failed to maintain computerized systems in a validated state.

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 30 day's to the NWJ-DO Director of Compliance.
- If not thorough then:
- Example, "Your follow up to these documented deviations did not include training of operators or those supervising formulation operations."

WARNING LETTER'S (WHAT TRIGGERS THEM)

- Re-occurring violations, significant violations that show adulteration or misbranding.
- No response to FDA-483 or response was not adequate (packages are reviewed by CDER/CVM, which will include any response from firm).

CONCLUSION

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

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