Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations - Premarket Notification (510(k)) Submissions

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
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Preface

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Draft Guidance for Industry and Food and Drug Administration Staff

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I. Introduction

FDA is issuing this draft guidance to provide labeling recommendations for hydrogen peroxide-based contact lens care products (HPCPs) submitted in premarket notification (510(k)) submissions. These labeling recommendations are important because misuse associated with these devices has resulted in serious eye injuries. FDA believes that the labeling recommendations in this guidance may help manufacturers develop labeling with information about specific risks and directions for use of the HPCPs in conjunction with a user's prescribed contact lenses. These labeling recommendations are intended to promote the safe and effective use of HPCPs and ensure that consumers receive and understand information regarding the benefits and risks associated with the use of the device.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

Hydrogen peroxide-based contact lens care product solutions, as well as other multipurpose solutions, both clean and disinfect contact lenses by breaking up and helping to remove trapped debris, protein, fatty deposits, and microorganisms. Unlike other multipurpose solutions, hydrogen peroxide-based contact lens care product solutions are generally preservative-free, which makes them a suitable option for those who are allergic or sensitive to the preservatives found in multipurpose solutions. They are not risk-free, however, and should be used by following appropriate labeling considerations.[1] Consumers should be aware of these considerations prior to choosing, and while using, this type of medical device.

To implement section 520(*l*) of the Federal Food, Drug, and Cosmetic (FD&C) Act, which contains specific provisions on transitional devices (i.e., those devices regulated as drugs before the Medical Device Amendments of 1976 became law), FDA published a rule proposing to reclassify HPCPs from class III (premarket approval) to class II (special controls).[2] The final rule reclassifying HPCPs published on June 6, 1997,[3] amending 21 CFR 886.5918 and 21 CFR 886.5928 to classify rigid gas permeable contact lens care products and soft contact lens care products as class II, respectively. FDA also issued a guidance document, "Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products,"[4] and a subsequent addendum "Contact Lens Care Products Labeling."[5] These documents include details regarding, among other things, the labeling of contact lens care products.

The safety and effectiveness of HPCPs when used as directed has been well established in the last few decades; however, FDA has become aware of an increase in the number of adverse event reports related to the misuse of these products. Consumers have reported adverse events ranging from irritation to severe burning and stinging of the eyes and even blindness with the use of HPCPs. The reports received to date indicate that the packaging is not easily distinguishable from other lens care products, which FDA believes has likely resulted in improper use. FDA convened a meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee and the Risk Communication Advisory Committee on March 17, 2017, to discuss additional measures to mitigate the potential risk for misuse of these devices.[6] While the rate of

[1] For further information on hydrogen peroxide-based contact lens care products, see https://www.fda.gov/medical-devices/contact-lenses/hydrogen-peroxide-solution.

[2] See 62 FR 14277 (April 1, 1996). With the enactment of the Medical Device Amendments of 1976, transitional devices were classified in class III by operation of the statute, unless later classified by FDA in class I or II. See FD&C Act § 520(*l*)(1).

[3] See 62 FR 30985.

[4] https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/contact-lens-care-products-premarket-notification-510k-guidance.

[5] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contact-lens-care-products-labeling.

[6] March 17, 2017 Meeting: Ophthalmic Devices Panel for the Medical Devices Advisory Committee and the Risk Communication Advisory Committee (available at https://www.fda.gov/advisory-committees/ophthalmic-devices-panel/2017-meeting-materials-ophthalmic-devices-panel).

adverse events reported to the FDA is relatively low compared to the estimated number of HPCP users, the number of reports likely underestimate the actual occurrence of such events. The meeting covered a range of important issues, including appropriate labeling and packaging of these products, and the importance of clearly communicating the risks of misuse to the consumer public. The Panel emphasized a need for simplicity and clear messaging in terms of warnings and instructions for use, in addition to the ability to identify the bottles by utilizing a red tip and red cap as already used on most HPCP solutions. The Panel also recommended a redesign and standardization of the labeling so that it is different from other contact lens care products. In light of the well-documented low compliance rate among consumers with recommended lens care practices,[7] as well as the reasons outlined above, FDA is providing recommendations concerning the content and format of labeling for these devices. FDA believes the labeling content and format recommended in this guidance provides at least the same level of protection of the public health and safety as the labeling details contained in "Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products"[8] and its addendum "Contact Lens Care Products Labeling."[9]

III. Scope

This guidance document applies to all HPCPs. These devices are classified under 21 CFR 886.5918 and 21 CFR 886.5928 with the product codes listed in the table below:

Table 1: Applicable Product Codes

Product Code	Product Code Name	Regulation Number
MRC	Products, Contact Lens Care, Rigid Gas Permeable	21 CFR 886.5918
LPN	Accessories, Soft Lens Products	21 CFR 886.5928

Although not in the scope of this guidance, the Panel also suggested making a change in the bottle shape, size, color, tactile features or other characteristics that would distinguish HPCPs from other contact lens care products that do not contain hydrogen peroxide. While FDA does not intend to recommend the type of bottle to be used to contain HPCP solutions, FDA recommends, to the extent possible, containers should appear distinct from those of multipurpose solutions or other products without hydrogen peroxide, which could minimize potential product selection errors and product misuse.

Based on the adverse event reports and feedback obtained during the March 2017 Panel Meeting, device misuse may be exacerbated if the directions for use and warnings or precautions in the device labeling are not clear. FDA believes that these problems can be mitigated by emphasizing and simplifying important warnings and directions for use on the bottle and carton labeling for HPCP solutions. The inclusion of such information should also be helpful in developing labeling with adequate information for use under 21 CFR 801.5. For example, FDA believes the

[7] Ky W, Scherick K, Stenson S. Clinical survey of lens care in contact lens patients. CLAO J. 1998 Oct;24(4):216-9.
[8] https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/contact-lens-care-products-premarket-notification-510k-guidance.
[9] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contact-lens-care-products-labeling.

appropriate design and standardization of labeling would help inform consumers of device risks, thereby increasing the likelihood of appropriate device use and helping to mitigate against device misuse.

Since these recommendations are based on known safety issues, FDA recommends that this information be considered for inclusion as current product labeling is updated, and that labeling included as part of future premarket submissions for HPCPs incorporate the recommendations. For currently marketed HPCPs, manufacturers should evaluate their labeling changes according to FDA's guidance, "Deciding When to Submit a 510(k) for a Change to an Existing Device."[10]

This guidance is not intended to include a complete listing of all labeling components for HPCPs. This guidance should be used as a complement to FDA's "Guidance on Medical Device Patient Labeling,"[11] (hereafter referred to as the "Patient Labeling guidance," which describes FDA's current thinking on making medical device patient labeling understandable to and usable by patients), existing regulations, and other relevant guidance documents containing additional labeling recommendations. This guidance also complements FDA's guidance "Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products"[12] and its addendum "Contact Lens Care Products Labeling."[13] This guidance provides recommendations that are specific to HPCPs and may assist in complying with some special controls.

IV. Specific Consumer Labeling Recommendations

A. General Considerations

Contact lens care products, including HPCPs, are subject to the general labeling requirements for all medical devices outlined in 21 CFR 801. The premarket notification submission must include proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Consumer labeling for HPCPs includes information contained on the package insert, carton, and bottle, and is directed to the contact lens wearer. The consumer labeling for HPCPs should instruct the consumer on product care to ensure contact lenses are used safely and effectively, to identify potential risks and benefits, and to explain what to expect when these care products are used. The labeling should contain sufficient information to describe the device, its intended use, precautions, warnings, and contraindications.

Consumer labeling should be written in simple, plain language that does not exceed the eighth-grade reading level. Regardless of the reading level, poorly designed text can still be confusing and misleading. The consumer labeling should be directed to users and potential consumers of HPCPs and should address the following questions:

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[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.

[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling.

[12] https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/contact-lens-care-products-premarket-notification-510k-guidance.

[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contact-lens-care-products-labeling.

- How do Hydrogen Peroxide-Based Contact Lens Care Products work?
- How should I use Hydrogen Peroxide-Based Contact Lens Care Products correctly?
- What are the risks associated with Hydrogen Peroxide-Based Contact Lens Care Product use?
- Who should I contact if there is a problem?

The lay language should provide a balanced presentation of adverse events and the risks and benefits of the device. It should not introduce implied or actual statements regarding performance that are unsubstantiated or that may be misleading to consumers. In order to increase the likelihood that the consumer labeling is read and understood by the consumer, we recommend that manufacturers consider placing consumer labeling on their website to help consumers obtain the most up-to-date information.

We recommend that consumer labeling contain the information in the sections outlined in the Patient Labeling guidance. The sections suggested in the Patient Labeling guidance may be adapted as appropriate for HPCPs and should enable the consumer to easily find and understand information that answers the questions identified above. The recommendations in this draft guidance are intended to supplement and enhance the information that is often already identified in labeling for these device types. To the extent the recommendations in this document depart from previously issued recommendations in the 2010 guidance, "Contact Lens Care Products Labeling,"[14] this document supersedes those previous recommendations as applied to hydrogen peroxide-based contact lens care products under product codes MRC and LPN. This guidance presents FDA's format and content recommendations for specific labeling components, and FDA has provided examples of each in the appendices to help illustrate the recommendations.

B. Suggested Format and Content of Consumer Labeling

(1) Package Insert Labeling

To help manufacturers develop appropriate labeling and to mitigate the safety issues related to HPCP misuse, FDA is providing the following recommendations for the package insert labeling. The package insert should include the following information where applicable. An example of package insert labeling is provided in Appendix A.

a. General Instructions and Description

FDA believes that the package label insert should include general instructions and description as outlined below:

- A section that describes the general process involved with the use of HPCPs including: a description of the disinfecting and neutralization process, and whether it is a one-step or two-step process.
- A statement to read the instructions carefully and to retain the information for future use.

[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contact-lens-care-products-labeling.

- The trade name and identification of the active ingredient(s) (optional, list of inactive ingredients), sterility status, and when applicable, a description of the contents (e.g., case, disk or tablet) and any additional components. FDA believes that prominent text identifying that the product contains 3% hydrogen peroxide should be included in this section.
- A description of the function of the device (i.e., how the device works in relation to the contact lenses). When applicable, the actions may also be listed with the indications for use.
- The indications for use statement as described in the submission.

b. Contraindications

Contraindications describe situations in which the device should not be used because the risk of use of the device clearly outweighs any reasonably foreseeable benefit. FDA recommends that manufacturers include all contraindications specific to the device. For example, such contraindications may include a statement identifying that the device should not be used if allergic to any ingredient in the device. If there are no contraindications, a statement may be provided noting that there are no known contraindications.

c. Warnings

FDA recommends that manufacturers prominently display (e.g., using emphasized text) appropriate warnings regarding how to avoid known hazards associated with the use of HPCPs. These warnings may alert consumers to the possibility of serious adverse reactions, situations which, if not avoided, could result in death or serious injury, and steps that should be taken if they occur. FDA believes such warnings include the following examples of (1) general warnings that should be prominently listed in all labeling types (package insert labeling, carton labeling, and bottle labeling) and (2) additional warnings that should be included in the package insert.

General Warnings

FDA believes general warnings should include the following information:

- A statement that the solution should only be used with the case provided and warn against the use of flat lens cases.
- A statement identifying the minimum time to ensure the completion of the neutralization process prior to lens insertion and a statement that unneutralized disinfecting solution should not be put into the eye.
- Directions for when unneutralized solution does come in contact with the eyes.
- A statement that warns against the reuse of the neutralized HPCP solutions.
- A statement that warns against rinsing your lenses with the HPCP solution, which would cause severe burning or stinging.
- A statement that warns against squirting the HPCP solution into the eyes.

The statements above, wherever possible, should also warn consumers of the risks associated with inserting HPCP solution into the eye (e.g., severe burning and stinging).

Additional Warnings

FDA recommends that manufacturers include warnings emphasizing that it is essential for consumers to follow all labeling instructions for proper use of contact lenses and lens care products. FDA recommends such additional warnings include the following instructions for use and warnings pertaining to contact lens wear:

- A statement warning against reuse or "topping off solutions." Reuse may reduce 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 in the lens case. A statement referencing the use of fresh, sterile or unexpired solution each time you use your contact lenses should be included. Graphics warning against reuse or topping off of solution are also recommended.
- A statement against storing your lenses or rinsing your lens case with water or any non-sterile or expired saline solution (e.g., these practices may lead to ocular infections).
- A statement that warns against risks associated with contact lens exposure to water from showering, swimming in pools, lakes, or oceans (e.g., may harbor microorganisms that lead to severe infection, vision loss, or blindness).
- A statement that warns against using inappropriate liquids to disinfect your lenses, since not using the recommended disinfectant may lead to severe infection, vision loss or blindness.
- A statement that warns of the risks associated with using solutions past their discard date since the performance of solutions have not be tested past their discard date. The discard date refers to the time you can safely use the contact lens care product after the bottle has been opened. It is not the same as the shelf-life/expiration date, which is the last date that the product is still effective before it is opened.
- A statement that warns of the potential contamination of the solution, which may reduce the effectiveness of solutions and result in contamination of lenses (e.g., avoid touching surfaces or transferring solutions).
- A statement that warns of the risks associated with ingestion of hydrogen peroxide, which may occur if small children have access to the product. A statement should be added advising consumers to seek immediately medical attention if ingested and/or promptly contact their eye care practitioner.
- When applicable, a statement that warns of possible effects associated with rubbing rigid gas permeable (RGP) lenses with peroxide solution (e.g., that may result in skin discoloration). A statement should be added advising consumers to wash and rinse their hands after rubbing RGP lenses.
- When applicable, a statement that warns against ingestion of neutralizing tablets that may result in upset stomach and vomiting. A statement should be added advising consumers not to ingest tablets and to seek immediately medical attention if ingested and/or promptly seek medical assistance or a poison control center.
- When applicable, statements against improper use of neutralization tablets that may result in inadequate neutralization. Statements should be added advising consumers of situations that may result in inadequate neutralization or disinfection (e.g., crushing a neutralizing tablet, number of times a neutralizer disk may be used).

Non-Product Specific Warning

Additionally, FDA recommends that manufacturers include a non-product specific warning that specifies that consumers should follow the directions of the eye care practitioner and all labeling instructions for proper use and care of both their lenses and lens care products, including the lens case since problems with contact lenses and lens care products could result in serious injury to the eye. FDA recommends that this warning also include the following information:

- Specifying that daily wear lenses are not indicated for overnight wear and that clinical studies have shown that there is an increased risk for serious adverse reactions when worn overnight.
- Specifying that extended wear lenses should be regularly removed for cleaning and disinfection or disposal and replacement as prescribed by the eye care practitioner, and that clinical studies have shown that there is an increased incidence of serious adverse reaction in extended wear contact lens wearers compared to daily wear contact lens wearers. Studies have also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement.
- Specifying that studies have also shown that smokers who wear contact lenses have a higher incidence of adverse reactions.
- Specifying that if the consumer experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, that they should remove their contact lenses and contact their eye care practitioner.

d. Precautions

FDA recommends that precautions include information for the safe and effective use of the device by the consumer to mitigate minor or moderate injury. Listed below are examples of general precautions that pertain to all HPCP solutions and specific precautions for neutralizing products. FDA believes such precautions include the following:

General Precautions

- A statement that consumers should always wash and dry their hands prior to manipulating lenses because residual dirt, oils, and/or contamination may result in subsequent stinging or ocular infection.
- A statement that consumers should never use generic hydrogen peroxide not specifically intended for use with contact lenses or mix HPCP solutions because this may result in insufficient disinfection, neutralization, and/or damage to contact lenses.
- Statements that consumers should never reuse solutions, should always use fresh, unexpired solution, and should never store lenses in used neutralized solution for more than 24 hours because this will help ensure sufficient disinfection.
- Statements regarding activities during or after use of HPCP solutions that may reduce the product effectiveness, enhance deterioration and/or cause lens damage. These activities may include: shaking/inverting the lens case during disinfection, failure to discard the contents of the bottle "X" months after first opening, failure to keep the bottle closed when not in use, failure to store the bottle at a certain temperature and/or range, failure to keep the lenses immersed in the storage solution when not worn; and heating the solution or contact lenses.

Precautions for Neutralizing Products

FDA recommends the inclusion of statements regarding activities during or after use of neutralizing tablets that may reduce the product effectiveness, enhance deterioration and/or cause lens damage. These activities may include: using tablets that appear to be broken, chipped, or discolored; using tablets from packages that are torn or punctured; substituting neutralizing components; and using neutralizing tablets in a heat disinfection unit.

e. Adverse Reactions

FDA recommends that the package insert labeling should inform consumers about the potential adverse reactions associated with the use of the product and that eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. The package insert labeling should also include a statement that if a consumer notices any adverse reactions (e.g., stinging and burning, eye discomfort, excessive tearing, among others), they should immediately remove lenses. Statements should be added to the package insert advising the consumer on instructions for lens removal thereby reducing the potential for ocular damage. The package insert labeling should also include statements that consumers immediately contact their eye care practitioner if problems persist or worsen, to seek immediate professional care, and to report all adverse events to the manufacturer. A statement should be added to inform the consumer that they can also report adverse events to FDA Medwatch. This is important to diagnose or document any adverse events associated with the product.

f. General Directions for Use

FDA recommends all directions for use contain the major steps of the process (e.g., rinse with solution, fill provided container, and soak) to ensure proper use of HPCP solutions. Each step should be briefly described using simple language for easy understanding. The use of graphics in device labeling has been shown to contribute to better comprehension.[15] As such, FDA recommends that simple graphics, where appropriate, should be included. In order to provide a complete set of directions for consumers, FDA recommends that these directions include the following:

- Instructions for safe handling of contact lenses to minimize residual dirt, oils, and/or contamination, which may result in subsequent stinging or ocular infection.
- Specific, detailed directions based on the lens type (e.g., soft and RGP lenses) to convey important differences in the cleaning/disinfection regimen. FDA recommends reemphasizing warning statements regarding not putting HPCP solution into the eye because unneutralized hydrogen peroxide exposure may result in corneal burns, redness and stinging (see Appendix A for examples for soft lenses and for RGP lenses).
- Information for lens case care and replacement. This is important to ensure that users appropriately clean and care for the lens case as they have been shown to be a source of microbial contamination.
- Information regarding how the product is supplied (e.g., sterile, quantity of contents, type of packaging, lot number), distributor/manufacturer name and address, and the date the

[15] Kools M, van de Wiel MW, Ruiter RA, Kok G. Pictures and text in instructions for medical devices: effects on recall and actual performance. Patient Educ Couns. 2006 Dec;64(1-3):104-11. Epub 2006 Feb 10.

labeling was printed. This is important to allow traceability and identification for adverse event reporting or for consumer questions.

(2) Carton Labeling

In order to highlight warnings, precautions, and to minimize crowding, FDA recommends that the directions for use should not be included in carton labeling. However, a statement should be added directing users to follow directions on the bottle and in the package insert. FDA also recommends that the carton labeling contain a red banner (e.g., at least 1 inch in height) encircling the top of the carton that includes text emphasizing that the HPCP solution should not be put into the eyes. We also recommend that manufacturers include two identical statements, such as "DO NOT PUT IN EYES," that span the circumference of the bottle with associated graphics, in emphasized font. The banner should be similar to the banner placed on the bottle. FDA recommends a minimalist approach to the content of the carton labeling and font sizes consistent with the Patient Labeling guidance, which aligns with 2017 Panel recommendations. An example of carton labeling is provided in Appendix B.

a. Manufacturer and product information

HPCPs are over-the-counter devices and labeling must comply with 21 CFR 801.60 - Principal display panel, as well as 21 CFR 801.61 - Statement of identity, 21 CFR 801.62 - Declaration of net quantity of contents. In addition, the labeling must comply with 21 CFR 800.12 – Contact lens solutions and tablets; tamper-resistant packaging, and 21 CFR 800.10 – Contact lens solutions; sterility, and should also contain the following recommended information:

Principal Display Panel (*see* 21 CFR 801.60):

- Product Trade Name [including emphasis on "3% Hydrogen Peroxide [Solution]" (e.g., in prominent text)] (see Patient Labeling guidance for recommendations on font sizes for Headings)
- Actions and Indications (*see* 21 CFR 801.61; e.g., cleans, disinfects)
- Lens Compatibility (i.e., the type of lenses for which the device may be used)
- Net Quantity Contents (21 CFR 801.62)
- Sterile

Outer Carton Panels

- Special Storage Conditions (e.g., store at room temperature)
- A statement referring customers to the bottle and package insert for information on proper use of the product
- Tamper-Resistant Statement (21 CFR 800.12)
- A statement to keep product out of the reach of children
- [Insert information on whom to contact for concerns, adverse reactions, and additional information: [Distributed by/Manufactured by/Manufactured for] Address including zip code, website, and phone number.]
- Lot Number
- Expiration Date
- Product Information:

  - Description (i.e., Active Ingredients)
  - Package contents (e.g., a lens case is included)
- A statement referring customers to consult the package insert for complete safety information
- Website and social media connections (e.g., Quick Response (QR) code, website link) to manufacturers and FDA (e.g., "Hydrogen Peroxide Solution" https://www.fda.gov/medical-devices/contact-lenses/hydrogen-peroxide-solution)

b. Contraindications

FDA recommends that the same contraindications that are included in the package insert labeling as outlined in Section IV.B.1.b of this guidance also be included on the carton labeling.

c. Warnings

To minimize overcrowding, FDA recommends that manufacturers include only those warnings statements in the carton labeling that inform the consumers of the risks associated with HPCP solution that is not neutralized. This is important because unneutralized hydrogen peroxide exposure may result in corneal burns, redness and stinging. Statements using emphasized text (e.g., red and bold text) should be added to the warnings section on the carton to highlight these concerns, but bold text should be limited to emphasize key details only. In addition, FDA recommends that consumers be referred to the package insert for a complete list of warnings. Manufacturers should include the following statements/warnings with associated graphics on the carton labeling to inform consumers of the risks associated with unneutralized hydrogen peroxide:

- A statement that the solution should only be used with the case provided and warn against the use of flat lens cases.
- A statement identifying the minimum time to ensure the completion of the neutralization process prior to lens insertion.
- A statement that warns against rinsing your lenses with the HPCP solution, which would cause severe burning or stinging.
- A statement that warns against squirting the HPCP solution into the eyes.
- The statements above, wherever possible, should also warn the consumer of the risks associated with inserting HPCP solution into the eye (e.g., severe burning and stinging).
- A statement that the product contains hydrogen peroxide and that users should follow all directions on the bottle and in the package insert to avoid injury.

Since most non-hydrogen peroxide contact lens care products are used with flat lens cases that do not neutralize hydrogen peroxide, consumers may be confused regarding the need for the special neutralizing case provided with HPCP solutions. Therefore, to increase the likelihood that consumers understand these risks, and to emphasize the need for the neutralization of hydrogen peroxide, FDA recommends manufacturers include additional warnings, including graphics, against the use of flat lens cases on the top left and right carton flaps (in emphasized text), in addition to the body of the carton labeling. This labeling recommendation is consistent with the

2017 Panel recommendations, which advised graphics on the opening flap of the box since this warning is the first message consumers encounter as they open the product.

d. Precautions

FDA recommends that carton labeling only include precautions for the safe use of the device by the user to mitigate minor or moderate injury. These may include precautions that warn against the use of generic hydrogen peroxide or activities that may result in inadequate neutralization of hydrogen peroxide prior to use. FDA recommends that manufacturers should include a statement that refers consumers to the package insert for a complete list of precautions.

(3) Bottle Labeling

To help manufacturers develop bottle labeling that is clear, simple and consistent across products and to help mitigate the safety issues for HPCPs, FDA is providing the following labeling recommendations, which also align with recommendations provided at the 2017 Panel Meeting. FDA recommends that the bottle's design include a red cap and red tip as an indication that the solution should not be instilled directly into the eyes.[16,17] FDA recommends that bottle labeling consist of three equal-sized panels with a red banner (e.g., at least 1 inch in height) encircling the top of the bottle that includes text emphasizing that the HPCP solution should not be put into the eyes. We recommend manufacturers include two identical statements such as "DO NOT PUT IN EYES," in emphasized font that span the circumference of the bottle with associated large graphics (e.g., an image of bottle squirting in the eye crossed out). The red banner on the bottle labeling should be consistent with the banner on the carton labeling. Please see Appendix C for an example of the bottle labeling.

To minimize overcrowding, the bottle label should include the minimum information needed for consumers to safely use the product and include the product information, directions for use, and warnings. The labeling text should be written using clear, simple and concise language. FDA recommends font sizes consistent with the Patient Labeling guidance. FDA recommends the bottle labeling contain the following information:

a. Manufacturer and product information

- Distributer's/Manufacturer's name and address including zip code, phone number
- Lot Number
- Expiration Date
- Date Opened ____/or Discard Date_____
- Product Trade Name
- Description (i.e., Active Ingredients), including emphasis on "3% Hydrogen Peroxide [Solution]" (e.g., in prominent text) located near the Product Trade Name (see Patient Labeling guidance for recommendations on font sizes for Headings)

[16] March 17, 2017 Meeting: Ophthalmic Devices Panel for the Medical Devices Advisory Committee and the Risk Communication Advisory Committee (available at https://www.fda.gov/advisory-committees/ophthalmic-devices-panel/2017-meeting-materials-ophthalmic-devices-panel).

[17] For further information on hydrogen peroxide-based contact lens care products, see https://www.fda.gov/medical-devices/contact-lenses/hydrogen-peroxide-solution.

- Actions and Indications (21 CFR 801.61) (e.g., cleans, disinfects, etc.)
- Lens Compatibility (i.e., the type of lenses that the HPCP can be used with)
- Net Quantity Contents (21 CFR 801.62)
- Sterile
- Special Storage Conditions (e.g., store at room temperature)
- A statement advising users to keep out of reach of children
- A statement referring customers to consult the package insert for complete safety information
- Website and social media connections (e.g., Quick Response (QR) code, website link) to manufacturers and FDA (e.g., "Hydrogen Peroxide Solution" https://www.fda.gov/medical-devices/contact-lenses/hydrogen-peroxide-solution)

b. Directions for Use

The directions for use should contain the major steps of the process (e.g., rinse with solution, fill provided container, and soak) as referenced in the package insert. Each step should be briefly described using simple language for easy understanding. Simple graphics, where appropriate, should be included to aid in understanding.

c. Contraindications

FDA recommends that all known contraindications specific to the device be included on the bottle labeling as identified in the package insert section IV.B.1.b of this draft guidance.

d. Warnings

To minimize overcrowding, FDA recommends that manufacturers only include warning statements that inform the consumer of the risks associated with unneutralized HPCP solution (e.g., severe burning and stinging) on the bottle labeling. As noted previously, this is important because unneutralized hydrogen peroxide exposure may result in corneal burns, redness and stinging. Statements using emphasized text (e.g., red and bold text) should be added to the warnings section to highlight these concerns and any key details. In addition, clear warnings with associated graphics should be added to aid in understanding of how consumers may be exposed to unneutralized hydrogen peroxide. Manufacturers should include the following:

- A statement that the solution should only be used with the case provided and warn against the use of flat lens cases.
- A statement identifying the minimum time to ensure the completion of the neutralization process prior to lens insertion.
- A statement that warns against rinsing your lenses with the HPCP solution, which would cause severe burning or stinging.
- A statement that warns against squirting the HPCP solution into the eyes.
- The statements above, wherever possible, should also warn the consumer of the risks associated with inserting HPCP solution into the eye (e.g., severe burning and stinging).

Appendix A: Package Insert Labeling Example

This section provides an example of a package insert for an HPCP, as described in Section IV.B.1.

GENERAL

Hydrogen peroxide placed directly into the eyes or onto contact lenses prior to insertion can cause stinging, burning, and transient corneal damage. When using hydrogen peroxide, the disinfecting process must be followed with neutralization. The neutralization of hydrogen peroxide into water and oxygen makes it safe to put your lenses back into the eyes.

Neutralization can be either a one-step or two-step process. The one-step process neutralizes the lenses *during* the disinfecting stage, while the two-step process neutralizes the lenses *after* the disinfecting stage.

Some storage cases have a neutralizer built-in, making it a simple one-step process. With other cases, a neutralizing tablet that comes with the hydrogen peroxide-based contact lens care product solution must be added. This is the two-step process.

IMPORTANT - Please read carefully and keep this information for future use.

TRADE NAME

[TRADENAME (TN)]
3% Hydrogen Peroxide Solution

DESCRIPTION/CONTENTS:

[Include "sterile;" list active ingredients (optional, list inactive ingredients). When applicable, include the following additional descriptive information:

Case, Disk, or Tablet, and describe each item and any additional components]

ACTIONS:

[Include a concise description of the function of the device (i.e., how the device works in relation to the contact lens). When applicable, the actions can be listed with the indications (i.e., INDICATIONS/ACTIONS).]

INDICATIONS (USES):

[Include the Indication for Use Statement as described in the marketing submission.]

CONTRAINDICATIONS:

- [Include all known contraindications. If there are no known contraindications, add the statement "There are no known contraindications for use of this product."]
- If you are allergic to any ingredient in this device, DO NOT USE.

GENERAL WARNINGS:

- **[TN] Solution is neutralized only with the special [TN] Solution case. NEVER use a flat lens case. It will cause severe burning and stinging!**
- **NEVER soak lenses in [TN] Solution for less than [X] hours to ensure completion of the neutralization process prior to lens insertion. It may cause severe burning and stinging. DO NOT PUT [TN] DISINFECTING SOLUTION THAT HAS NOT BEEN NEUTRALIZED IN YOUR EYE. Should unneutralized [TN] solution get in your eye, remove your lenses immediately, flush (wash) your eyes with a large amount of water or sterile saline for a few minutes. If burning and/or irritation persist, seek assistance from an eye care professional.**
- **The red dropper tip indicates that [TN] solution should not be put directly in your eye. DO NOT REUSE NEUTRALIZED HYDROGEN PEROXIDE SOLUTION.**
- **NEVER rinse your lenses with [TN] Solution and put them in your eyes! It will cause severe burning and stinging!**
- **NEVER squirt [TN] Solution into your eyes! It will cause severe burning and stinging!**

ADDITIONAL WARNINGS:

- You should 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 in the lens case.
- Do not store your lenses or rinse your lens case with water or any non-sterile or expired saline solution. Use fresh, sterile or unexpired saline solution so you do not contaminate your lenses or lens case. Use of non-sterile or expired solution can lead to severe infection, vision loss, or blindness.
- Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If the contact lenses have been exposed to water, such as when showering, swimming in pools, lakes, or oceans, you should discard them and replace them with a new pair. You should ask your eye care professional for recommendations about wearing your lenses during any activity involving water.
- 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.
- Using peroxide solutions beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss, or blindness.
- To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.
- To avoid contaminating your solution, DO NOT transfer to other bottles or containers.

- Keep out of the reach of children. If accidentally swallowed, an upset stomach and vomiting may result. Seek immediate professional medical assistance or contact a poison control center.
- While rubbing RGP lenses with [TN] solution, some consumers may experience a mild, temporary skin discoloration (bleaching) of the fingers or hands. Always wash and rinse your hands after rubbing your lenses with the solution.
- [When applicable] This tablet is not to be taken internally. If accidentally swallowed, an upset stomach and vomiting may result. Seek immediate professional medical assistance or contact a poison control center.
- [When applicable] DO NOT crush the [TN] Neutralizing Tablet. If a crack occurs in the coating, the tablet may begin to neutralize the [TN] Disinfecting Solution before adequate disinfection occurs.
- [When applicable] DO NOT use [TN] Neutralizer disk for more than [X] uses or [X] months of daily use. [Note: Uses and time period should be determined by testing data.]
- PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. Follow your eye care practitioner's directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown the risk of serious adverse reactions is increased when these lenses are worn overnight. Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care practitioner. Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement. Studies have also shown that smokers who wear contact lenses have a higher incidence of adverse reactions. If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove your lenses and promptly contact your eye care practitioner. All contact lens wearers should see their eye care practitioner as directed.

GENERAL PRECAUTIONS:

- Always wash and dry your hands before handling your lenses.
- DO NOT USE OVER-THE-COUNTER GENERIC HYDROGEN PEROXIDE. Generic hydrogen peroxide solutions are not intended for ophthalmic use and may contain ingredients not tested for ocular safety or toxicity. Use of generic hydrogen peroxide may cause severe burning and stinging if not neutralized before use. In addition, generic hydrogen peroxide may contain ingredients that cause DISCOLORATION OR DAMAGE TO YOUR CONTACT LENSES.
- Do not mix or substitute other hydrogen peroxide-based contact lens care products or lens cases as inadequate neutralization of hydrogen peroxide may cause severe burning and stinging.

- If lenses are stored for more than 24 hours in [TN] disinfecting solution, disinfect your lenses again by replacing the solution in the barrel lens case with fresh [TN] disinfection solution and leave to soak for [X] hours to complete the neutralization before inserting lenses in the eye.
- Never reuse the [TN] disinfecting solution. Always discard the remaining solution from the lens case.
- Use before the expiration date marked on the carton and bottle. Always use fresh, unexpired lens care solutions.
- Do not shake/invert the lens case during the disinfection.
- Discard contents of the bottle [X] months after first opening.
- Keep the bottle tightly closed when not in use.
- Store at [X degrees or specify temperature range].
- Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (stored). Prolonged periods of drying will damage lenses/reduce the ability of the lens surface to return to a wettable state.
- Do not heat the solution and lenses.

PRECAUTIONS FOR NEUTRALIZING PRODUCTS [WHEN APPLICABLE]:

- DO NOT use tablets that appear to be broken, chipped, or discolored.
- DO NOT use tablets from packages which are torn or punctured.
- DO NOT substitute [TN] Neutralizer components.
- DO NOT use neutralizing tablets in a heat disinfection unit.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO):

WARNING:
EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF YOU EXPERIENCE:

- Stinging and burning
- Eye discomfort
- Excessive tearing
- Unusual eye secretions
- Vision changes
- Loss of vision
- Eye redness
- Sensitivity to light (photophobia)
- Dry eyes
- Other eye problems

YOU SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

- If you experience stinging and burning, **remove your lenses immediately, flush (wash) your eyes with a large amount of water or sterile saline for a few minutes. If burning and/or irritation persist, seek assistance from an eye care professional.**
- If the discomfort or problem stops, remove and inspect the lens.

- If the lens is in any way damaged, **DO NOT** put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner.
- If the lens is not damaged but has dirt, an eyelash, or other foreign body on it, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them.
- After reinsertion, if the problem continues, **IMMEDIATELY** remove the lenses and consult the eye care practitioner.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

All adverse reactions observed while using [TN] should be reported to:

[Manufacturer's Name]
[Manufacturer's Address]
[Manufacturer's Website]
[U.S.-Based Toll Free Telephone Number]

and can also be reported to FDA MedWatch,
https://www.accessdata.fda.gov/scripts/medwatch/index.cfm.

GENERAL DIRECTIONS FOR USE:

- Always wash and rinse your hands before handling your lenses. This will help to prevent eye infections by removing dirt and oils that could get on the lenses.

1) Place lenses in holder of special [TN] Solution case. Squirt some solution over them.
2) Fill the special [TN] Solution case up to the fill line. Put the lens holder in the case. Tighten the cap on the [TN] Solution case.
3) Soak the lenses in the special [TN] Solution case for a minimum of [X] hours. Your lenses are ready to wear after soaking for at least [X] hours.

DIRECTIONS FOR USE - Soft Lenses:

Do not put [TN] solution on your lenses and insert directly into the eye or burning and stinging will result.

TO CLEAN, DISINFECT, AND NEUTRALIZE YOUR LENSES:

- Remove and place each lens into the appropriately marked L/R domed lens holder.

- [Specify the total rinse time, in addition to stating the minimum lens rinsing time for each side of the lens. In addition to your directions that state to rinse the lenses for x seconds each, you should also state that the rinse time is "for a total of [X] seconds".]

- Fill the lens case to fill line with [TN] solution and place the lens holder in the case.

- Tighten the cap and store lenses for at least [insert recommended duration] hours or overnight. DO NOT SHAKE THE CASE. NOTE: To prevent damage to your lens, center the lens on the dome in the lens holder. Be sure the lens does not touch the basket rim, then close the basket lid.

- After soaking for [insert recommended duration] hours, your lenses are ready to wear. **Never rinse your lenses with [TN] solution prior to insertion or burning and stinging will result.** If desired, lenses can be rinsed with sterile saline before inserting.

- Discard the neutralized disinfectant from the cup. Rinse the lens cup with fresh saline or [TN] solution and allow the case to air dry with the lens holder inverted outside the case. Do not place the lens holder on its side.

Your eye care professional may recommend additional products or procedures to care for your lenses based on individual tear chemistry and lens wearing schedule. Always follow your eye care professional's instructions. Seek advice from your eye care professional before making changes to your care regimen to ensure compatibility with lenses.

DIRECTIONS FOR USE – RGP Lenses:

Do not put [TN] solution on your lenses and insert directly into the eye or burning and stinging will result.

- Remove your lenses one at a time and place them into the appropriately marked dome basket holder.

- Place each lens in the palm of your hand, apply 2 to 4 drops of [TN] solution and rub. While rubbing your lenses with [TN] solution, some users may experience a mild, temporary skin discoloration (bleaching) of the fingers or hands. Always wash and rinse your hands after rubbing your lenses with the solution.

- Return the lenses to the appropriate holder and close the baskets. Thoroughly rinse the lenses for [insert recommended duration] seconds through the basket with [TN] solution.

- Fill the lens case with [TN] solution and place the lens holder in the case. Tighten the cap and store lenses for at least [insert recommended duration] hours. DO NOT SHAKE THE CASE. Do not rinse the lenses. Place the lenses directly on the eye from the solution or place a few drops of a contact lens rewetting drop on the lens for extra cushioning.

Your eye care professional may recommend additional products or procedures to care for your lenses based on individual tear chemistry and lens wearing schedule. Always

follow your eye care professional's instructions. Seek advice from your eye care professional before making changes to your care regimen to ensure compatibility with lenses.

LENS CASE CARE

- Rinse your lens case with sterile or unexpired 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 every [insert a recommended time period]. Contact lens cases can be a source of bacterial growth.

HOW SUPPLIED:

[Describe how device is packaged for distribution (e.g., quantity of contents, sterile, packaged in bottle, and marked with lot number and expiration date).]

MANUFACTURER OR DISTRIBUTOR NAME AND ADDRESS:

[Include the information that expresses the following information: [Distributed by/Manufactured by/Manufactured for] Address including zip code, and Manufacturer's website.]

PRINTED [MONTH AND YEAR]

Appendix B: Carton Labeling Example

This section provides an example of carton labeling for an HPCP containing important product information, warnings, and precautions, as described in Section IV.B.2.

PRODUCT INFORMATION:

Principal Display Panel:

- [Product Trade Name, including emphasis on "3% Hydrogen Peroxide [Solution]" (e.g., in prominent text) (see Patient Labeling guidance for recommendations on font sizes for Headings)]
- [Actions and Indications (21 CFR 801.61) (e.g., cleans, disinfects)]
- [Lens Compatibility (i.e., the type of lenses for which the device may be used)]
- [Net Quantity Contents (21 CFR 801.62)]
- Sterile

Outer Carton Panels:

- [Special Storage Conditions (e.g., store at room temperature)]
- [A statement referring customers to the bottle and package insert for information on proper use of the product]
- [A statement advising users to keep out of reach of children]
- [Tamper-Resistant Statement (21 CFR 800.12)]
- [Insert information on whom to contact for concerns, adverse reactions, and additional information: [Distributed by/Manufactured by/Manufactured for] Address including zip code, website, and phone number.]
- [Lot Number]
- [Expiration Date]
- Product Information:
  - [Description (i.e., Active Ingredients)]
  - [Package contents (e.g., a lens case is included)]
- [A statement referring customers to consult the package insert for complete safety information]
- [Website and social media connections (e.g., Quick Response (QR) code, website link) to manufacturers and FDA (e.g., "Hydrogen Peroxide Solution" https://www.fda.gov/medical-devices/contact-lenses/hydrogen-peroxide-solution)]

CONTRAINDICATIONS:

- [Include all known contraindications. If there are no known contraindications, add the statement "There are no known contraindications for use of this product."]
- If you are allergic to any ingredient in this device, DO NOT USE.

WARNINGS:

- [TN] Solution is neutralized only with the special [TN] Solution case. NEVER use a flat lens case. It will cause severe burning and stinging!
- NEVER soak lenses in [TN] Solution for less than [X] hours. It may cause severe burning and stinging!
- NEVER rinse your lenses with [TN] Solution and put them in your eyes! It will cause severe burning and stinging!
- NEVER squirt [TN] Solution into your eyes! It will cause severe burning and stinging!
- **Contains Hydrogen Peroxide,** To avoid injury, follow all directions on the bottle and package insert.

Top Left and Right Carton Flaps [in emphasized (e.g., bold, red) text]

Left Flap: [A schematic of a flat lens case, encircled with a line through it, with the accompanying verbiage in bold type: "DO NOT USE FLAT LENS CASE."]

Right Flap: [A schematic of your lens case, with the accompanying verbiage in bold type: "USE ONLY THE [TN] LENS CASE PROVIDED."]

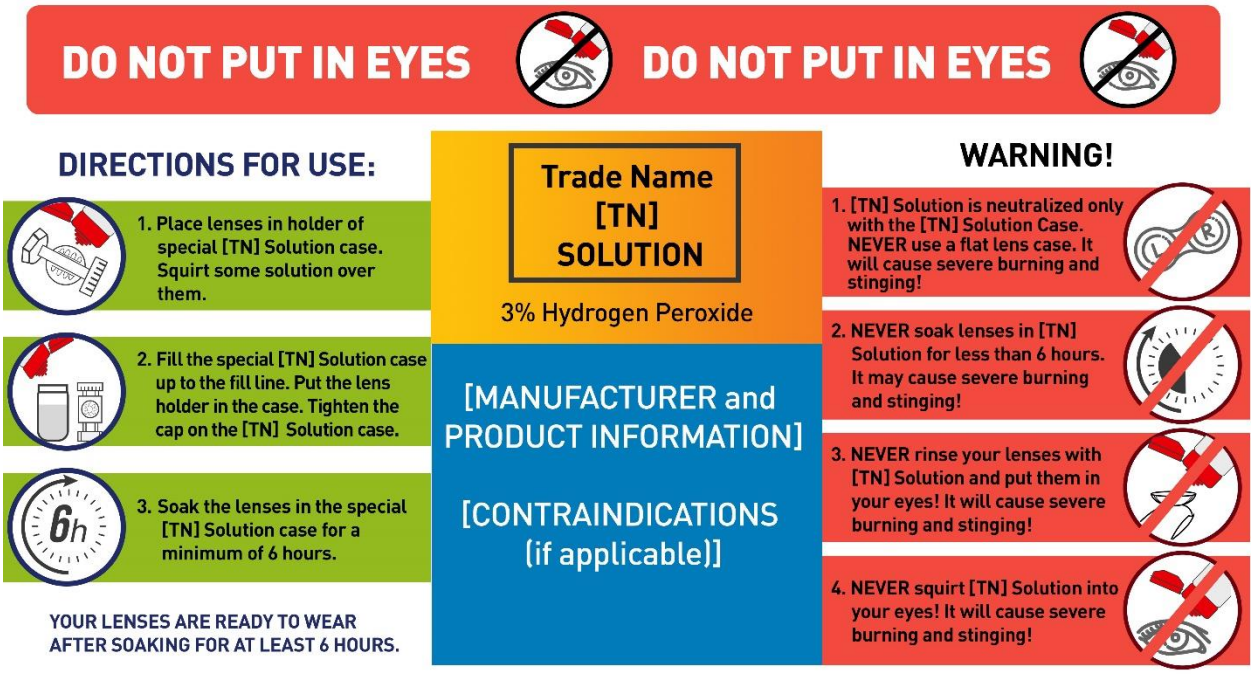
PRECAUTIONS:

- DO NOT USE OVER-THE-COUNTER GENERIC HYDROGEN PEROXIDE. Generic hydrogen peroxide solutions are not intended for ophthalmic use and may contain ingredients not tested for ocular safety or toxicity. Use of Generic hydrogen peroxide may cause severe burning and stinging if not neutralized before use.
- Do not mix or substitute other hydrogen peroxide-based lens care products or lens cases as inadequate neutralization of peroxide may cause severe burning and stinging.

Appendix C: Sample Bottle Labeling

This section provides an example of bottle labeling for an HPCP solution that contains important warnings and directions for use as well as relevant product information, as described in Section VI.B.3.

Figure 1: Example of Bottle Labeling



MANUFACTURER and PRODUCT INFORMATION:

- [Distributer's/Manufacturer's name and address including zip code, phone number]
- [Lot Number]
- [Expiration Date]
- [Date Opened ____/or Discard Date_____]
- [Product Trade Name]
- [Description (i.e., Active Ingredients), including emphasis on "3% Hydrogen Peroxide [Solution]" (e.g., in prominent text) located near the Product Trade Name (see Patient Labeling guidance for recommendations on font sizes for Headings)]
- [Actions and Indications (21 CFR 801.61) (e.g., cleans, disinfects, etc.)]
- [Lens Compatibility (i.e., the type of lenses for which the device may be used)]
- [Net Quantity Contents (21 CFR 801.62)]
- Sterile
- [Special Storage Conditions (e.g., store at room temperature)]
- [A statement advising users to keep out of reach of children]

- [A statement referring customers to consult the package insert for complete safety information]
- [Website and social media connections (e.g., Quick Response (QR) code, website link) to manufacturers and FDA (e.g., "Hydrogen Peroxide Solution" https://www.fda.gov/medical-devices/contact-lenses/hydrogen-peroxide-solution)]

DIRECTIONS FOR USE:

1) Place lenses in holder of special [TN] Solution case. Squirt some solution over them.
2) Fill the special [TN] Solution case up to the fill line. Put the lens holder in the case. Tighten the cap on the [TN] Solution case.
3) Soak the lenses in the special [TN] Solution case for a minimum of [X] hours. Your lenses are ready to wear after soaking for at least [X] hours.

CONTRAINDICATIONS:

- [Include all known contraindications. If there are no known contraindications, add the statement "There are no known contraindications for use of this product."]
- If you are allergic to any ingredient in this device, DO NOT USE.

WARNINGS:

- [TN] Solution is neutralized only with the [TN] Solution case. NEVER use a flat lens case. It will cause severe burning and stinging.
- NEVER soak lenses in [TN] Solution for less than [X] hours. It may cause severe burning and stinging.
- NEVER rinse your lenses with [TN] Solution and put them in your eyes! It will cause severe burning and stinging!
- NEVER squirt [TN] Solution into your eyes! It will cause severe burning and stinging!