

US Regulation for Safe Use of Contact Lenses

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Medical Device¹

- 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 Classification¹

- 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



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)

¹<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/ucm062319.htm>

Demographics of Contact Lens Use

Approximately 45 million Americans wear contact lenses¹

- 35% wear daily disposable contact lenses²
- 66.6% are female³
- Over 90% of adult CL wearers use soft contact lenses¹
- 3.6 million wearers between 12 to 17 years¹
- 7.5 million wearers between 18 to 24 years¹



¹ <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>

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%)

¹Wang C, Hefflin B, Cope JU, et al. Emergency department visits for medical device associated adverse events among children. Pediatrics 2010;126:247-259


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 Lenses¹

- Properties unique to each contact lens product that may affect performance
 - Material composition (USAN[†] 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>

[†]USAN-United States Adopted Name Council

^{*}RI-refractive index

^{**}Dk-oxygen permeability

^{***}Transmission

Clinical Assessment of CL Performance^{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)

¹<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080928.htm>

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

FDA Recognized Consensus Standards*



ISO	9394 Third edition 2012	Ophthalmic Optics-Contact Lenses and Contact Lens Care Products-Determination of Biocompatibility by Ocular Study with Rabbit Eyes
ISO	11980 Third edition 2012	Ophthalmic Optics -- Contact Lenses and Contact Lens Care Products -- Guidance for Clinical Investigations
ISO	11981 Second edition 2009	Ophthalmic Optics -- Contact Lenses and Contact Lens Care Products -- Determination of Physical Compatibility of Contact Lens Care Products with Contact Lenses
ISO	11986 Second edition 2010	Ophthalmic Optics -- Contact Lenses and Contact Lens Care Products -- Guidelines for Determination of Preservative Uptake and Release
ISO	13212 Second edition 2011	Ophthalmic optics -- Contact lens care products -- Guidelines for determination of shelf-life
ISO	14729 First edition 2001	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)]
ISO	14730 First edition 2009	Ophthalmic Optics -- Contact Lens Care Products -- Antimicrobial Preservative Efficacy Testing and Guidance on Determining Discard Date
ISO	18369-1 First edition 2006	Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications [including: Amendment 1: 2009]
ISO	18369-2 Second edition 2012	Ophthalmic optics - Contact lenses - Part 2: Tolerances
ISO	18369-3 First edition 2006	Ophthalmic optics - Contact lenses - Part 3: Measurement methods
ISO	18369-4 First edition 2006	Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials
ISO	18259 First Edition 2014	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
ISO	18189 First edition 2016	Ophthalmic optics — Contact lens care products — Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interactions
ANSI	Z80.18 -2010	American National Standard for Ophthalmics - Contact Lens Care Products: Vocabulary, Performance Specifications and Test Methodology
ANSI	Z80.20-2010	American National Standard for Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemical Properties

*For use in satisfying premarket submission requirements—recognized standards database

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

FDA Guidance¹

- 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 manufacturers²

¹www.fda.gov/cdrh/guidance.html

²<http://www.fda.gov/RegulatoryInformation/Guidances/ucm080928.htm>

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.](#)
Green JA, Phillips KS, Hitchins VM, Lucas AD, Shoff ME, Hutter JC, Rorer EM, Eydelman MB.
 - [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, Brocius 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

¹<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=699>

²<https://web.archive.org/web/20100307130157/http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm111136.htm>

³<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OphthalmicDevicesPanel/ucm385476.htm>

⁴<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm409778.htm>

⁵<https://www.federalregister.gov/documents/2016/07/11/2016-16353/controlling-the-progression-of-myopia-contact-lenses-and-future-medical-devices-public-workshop>

⁶<https://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”
http://www.medscape.com/viewarticle/774062_3
- “Decorative Contact Lenses: Truly Frightening”
<http://www.medscape.com/viewarticle/773106>

Outreach: Videos

- **FDA Video**

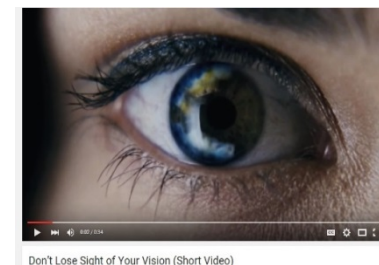
- “Improper Use of Decorative Contact Lenses May Haunt You”

<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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