US Regulation for Safe Use of Contact Lenses

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Medical Device

• Definition
  – Intended to diagnose, cure, mitigate, treat or prevent a disease/condition, or
  – Intended to affect the structure or function of the body, and
  – Does not achieve intended use through chemical action or metabolism

• There are no generic medical devices

¹Sec. 201, Food, Drug and Cosmetic Act
Device Classification

• CLASS I
  – Simple design, low risk
  – General Controls
  – Most exempt from premarket submission

• CLASS II
  – More complex, moderate risk
  – General Controls plus Special Controls
  – Premarket Notification [510(k)]
    » Demonstration of substantial equivalence

• CLASS III
  – Most complex, highest risk
  – General Controls and Premarket Approval (PMA)
    » Reasonable assurance of safety and effectiveness

1 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/
Contact Lenses (CLs)

• FDA regulates all contact lenses (CLs)

• Classification
  – Class II: Daily wear lenses (soft and rigid gas permeable)
  – Class III: Extended wear lenses (soft and rigid gas permeable)
    » available for overnight or continuous wear ranging from one to six nights or up to 30 days¹

• CL indications
  – to correct refractive error
  – to promote corneal healing (bandage CLs)
  – for the temporary reduction of myopia (orthokeratology CLs)
  – to enhance or alter the appearance of the eye (decorative CLs)

¹https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/ucm062319.htm
Demographics of Contact Lens Use

- Approximately 45 million Americans wear contact lenses
  - 35% wear daily disposable contact lenses
  - 66.6% are female
  - Over 90% of adult CL wearers use soft contact lenses
  - 3.6 million wearers between 12 to 17 years
  - 7.5 million wearers between 18 to 24 years

1 [https://www.cdc.gov/mmwr/volumes/66/wr/mm6632a2.htm](https://www.cdc.gov/mmwr/volumes/66/wr/mm6632a2.htm)
2 Nichols JJ. Contact Lenses 2017. Contact Lens Spectrum January 2018
3 [https://www.cdc.gov/contactlenses/fast-facts.html#two](https://www.cdc.gov/contactlenses/fast-facts.html#two)
Risks from Use of Contact Lenses

- Microbial keratitis
- Allergies affecting the eyes
- Giant Papillary Conjunctivitis (GPC)
- Corneal abrasion
- Contact Lens-induced Acute Red Eye (CLARE)
- Corneal infiltrates
- Dry eyes
- Neovascularization

https://www.cdc.gov/contactlenses/other-complications.html
Emergency Room Medical Record Reports from the National Electronic Injury Surveillance System database (1/1/04-12/21/05)¹

• Compared to all other MDAEs², contact lenses accounted for most MDAEs (23%)

²MDAEs: Medical device-associated adverse events
FDA Safeguards

• Review of premarket submissions
• Standards
• Guidance
• Postmarket surveillance
  – MedWatch, PAS, and 522 studies
• Research
• Outreach
CL Premarket Submissions

- Materials/Chemistry
- Manufacturing
- Sterility
- Shelf Life
- Biocompatibility
- Performance testing: nonclinical
- Performance testing: clinical

General recommendations described in FDA Guidance and FDA-recognized consensus standards
Chemistry Review of Contact Lenses

• Properties unique to each contact lens product that may affect performance
  – Material composition (USAN\(^\dagger\) designation)
  – Physical properties (e.g., water, RI\(^*\), modulus, Dk\(^**\), %T\(^***\))
  – Surface characteristics/treatments
  – Packaging solution composition
  – Material and manufacturing residuals (Biocompatibility)
  – Interaction with care product solutions
  – Lens design (e.g., lens edge design)

\(^1\)http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080928.htm
\(^\dagger\)USAN-United States Adopted Name Council
\(^*\)RI-refractive index
\(^**\)Dk-oxygen permeability
\(^***\)Transmission
Clinical Assessment of CL Performance\textsuperscript{1,2}

- Clinical evidence supports marketing clearance/approval for each new lens material
- The following outcomes are assessed:
  - Adverse Reactions
  - Slit Lamp Examination
  - Symptoms/Problems/Complaints
  - Keratometric Changes/Refractive Changes
  - Visual Acuity
  - Average Wear Times
  - Discontinued Eyes
  - Lens Replacements
  - Contact Lens Performance (i.e., lens centration and movement)
  - Lens Surface characteristics (i.e., wettability and deposition)

\textsuperscript{1}http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080928.htm
\textsuperscript{2}http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080218.pdf
Contact Lens Labeling

CL labeling typically contains the following prescription elements:

• Manufacturer’s brand name
  – Refers to the entire device inclusive of the material name, manufacturing process, packaging solution and other factors which may impart unique attributes to the lens material
  – Distinguishing attributes can result in differences among USAN materials, in contact lens fitting, performance and ocular health
Contact Lens Labeling (cont’d)

• Base Curve (BC)
  – Affects the alignment of the lens to the topography of the central cornea
  – Same BC for different brands may not be clinically equivalent

• Diameter
  – Affects lens centration
  – Same diameter for different brands may not be clinically equivalent

• Dioptric Power
  – Affects strength of correction
  – Improper power may result in reduced visual acuity, eye strain and headaches
Possibility of CL Brand Substitution

- There is currently no regulatory pathway for marketing of generic CLs
- The current clinical care paradigm does not support substitution of CLs brands without a clinical evaluation
- Additional research and education is needed regarding critical design and material properties to support clinical equivalency between lens brands
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<th>Description</th>
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<tr>
<td>ISO 9394</td>
<td>Third edition 2012</td>
<td>Ophthalmic Optics-Contact Lenses and Contact Lens Care Products-Determination of Biocompatibility by Ocular Study with Rabbit Eyes</td>
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<td>ISO 11980</td>
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<td>ISO 11981</td>
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<td>ISO 13212</td>
<td>Second edition 2011</td>
<td>Ophthalmic optics -- Contact lens care products -- Guidelines for determination of shelf-life</td>
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<td>ISO 14729</td>
<td>First edition 2001</td>
<td>Ophthalmic Optics - Contact Lens Care Products - Microbiological Requirements and Test Methods for Products and Regimens for Hygienic Management of Contact Lenses [including Amendment 1 (2010)]</td>
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<tr>
<td>ISO 14730</td>
<td>First edition 2009</td>
<td>Ophthalmic Optics -- Contact Lens Care Products -- Antimicrobial Preservative Efficacy Testing and Guidance on Determining Discard Date</td>
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<td>ISO 18369-4</td>
<td>First edition 2006</td>
<td>Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials</td>
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<tr>
<td>ISO 18259</td>
<td>First Edition 2014</td>
<td>Ophthalmic optics — Contact lens care products — Method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms</td>
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<td>ISO 18189</td>
<td>First edition 2016</td>
<td>Ophthalmic optics — Contact lens care products — Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interactions</td>
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<tr>
<td>ANSI Z80.18</td>
<td>-2010</td>
<td>American National Standard for Ophthalmics - Contact Lens Care Products: Vocabulary, Performance Specifications and Test Methodology</td>
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<tr>
<td>ANSI Z80.20</td>
<td>-2010</td>
<td>American National Standard for Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemical Properties</td>
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*For use in satisfying premarket submission requirements—recognized standards database http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
FDA Guidance

• Describes FDA’s interpretation of, or policy on, a regulatory issue
  – Product-specific
  – Labeling
  – Manufacturing
  – Clinical studies
    » Sample Size
    » Study Design
    » Data Analysis

• FDA Contact Lens Guidance outlines recommended testing for manufacturers
Postmarket

- To report adverse events including contact lens related infections
  - FDA Medwatch
    https://www.fda.gov/Safety/MedWatch/default.htm

- To report unlawful internet sales or contact lens vendors selling without a prescription
  - FDA Website: Report a Problem
    https://www.fda.gov/Safety/ReportaProblem/ucm059315.htm

- 522 study: FDA mandated post market surveillance study
  - List of studies and study status available to the public
    https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cf
FDA Research

• FDA conducted research to:
  – Categorize the numerous silicone hydrogel lenses to address concerns with dimensional stability and toxicity
  – Evaluate the efficacy of care product solutions in the presence of lenses - real world testing
  – Develop Acanthamoeba test method

• Outcomes of research published in Eye and Contact Lens:
  – Material Properties That Predict Preservative Uptake for Silicone Hydrogel Contact Lenses.  
  – Impact of Contact Lens Materials on Multipurpose Contact Lens Solution Disinfection Activity Against Fusarium solani.  
    Clavet CR, Chaput MP, Silverman MD, Striplin M, Shoff ME, Lucas AD, Hitchins VM, Eydelman MB.
  – The Effects of Contact Lens Materials on a Multipurpose Contact Lens Solution Disinfection Activity Against Staphylococcus aureus.  
    Shoff ME, Lucas AD, Brown JN, Hitchins VM, Eydelman MB.
  – Strategies to Optimize Conditions for Testing Multipurpose Contact Lens Solution Efficacy Against Acanthamoeba.  
    Shoff M, Eydelman MB.
  – Proposed Silicone Hydrogel Contact Lens Grouping System for Lens Care Product Compatibility Testing.  
    Hutter JC, Green JA, Eydelman MB.
  – Preclinical Research to Aid in the Development of Test Methods for Contact Lenses and Their Care Products.  
    Eydelman MB, Kiang T, Tarver ME, Alexander KY, Hutter JC.
  – The Food and Drug Administration's Role in Establishing and Maintaining Safeguards for Contact Lenses and Contact Lens Care Products.  
    Eydelman MB, Tarver ME, Kiang T, Alexander KY, Hutter JC.
  – Optimized Protocol for Testing Multipurpose Contact Lens Solution Efficacy Against Acanthamoeba.  
    Fedorko DP, Brocious JM, Adams KD, Hitchins VM, Hampton DL, Eydelman MB.
Outreach: Public Meetings

• 2008: Ophthalmic Advisory Panel Meeting¹
• 2009: Contact Lens Care Product Microbiology Workshop²
• May 2014: Ophthalmic Advisory Panel Meeting³
• September 2014: Microbiology Workshop⁴
• September 2016: Controlling the Progression of Myopia: Contact Lenses and Future Medical Devices⁵
• March 2017: Ophthalmic Advisory Panel Meeting⁶

²https://web.archive.org/web/20100307130157/http:/www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm111136.htm
³http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OphthalmicDevicesPanel/ucm385476.htm
⁴http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm409778.htm
⁶https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OphthalmicDevicesPanel/default.htm
Outreach: Websites & Consumer Updates

• Consumer-focused articles distributed to over 75,000 subscribers
  – “Decorative Contact Lenses: Is Your Vision Worth It?”
    http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm275069.htm
  – “Improper Use of Decorative Contact Lenses May Haunt You”
    http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048902.htm
  – “FDA Teams Up for Novel Campaign on Risks of Decorative Contact Lenses”
    http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm402704.htm

• Websites:
  – FDA
    http://www.fda.gov/contactlenses
    http://www.fda.gov/decorativecontacts
  – In Partnership with CDC
    http://www.cdc.gov/contactlenses/decorative-contacts.html
Outreach: Medscape
Commentaries & Interviews

• “Telling the FDA: Why Contact Lens Adverse Events Matter”

• “Decorative Contact Lenses: Truly Frightening”
Outreach: Videos

• FDA Video
  – “Improper Use of Decorative Contact Lenses May Haunt You”
    http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm187691.htm

• Public Service Videos
  – Two public service videos created in partnership with American Optometric Association, the Entertainment Industries Council and artists from American Horror Story
  – Informs on proper way to wear the lenses
  – Recommends getting an eye exam and valid prescription
Outreach: Social Media

• FDA launched a Twitter campaign regarding decorative CLs in 2012
  – Twilight Conferences (nationwide), Comic-Con, Hunger Games movie release, Chicago Comic & Entertainment Expo, Anime Boston
  – Sample message:
    » Want to look like your favorite vampire? See an eye doctor before buying costume/fashion lenses. Link to flyer @twi_tour, #twilight

• FDA participated in CDC’s Contact Lens Health Week Twitter Chat in 2015, 2016, and 2017

• FDA launched a Google AdWords Campaign in August 2015 during the CDC / FDA Twitter Chat
Questions?

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