

Guidance for Industry and Food and Drug Administration Staff

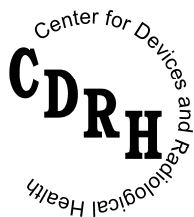
Contact Lens Care Products Labeling

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This document is an addendum to that portion of the GUIDANCE FOR LABELING OF CONTACT LENS CARE PRODUCTS IN 510(K) MARKETING CLEARANCE APPLICATIONS THAT SPECIFICALLY ADDRESSES THE PRODUCT LABELING AND INSTRUCTIONS FOR USE BY THE CONSUMER.

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Food and Drug Administration
Center for Devices and Radiological Health
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Preface

Public Comment

You may submit written comments and suggestions at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Submit electronic comments to www.regulations.gov. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm1725.htm>. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-827-8149 to receive a hard copy. Please use the document number 1725 to identify the guidance you are requesting.

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Guidance for Industry and Food and Drug Administration Staff (add others as appropriate, e.g., Third Parties)

Contact Lens Care Products Labeling

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

This guidance document is an addendum to a special control guidance that supports the classification of the Contact Lens Care Products as class II (special controls).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Scope

The scope of this document is limited to the devices described below.

21 CFR 886.5918 Rigid gas permeable contact lens care products.

Product Codes:

- MRC products, contact lens care, rigid gas permeable

(a) Identification. A rigid gas permeable contact lens care product is a device intended for use in the cleaning, conditioning, rinsing, lubricating/rewetting, or storing of a rigid gas permeable contact lens. This includes all solutions and tablets used together with rigid gas permeable contact lenses.

(b) Classification. Class II (Special Controls) Guidance Document: "Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

21 CFR 886.5928 Soft (hydrophilic) contact lens care products

Product Codes:

- LPN accessories, soft lens products
- LYL accessories, solution, ultrasonic cleaners for lenses
- LRX case, contact lens
- HRD sterilizer, soft-lens, thermal, ac-power
- HRC sterilizer, soft-lens, thermal, battery

(a) Identification. A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/rewetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat.

(b) Classification. Class II (Special Controls) Guidance Document: "Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

This document provides additional guidance on strengthening warnings and directions for use labeling of contact lens care products (e.g., contact lens solutions, lens cases, and contact lens accessories) described in the 1997 guidance document.

3. General Considerations

Patient information labeling includes information contained on the outside packaging, package insert and primary container and is directed to the contact lens wearer. The patient labeling should instruct the patient on product care to ensure lenses are used safely and effectively, potential risks and benefits, and what to expect when they use these care products. When translating information from professional terminology into lay language, the manufacturer should not alter the intent of the indications, contraindications, warnings and precautions. The labeling should contain sufficient information to describe the device, its intended use, and specific descriptions of the patients for whom the product would not be a good choice (e.g., allergy to specific components of the product(s)).

The lay language should provide a balanced presentation of adverse events and the risks and benefits of the device. It should not introduce new device performance claims that were not cleared in the pre-market notification submission. Patient information labeling, if possible, should not exceed the eighth grade reading comprehension level.

To increase the likelihood that the patient labeling will be provided to the patient and be read by the patient, consider:

- Recommending that all eye care professionals review this labeling with their patients.
- Placing patient labeling on your web site, if you maintain one, to help patients get the most up-to-date information.

For specific directions on writing effective labeling for devices, please refer to the April 19, 2001 Office of Communication, Education, and Radiation Programs (OCER) “Guidance on Medical Device Patient Labeling”¹. We recommend reviewing the “Recommended Content of an Effective Warning or Precaution” section on page 40 of 54 of that document.

4. Suggested Content of Patient Labeling

In addition to the information contained in the current special controls guidance, we recommend that the patient labeling contain the following sections to aide the user’s understanding of proper use and care of these devices. FDA views this information as critical to the safe use of contact lenses.

A. Glossary

The use of a brief glossary is highly recommended. It should be placed after the table of contents to alert readers that it is there to help them. Words or phrases that are explained in the Glossary are generally identified at each occurrence in the text by highlighting with italics, or bolding, or etc., where possible. Whether or not a glossary is used, meanings of key words and phrases should appear in the text.

B. Emphasized Instructions for use and warnings

Rub and Rinse

Information presented at a June 2008 meeting of the FDA’s Ophthalmic Devices Advisory Panel noted that the “rub and rinse” cleaning regimen helps prevent potentially infectious microbes from forming on the lenses. “No-rub” contact lens care products have always had directions for both “rub” and “no-rub” regimens, based on practitioner’s directions to their individual patients and their health care requirements.

While there are scientific data that support both “no-rub” and “rub-and-rinse” cleaning regimens, there is evidence that the “rub-and-rinse” regimen results in a greater reduction in microbes. Some microbes interact with some of the silicone hydrogel contact lenses and adhere to the surface. Rubbing lenses may remove these microbes. However, there is a risk of contamination if users rub or otherwise handle their contact lenses without thoroughly washing their hands.

¹ <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070801.pdf>

We recommend that manufacturers of contact lens multi-purpose solution products that include “no rub” directions remove the “no-rub” from product labeling and emphasize the importance of “rubbing and rinsing” in caring for contact lenses. Our recommendation is consistent with several professional eye organizations.

In the interest of improving lens care hygiene, we recommend that the directions for use also include a rinse step before placing the lenses on the eye. Any debris remaining on contact lenses following the soaking step that is potentially clinically significant may not be readily visible to the user. We recommend that this direction appear on the bottle for easy reference by the user.

The Quality System Regulation 21 CFR 820.30 requires that manufacturers establish and maintain design controls to ensure adherence to specified design requirements. Labeling for this product should provide adequate directions for use (e.g., rubbing and rinsing times for daily cleaning, soak times for disinfection, and maximum storage times following disinfection) for all intended uses identified above. While labeled rubbing or rinsing times are usually consistent with those used in pre-clinical microbiology testing, we also recommend that these times not be excessive to diminish compliance by the user. In order to address the needs of the user, we recommend that you consider reasonable rinse times as a design input to address the needs of the user.

For example, a labeling direction for the user to rinse each side of the lens for 10 seconds, or a combined total of 20 seconds, may not be a realistic expectation for users to comply. Excessively prolonged rinse times do not provide the type of device information that would foster patient compliance with directions for use.

Multi-Purpose

We recommend that multi-purpose products be for cleaning, disinfecting, storing and rinsing only. A contact lens solution that cannot perform all of the functions indicated in the labeling should not be labeled as a multi-purpose contact lens care solution.

As discussed in the 1997 Guidance, we do not recommend that a multi-purpose solution be labeled as an ALL-IN-ONE solution since lubricating and rewetting drops or enzyme treatments used for complete lens care are not functions of a multi-purpose solution.

The 1997 Guidance also addressed the concern regarding contamination as a basis for not recommending that multi-purpose solutions be labeled for lubricating and rewetting lenses during wear even if the chemical compositions of the multi-purpose solution and lubricating and rewetting drops are identical.

Current General Warning

The current labeling guidance includes a recommendation that a consumer who develops an eye infection should “immediately remove their lenses and promptly contact their eye care provider.” Often the warning is a single block of text, which is not easily readable. We recommend formatting to enhance readability. We also recommend that the labeling

advise the user to bring their lenses, solutions and lens case with them to their eye care provider for culturing in order to better establish the identity of any organism associated with the patient's infection.

Current Precautions

We recommend that this section be organized by individual precautions, listed separately. Manufacturers of currently marketed products are encouraged to update their labeling in a similar manner at the next printing of the labeling.

Labeling Enhancements

Based on input and recommendations from the Ophthalmic Devices Advisory Panel we recommend that each of the following topics be addressed in the section of your labeling that addresses product care. Note that while some current labeling may provide for similar statements in the instructions for use or in a safety tip section, very few currently include specific warnings to address these topics.

Soaking and Storing Your Lenses

Instruction for Use:

Use only fresh multi-purpose (contact lens disinfecting) solution each time you soak (store) your lenses.

Proposed WARNING:

Do not reuse or "top off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-Off" is the addition of fresh solution to solution that has been sitting your case.

Note: We recommend that the re-use or "topping off" warning be printed on the product carton and bottle label as well as the package insert.

Rub and Rinse Time

Instruction for Use:

- Rub and rinse your lenses for "X" seconds or more (e.g., 10 seconds or more) and then repeat with the second side for a total of 2 times "X" seconds (e.g., 20 seconds or more).
- Follow the complete recommended lens rubbing and rinsing times in the labeling to adequately disinfect your lenses and reduce the risk of contact lens infection.

Proposed WARNING:

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

Lens Case Care

Instruction for Use:

- Rinse your lens case with sterile contact lens solution (never use tap water) and leave the lens case open to dry after each use. Turn the case over and shake any excess solution out of the case. Be sure that no residual solution remains in the case before you allow it to air dry.
- Replace your lens case at least once every < *insert a recommended time period* >. Contact lens cases can be a source of bacterial growth.

Proposed WARNING:

Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution (or sterile saline solution) so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

Water Activity

Instruction for Use:

- Do not expose your contact lenses to water while you are wearing them.

Proposed WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water such as when swimming in pools, lakes, or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

Discard Date

Instruction for Use:

- Discard any remaining solution < *insert a recommended time period* > after opening.

Proposed WARNING:

Using your multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

Please note that labeling Appendix A of the 1997 guidance, page 65 contains a recommendation for including a fill in the line space on the bottle label for “date opened or discard date”.

C. Emphasizing the Risks

We recommend that the current general warning of eye infection emphasize the possible risks and complications that can be associated with use of contact lens care products when labeling directions are not accurately followed. You may wish to provide a photo of an infected eye. If you use this approach, it is important to emphasize that the photo is only demonstrating how serious a red eye can become. Please emphasize that the consumer should not ever wait until their eye looks like the picture before seeking

medical care. If an eye is red, has pain, blurry vision and persistent discomfort the labeling should direct the consumer to contact an eye care professional as soon as possible.