

FDA PANEL for CONTACT LENS SOLUTIONS

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Areas of Discussion

- Testing of Solutions Under More Realistic Conditions
- Testing Under Known Conditions of Intractable Non-Compliance
- Improved Labeling



Testing of Solutions Under More Realistic Conditions

- Pathogenicity of Current Challenge Organisms
- More Resistant Standardized Challenge Organisms
- Testing with No Rub & Rinse Regimen to demand Increased 'cidal activity
- Testing with Organic Soil and/or Biofilms
- Testing using actual lens and case material to determine activity and toxicity



Pathogenicity of Current Challenge Organisms

More Resistant Standardized Challenge Organisms



Testing Regimen with No Rub & Rinse to demand Increased 'cidal activity

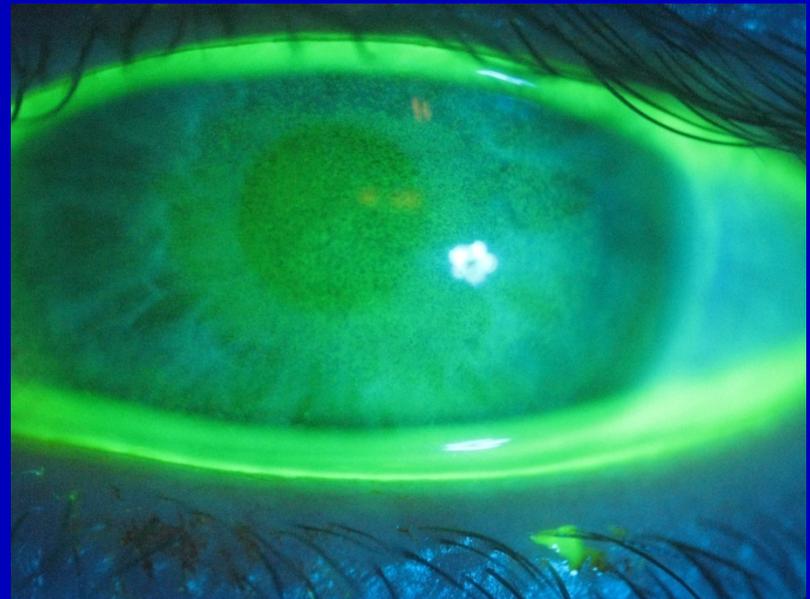


Testing with Organic Soil and Biofilms



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- Testing using actual lens and case material to determine activity and toxicity



Testing Under Known Situations of Intractable Non-Compliance

- Directions are considered to be too time-consuming, expensive, laborious
- Patients don't or won't follow directions
- No hand washing
- Dirty cases
- Topping off of solutions
- Evaporation



Directions are considered to
be too time-consuming,
expensive, laborious

Patients don't or won't follow
directions



- Poor Hand Washing
- Dirty Cases



Topping off of solutions

Evaporation



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Improved Labeling

- Major non-compliance issues should be more prominently displayed
- Mandatory discard date



Major Non-Compliance Issues

- “Wash hands before handling products and lenses”
- “Do not top off solutions”
- “Rub & rinse is necessary or recommended by your ECP”
- Hotline for instructions on use



Mandatory Discard Date

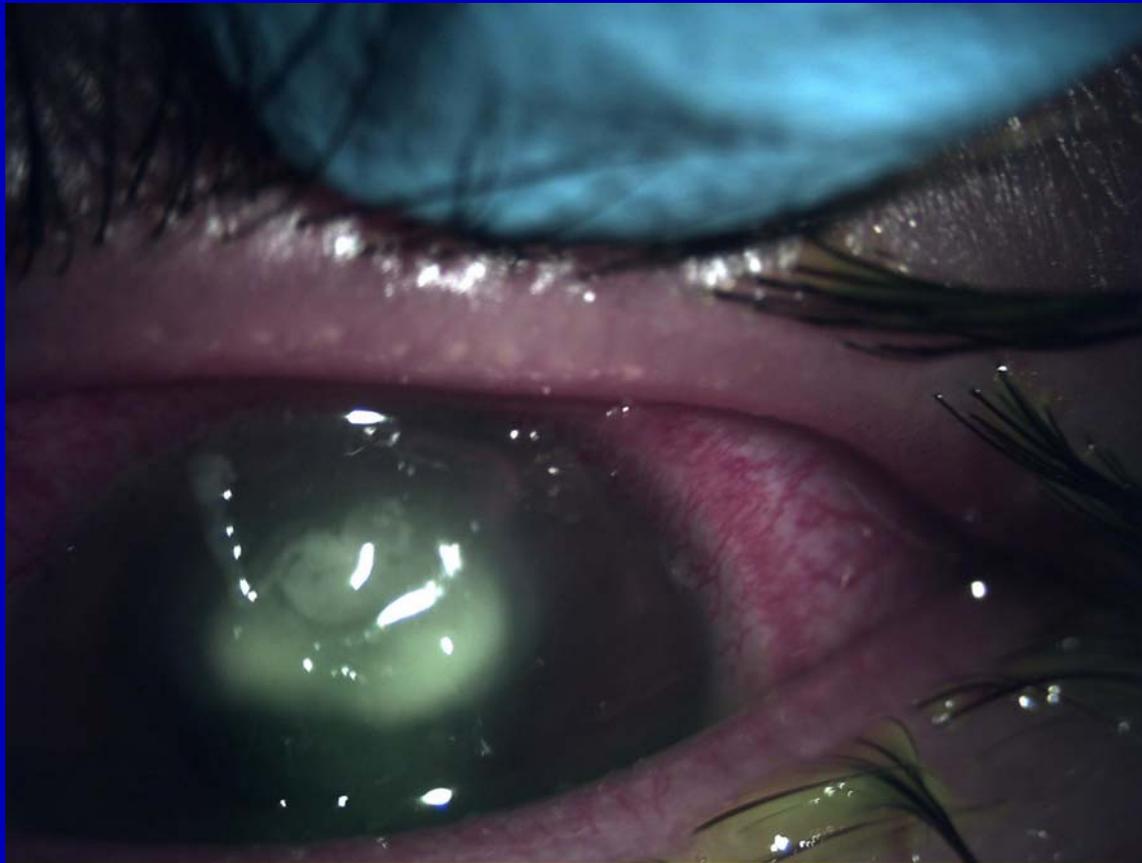


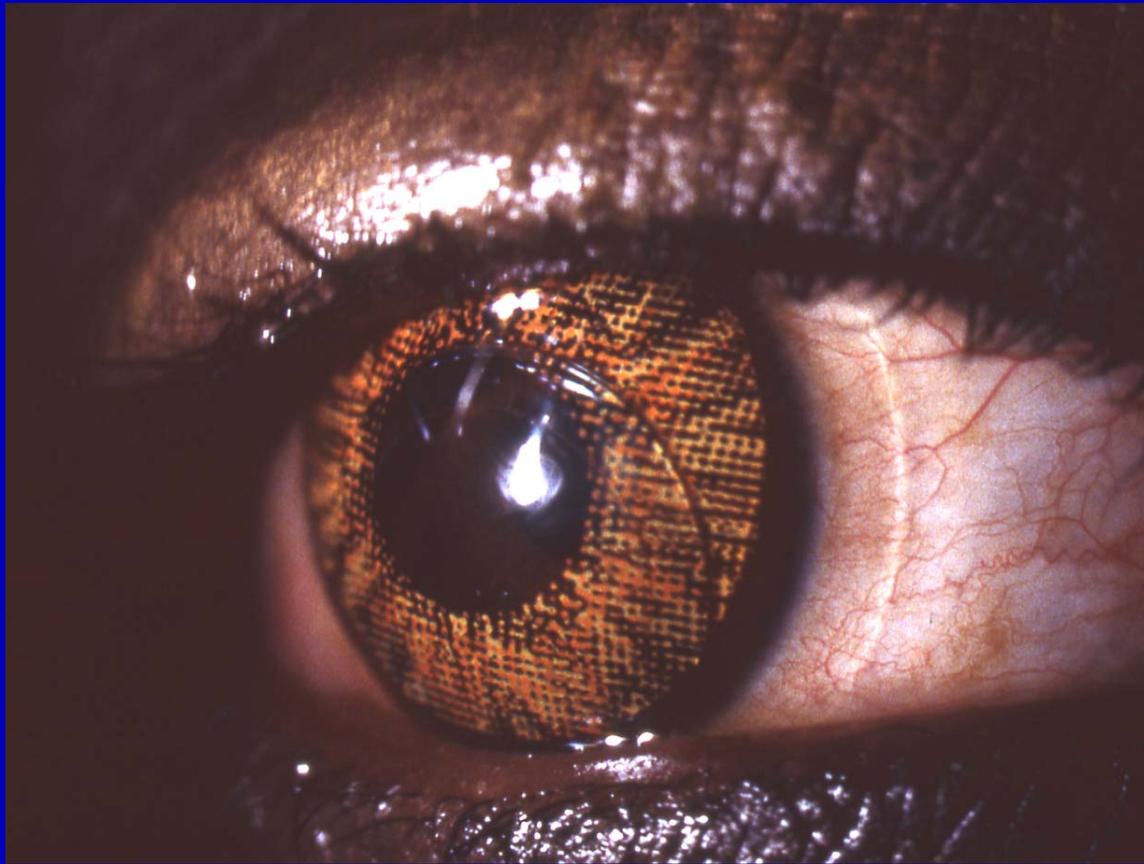
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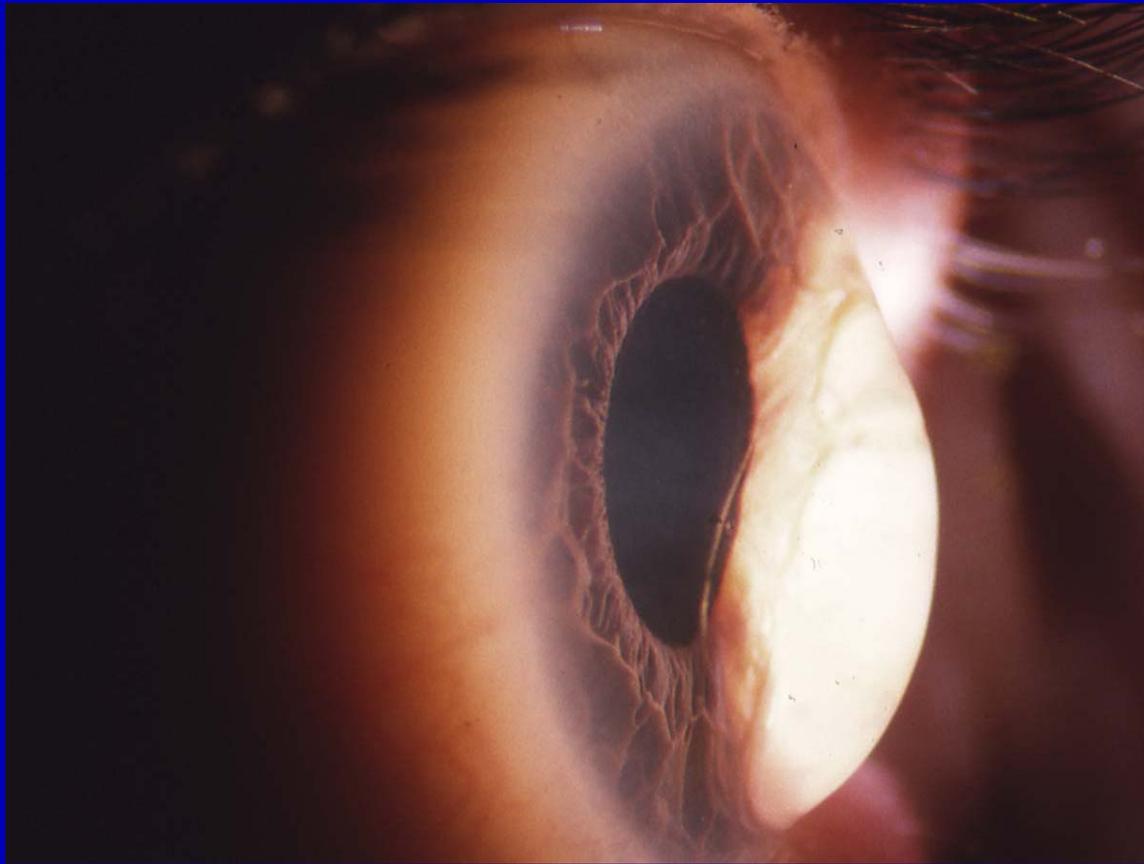


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Thank you for your attention



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