Compliance Issues

Allergenic Products Advisory Committee Meeting

February 22, 1999

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Enforcement Actions

- **Warning Letters**
- **Seizures**
- **Injunctions**
- **License Suspension**
- **License Revocation**

Warning Letters

- **Notification**
- **Prompt Correction**
- **Effect on product**
  - no prohibition to distribution
  - recalls

Outcome of Suspension

- Reinstatement
- Revocation
- Other agency actions

Revocation 21 CFR 601.5

- Unable to Gain Access
- Manufacturing Discontinued
- Failure to Report Change
- GMP Deficiencies
- New Method of Manufacturing
- Product Not Safe and Effective

Direct Revocation

- Suspension
- Willfulness
- Careless Disregard
- NO OPPORTUNITY TO CORRECT

Deficiencies in 11 WL's (cont)

- 9 - Equipment
- 6 - Component and Container Closures
- 7 - 21 CFR 600's
- 2 - QC Unit
- 2 - Training
- 2 - Stability
- 2 - Annual Review

Deficiencies in Suspensions

- Numerous GMP's
- Sterility issues
  - failure to assure aseptic processing
  - failure to investigate sterility failures
  - distribution of product prior to sterility testing
  - inadequate facilities
- Distribution of contaminated product

Issues to Consider

- Supply/sole manufacturer
  - Product shortages
    - Alice Gerkhardt-Godziemski
    - 301-827-6220
- Appropriate action
- Compliance History