LABELING--APPENDIX B

PROFESSIONAL FITTING AND INFORMATION GUIDE

Key:

Multiple brackets ([] []) - Select appropriate information.
Brackets with number sign ([#]) - Fill in appropriate number.
Brackets containing instructions - Follow instructions. Add information if it applies to your lens.
Parentheses (fill in generic name) - Follow instructions.
**Bold text as it appears in example.**

TRADE NAME (TN)
(fill in generic name)
[Soft (Hydrophilic)] [Rigid Gas Permeable] Contact Lenses

CAUTION: Federal Law Prohibits Dispensing Without a Prescription (or use the most recent statement required by regulation)

[The following warning is required, when applicable, to comply with the EPA Clean Air Act and the FDA regulation published in the Federal Register on June 29, 1993 (FR 58 34812)]: WARNING: Contains [or Manufactured with, if applicable] (insert name of substance), a substance which harms public health and environment by destroying ozone in the upper atmosphere. A notice similar to the above WARNING has been placed in the patient information of this product, pursuant to EPA regulation.]

[Add the following statement if the Package Insert is printed in the back of the Professional Fitting and Information Guide, and information is to be referenced to the Package Insert.] "See Package Insert for [specify."]

TABLE OF CONTENTS [ADD APPLICABLE SECTIONS, MODIFY AS NEEDED]:

INTRODUCTION:

The TN/generic name [Soft (Hydrophilic)] [Rigid Gas Permeable] Contact Lenses are made from [polymer/copolymer] with a water content of [%] by weight.

For a complete listing of available lens parameters, please refer to LENS PARAMETERS AVAILABLE.

[Include other applicable information]

PRODUCT DESCRIPTION:

[Include the information in the package insert under the heading entitled, DESCRIPTION]

LENS PARAMETERS AVAILABLE:

[Include in this section lens parameters available within the approved range taken from the DESCRIPTION section of the package insert, not simply the approved range of parameters]

ACTIONS:

[Include the information in the package insert under the heading entitled, ACTIONS, or reference the package insert if it is printed in the back of this guide. Add additional information if applicable]

INDICATIONS:

[Include the information in the package insert under the heading entitled, INDICATIONS]

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS SECTIONS:

[Either include the information in the package insert under the headings entitled, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS, or include a statement such as, "See package insert for [specify what is being referenced"]

SELECTION OF PATIENTS:

[Include applicable information for specific lens]

FITTING PROCEDURE OUTLINE [INCLUDE APPLICABLE INFORMATION FROM ITEMS BELOW AND MODIFY AS NEEDED]:

1. Pre-fitting examination
2. Initial lens power selection
3. Initial lens diameter selection
4. Initial lens base curve selection
5. Initial lens evaluation
6. Follow-up care

FITTING PROCEDURE:

1. **Pre-Fitting Examination**

   A pre-fitting patient history and examination are necessary to:

   - determine whether a patient is a suitable candidate for daily wear contact lenses (consider patient hygiene and mental and physical state),
   - make ocular measurements for initial contact lens parameter selection,
   - collect and record baseline clinical information to which post-fitting examination results can be compared,
   - [other, as appropriate]

   A prefitting examination should include [include applicable information].

2. **Initial Lens Power Selection**

   [Include applicable information]

3. **Initial Lens Diameter Selection**

   [Include applicable information]

4. **Initial Lens Base Curve Selection**

   [Include applicable information]

5. **Initial Lens Evaluation**

   [Include applicable information]

6. **Follow-up Care [Modify as Needed]**

   a. Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.

b. Prior to a follow-up examination, the contact lenses should be worn for at least [#] continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

c. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

d. After the lens removal, conduct a thorough biomicroscopy examination.

1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.

2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.

3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

4. [Other, specify]

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

IN OFFICE CARE OF TRIAL LENSES:

Eyecare practitioners should educate contact lens technicians concerning proper care of trial lenses.

[For soft (hydrophilic) contact lenses] Each contact lens is shipped sterile in a [container, specify] with [solution, specify]. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the vial should not be opened until immediately prior to use.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected. [Include instructions for disinfection; instructions are not applicable for disposable lenses. They should be discarded]

[For rigid gas permeable lenses, include the following caution and all other applicable information on handling newly received lenses, preparing the lenses for fitting, and instructions for disinfection prior to use: CAUTION: Non-sterile, clean and condition lenses prior to use.]

RECOMMENDED INITIAL WEARING SCHEDULE:

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

**Daily Wear**
**Maximum wearing time:**

| Day | Wearing Time (Hours) |
|---|---|
| 1 | [#] |
| 2 | [#] |
| 3 | [#] |
| 4 | [#] |
| 5 | [#] |
| 6 | [#] |
| 7 | [#] |
| 8 | [#] |
| 9 | [#] |
| 10 | [#] |
| 11 | [#] |
| 12 and after - all waking hours | [#] |

CLINICAL ASSESSMENT:

1. **Criteria of a Well-Fitted Lens**

   [Include applicable information]

2. **Characteristics of a Tight (Steep) Lens**

   [Include applicable information]

3. **Characteristics of a Loose (Flat) Lens**

   [Include applicable information]

**[Other information such as problem solving recommendations if applicable]**

[ADD IF APPLICABLE] MONOVISION FITTING GUIDELINES:

**[Note: The labeling noted below is for soft (hydrophilic) spherical lenses. Labeling for soft (hydrophilic) toric lenses and rigid gas permeable lenses will need to be modified as needed.]**

1. **Patient Selection**

   A. Monovision Needs Assessment

      For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than [#] diopter) in one eye may not be a good candidate for monovision with the TN Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

(1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(2) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "sight eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patients's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.

Example:

A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

**3. Special Fitting Considerations**

**Unilateral Lens Correction**

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

**4. Near Add Determination**

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

**5. Trial Lens Fitting**

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room

at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions are completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. **Adaptation**

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. **Other Suggestions**

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.

- Having a third contact lens (near power) to use when critical near viewing is needed.

- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.

- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions.

- Reverse the distance and near eyes if a patient is having trouble adapting.

- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.

- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

* **The decision to fit a patient with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.**

* **All patients should be supplied with a copy of the [Insert name of the patient instructions for the specific lens].**

[For presbyopic lenses, manufacturers should modify the information above pertaining to "monovision" and include applicable information]

HANDLING OF TN CONTACT LENSES:

1. Lens Placement:

[This section may be needed only if there is a unique feature about the lens that requires special instructions]

2. Lens Removal:

[This section may be needed only if there is a unique feature about the lens that requires special instructions]

PATIENT LENS CARE DIRECTIONS:

[Include the information in the package insert under the heading entitled, LENS CARE DIRECTIONS, or reference the package insert if it is printed in the back of this guide]

[Add if Applicable] Lens Deposits and Use of Enzymatic Cleaning Procedure:

[Include the information in the package insert under the heading entitled, LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE, or reference the package insert if it is printed in the back of this guide]

[Add if Lens can be Heat Disinfected] Heat (Thermal) Disinfection:

[Include the information in the package insert under the heading entitled, Heat (Thermal) Disinfection, or reference the package insert if it is printed in the back of this guide]

[Optional] Emergency (Alternate) Method for Heat (Thermal) Disinfection:

[Include the information in the package insert under the heading entitled, Emergency (Alternate) Method for Heat (Thermal) Disinfection or reference the package insert if it is printed in the back of this guide]

[Add if Applicable] Chemical Lens Disinfection (Including Hydrogen Peroxide)

[Include the information in the package insert under the heading entitled, Chemical Lens Disinfection (Including Hydrogen Peroxide) or reference the package insert if it is printed in the back of this guide]

[Add for Soft (Hydrophilic) Lens] Care for a Dehydrated Lens:

[Include the information in the package insert under the heading entitled, Care for a Dehydrated Lens or reference the package insert if it is printed in the back of this guide]

Care for a Sticking [Nonmoving] Lens:

[Include the information in the package insert under the heading entitled, Care for a Sticking Lens or reference the package insert if it is printed in the back of this guide]

[OPTIONAL] VERTEX DISTANCE CONVERSION CHART FOR MINUS LENSES:

[Include chart]

[OPTIONAL] VERTEX DISTANCE CONVERSION CHART FOR PLUS LENSES:

[Include chart]

[OPTIONAL, INCLUDE IF APPLICABLE] KERATOMETRY CONVERSION CHART:

[Include chart]

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing TN Contact Lenses or experienced with the lenses should be reported to:

Manufacturer's Name
Manufacturer's Address
1-800 Telephone Number

HOW SUPPLIED:

[Include specific information on how the lens is packaged (e.g., sterile/non-sterile in glass vial, flat pack, foil package, etc.] The container is marked with the base curve, diopter power, diameter, center thickness [for rigid gas permeable lenses], color (if applicable), UV-absorber [note if present], [other], lot number and expiration date.

PACKAGE INSERT [IF INCLUDED]

[Include the package insert if information from the package insert is referenced and the package insert is printed in the back of this guide]

Print Date: Month/Year

LABELING--APPENDIX C

PATIENT INSTRUCTIONS
For TN (generic) [Soft (Hydrophilic)] [Rigid Gas Permeable] Contact Lenses

Key:

Multiple brackets ([] []) = Select appropriate information.
Brackets with number sign [#] = Fill in appropriate number.
Brackets containing instructions = Follow instructions. Add information if it applies to your lens.
Parentheses (fill in generic name) = Follow instructions.
Bold text as it appears in the example.

Example:

CAUTION: **Federal Law Prohibits Dispensing Without a Prescription (or use the most recent statement required by regulation)**

[The following warning is required, when applicable, to comply with the EPA Clean Air Act and the FDA regulation published in the Federal Register on June 29, 1993 (FR 58 34812)]: WARNING: Contains [or Manufactured with, if applicable] (insert name of substance), a substance which harms public health and environment by destroying ozone in the upper atmosphere.]

TABLE OF CONTENTS:

INTRODUCTION:

[Include introduction for specific lens. Include in this section a general description of the lens material. (Separate patient instructions are needed for disposable lenses. For a disposable lens, this section would be an appropriate place to explain that daily wear disposable lenses are single-use devices, and once removed, they are to be discarded. They are not intended to be cleaned and disinfected. Patients should always carry a spare pair of lenses with them.) Throughout the Patient Instructions, technical terms should be kept to a minimum and defined, when necessary. If possible, Patient Instructions should not exceed the seventh grade reading comprehension level.]

WEARING RESTRICTIONS AND INDICATIONS:

[Include any specific wearing restrictions for your specific lens]

The TN Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with nondiseased eyes. [If the lens is a bifocal or aspheric lens indicated for presbyopia, include correction of presbyopia.] The lens may be disinfected using [either a heat or chemical] a [heat/chemical] disinfection system [only].

The TN contact lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eyecare practitioner. [Note: First sentence in this paragraph is not applicable for daily wear disposable contact lenses, and should be modified as needed.] DO NOT WEAR YOUR TN DAILY WEAR CONTACT LENSES WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE):

[Include the information in the package insert under the heading entitled, CONTRAINDICATIONS (REASONS NOT TO USE), and use bold print wherever bold print appears in the package insert]

WARNINGS:

[Include the information in the package insert under the heading entitled, WARNINGS, rewrite all information in the second person, and use bold print wherever bold print appears in the package insert]

PRECAUTIONS:

[Add the following for rigid gas permeable contact lenses: CAUTION: Non-sterile. Clean and condition lenses prior to use]

[Precautions pertaining to lens care regimens should be deleted for daily wear disposable lenses]

[Include the information in the package insert under the heading entitled, PRECAUTIONS, that pertain to patient precautions, rewrite all information in the second person, and use bold print wherever it appears in the package insert]

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO):

[Include the information in the package insert under the heading entitled, ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO), rewrite all information in the second person, and use bold print wherever it appears in the package insert]

PERSONAL CLEANLINESS FOR LENS HANDLING:

1. **Preparing the Lens for Wearing:**

   It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

   - Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
   - Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
   - Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

   Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. **Handling the Lenses:**

   - Develop the habit of always working with the same lens first to avoid mixups.
   - Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.
   - [Include additional steps needed for specific lens]

3. **Placing the Lens on the Eye:**

   [Include applicable instructions in step-by-step format; graphics can be helpful]

   There are other methods of lens placement. If the above method is difficult for you, your eyecare practitioner will provide you with an alternate method.

   Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the Lens," next in this booklet).

- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:

  a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.

  b. The lens is on the wrong eye.

  c. [Include for soft (hydrophilic) contact lenses] The lens is inside-out (it would also not be as comfortable as normal).

  d. [Include other items, if appropriate]

  **If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eyecare practitioner.**

4. **Centering the Lens:**

**Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow one of the procedures below.**

[Include procedure applicable to specific lens; graphics can be helpful]

5. **Removing the Lens:**

Always remove the same lens first.

a. Wash, rinse, and dry your hands thoroughly.

b. [Include additional steps as needed for specific lens; graphics can be helpful]

c. Remove the other lens by following the same procedure.

d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING).

Note: If this method of removing your lens is difficult for you, your eyecare practitioner will provide you with an alternate method.

CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING):

[This section will need to be modified or deleted for daily wear disposable contact lenses because they are not intended to be cleaned and disinfected; they are to be discarded when removed. The labeling should instruct the patient to always have a spare pair of lenses with him or her at all times]

1. **Basic Instructions:**

**For continued safe and comfortable wearing of your lenses, it is important that you first clean and rinse, then disinfect [and neutralize (for hydrogen peroxide systems)] your lenses after each removal, using the care regimen recommended by your eyecare practitioner. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. Disinfecting is necessary to destroy harmful germs.**

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure you have to put the lenses on and remove them while you are in your eyecare practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Patient Instructions for the TN Contact Lens.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.
- Use the recommended system of lens care, either heat (thermal) or chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

[Include next item if applicable]

- Disposable and lenses prescribed in a frequent replacement program should be thrown away after the recommended wearing period prescribed by your eyecare practitioner.

[Include next item for soft (hydrophilic) contact lenses]

- Never rinse your lenses in water from the tap. There are two reasons for this:

  a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.

  b. You might lose the lens down the drain.

- [Option 1] Your eyecare practitioner should recommend a care system that is appropriate for your TN Contact Lens. Each lens care product contains specific directions for use and important safety information, which you should read and carefully follow.]

  [Option 2] The lens care products listed below are recommended by [manufacturer] for use with your TN Contact Lens. Your eyecare practitioner may recommend alternate products that are appropriate for you to use with your TN Contact Lens.

Lens Care Table

| Product Purpose | Lens Care System | |
|---|---|---|
| | Heat (Thermal) | Chemical (Not Heat) |
| Clean | | |
| Rinse | | |
| Disinfect | | |
| Store | | |
| Enzyme | | |
| Lubricate/Rewet | | |

*---------- is a trade mark of [Manufacturer]

---------,--------, and -------, are trade marks of [Manufacturers]
*Select as appropriate.

- Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

- Clean one lens first (always the same lens first to avoid mixups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, disinfect lenses using the system recommended by your eyecare practitioner and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.

- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the package insert or your eyecare practitioner for information on storage of your lenses.

  [Include the next two items for rigid gas permeable lenses and when appropriate]

- Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eyecare practitioner for a recommendation on how to store your lenses.

- TN Contact Lenses <u>cannot</u> be heat (thermally) disinfected.

- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution. Replace lens case at regular intervals.

- Your eyecare practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

- [Include other information as appropriate]

2. Care for a Sticking [Nonmoving] Lens:

   [Include the information in the package insert under the heading entitled, CARE FOR A STICKING [NONMOVING] LENS, and rewrite all information in the second person]

3. [Include if Applicable and Lens can be Heat Disinfected] Heat (Thermal) Lens Disinfection:

[This section is not applicable for daily wear disposable lenses]

[Include the information in the package insert under the heading entitled, Heat (Thermal) Lens Disinfection, and rewrite all information in the second person]

4. [Optional] Emergency (Alternate) Method for Heat (Thermal) Disinfection:

[This section is not applicable for daily wear disposable lenses]

[Include the information in the package insert under the heading entitled, Emergency (Alternate) Method for Heat (Thermal) Disinfection, and rewrite all information in the second person]

5. [Add if Applicable and Lens can be Chemically Disinfected] Chemical (Not Heat) Disinfection:

[This section not applicable for daily wear disposable lenses]

[Include the information in the package insert under the heading entitled, Chemical (Not Heat) Disinfection, and rewrite all information in the second person]

6. [Add if Enzyme Cleaning is Recommended] Lens Deposits and Use of Enzymatic Cleaning Procedure:

[This section is not applicable for daily wear disposable lenses]

[Include the information in the package insert under the heading entitled, LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE, and rewrite all information in the second person]

7. Lens Case Cleaning and Maintenance:

[Include the information in the package insert under the heading entitled, LENS CASE CLEANING AND MAINTENANCE, and rewrite all information in the second person]

8. [Add for Soft (Hydrophilic) Contact Lens or When Applicable] Care for a Dehydrated Lens:

[This section is not applicable for daily wear disposable lenses]

[Include for soft (hydrophilic) contact lenses] If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply sterile saline before handling.

To rehydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least 1 hour until it returns to a soft state.
- Clean lens first, then disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, if the surface remains dry, DO NOT USE THE LENS UNLESS IT HAS BEEN EXAMINED BY YOUR EYECARE PRACTITIONER.

9. **Emergencies:**

**[Add the information included in the package insert under the heading entitled, EMERGENCIES, and rewrite all information in the second person]**

**[INCLUDE IF APPLICABLE] INSTRUCTIONS FOR THE MONOVISION WEARER:**

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

  If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.

- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.

- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.

* **The decision to be fit with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with you, after carefully considering and discussing your needs.**

[For presbyopic lenses, manufacturers should review the above information pertaining to "monovision" and include applicable information]

WEARING AND APPOINTMENT SCHEDULES:

Prescribed Wearing Schedule

| Day | Wearing Time (Hours) |
|---|---|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |
| 6 | |
| 7 | |
| 8 | |
| 9 | |
| 10 | |
| 11 | |
| 12 | |
| 13 | |
| 14 | |

Appointment Schedule

| Your appointments are on | | | Minimum number of hours lenses to be worn at time of appointment |
|---|---|---|---|
| Month | Year | Time | Day |
| | | | |
| | | | |
| | | | |

PATIENT/EYECARE PRACTITIONER INFORMATION:

[Include spaces to record such information as name, address, and telephone number of eyecare practitioner, specific care regimen recommended, and any other convenient and helpful patient/eyecare practitioner information that needs to be readily available]

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYECARE PRACTITIONER IMMEDIATELY.

NAME AND ADDRESS OF MANUFACTURER:

Manufacturer's Name
Address

PRINT DATE:

Month/year

LABELING--APPENDIX D

CONTAINER LABEL

TN (generic name) [Soft (hydrophilic)] [Rigid Gas Permeable] Contact Lens for Daily Wear

CONTENTS: One [sterile] contact lens [immersed in (composition of solution)]

[Add for RGP lenses: CAUTION: Non-sterile. Clean and condition lenses prior to use]

Base Curve:
Diameter:
Power:
Color, if applicable (e.g., blue, green, etc.):
UV Absorber [note if present]:
Center Thickness [for rigid gas permeable lenses]:
Water Content [for hydrophilic lenses]:

[Add parameters applicable to specific configurations; e.g., bifocal, toric, etc.]

Lot:
Expiration Date:

CAUTION: Federal law prohibits dispensing without a prescription (or use the most recent statement required by regulation).

Company Name and Address:

LABELING--APPENDIX E

DRAFT: September 16, 1987

**Labeling Suggestions for Ultraviolet Light (UV)**

**Absorbing Contact Lenses**

The minimum criteria for labeling of UV-absorbing contact lenses are as follows:

1. Spectral Transmittance Curves:

   a. A graph of the spectral transmittance curve for the UV-absorbing contact lens should be included in the "Description" section of the labeling (e.g. package insert) for the device. In addition, the spectral transmittance graph should include the transmittance curves for the human cornea from a 24-year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21, and human crystalline lens from a 25-year old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

   b. The spectral transmittance curve for the UV-absorbing contact lens should be obtained from measurements taken through the central 3-5 mm portion of the thinnest version of the UV lens to be marketed.

   c. The wavelength range of the spectral transmittance curve for the UV-absorbing contact lens should include the 250 nm to 760 nm range and be recorded continuously or at no more than 5 nm increments.

2. Descriptive Statements in the Labeling

   a. The "Description" section of the labeling should accurately describe the UV-absorbing lens to include, but not be limited to, a statement that the lens contains a UV-absorbing compound (e.g., as an additive or as a monomer) and statements describing the transmittance characteristics of the UV-absorbing lens.

   b. The labeling of the spectral transmittance curve for the UV-absorbing contact lens being displayed should accurately describe the lens and should include the center thickness and power of the lens as well as a statement in the legend that this curve represents the transmittance characteristics of the thinnest version of the UV-absorbing contact lens to be marketed.

Appropriate labeling for the transmittance curves of the human cornea and crystalline lens should also be included along with an appropriate reference to the publications from which the data were taken.

c. A bolded or highlighted statement should be included in the labeling to state, "**NOTE: The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV-light has not been established at this time.**"

d. A bolded or highlighted statement should be included in the labeling to state, "**WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.**"

# PROCEDURE FOR ADDING LENS FINISHING LABORATORIES FOR MANUFACTURING AND MARKETING OF CLASS II RIGID GAS PERMEABLE (RGP) CONTACT LENSES

## Introduction:

CDRH has developed a procedure to allow a lens manufacturer with a previously approved PMA/PMA supplement or an SE 510(k) for a class II finished RGP contact lens (hereafter referred to as the manufacturer), to provide for the manufacturing and marketing of the finished lens by independent contact lens finishing laboratories (hereafter referred to as the finishing laboratory). This procedure requires that the finishing laboratory use the same material and designs, the same indications for use, and the same labeling as previously approved in the PMA/PMA supplement or the SE 510(k). The use of this procedure eliminates the need for submission and clearance of a new 510(k) for each RGP contact lens finishing laboratory being authorized to manufacture and market the finished RGP contact lens covered by an RGP lens manufacturer's approved PMA/PMA supplement or SE 510(k).

**NOTE: THIS PROCEDURE SUPERSEDES THE MAY 9, 1985, POLICY ENTITLED "NEW PROCEDURES FOR ADDING LENS FINISHING LABORATORIES THROUGH SUPPLEMENTS TO APPROVED PREMARKET APPROVAL APPLICATIONS FOR RIGID GAS PERMEABLE CONTACT LENSES." PLEASE NOTE THAT THIS PROCEDURE APPLIES TO A CLASS II RGP CONTACT LENS; IT DOES NOT APPLY TO A CLASS II HYDROPHILIC CONTACT LENS.**

## Objectives:

Manufacturer's Objective: To obtain a one-time clearance for an acceptable procedure to allow one or more independent finishing laboratories to manufacture and market finished RGP contact lenses made from a lens blank supplied by a manufacturer with a previously approved PMA/PMA supplement or SE 510(k).

CDRH's Objectives: To ensure that the class II RGP finished contact lenses manufactured and marketed by finishing laboratories will conform to the specifications of the approved PMA/PMA supplement or SE 510(k)s; to ensure safe and effective RGP contact lenses; and to ensure that finishing laboratories will comply with all applicable class II special controls for contact lenses.

## Responsibilities:

CDRH considers the finishing of an RGP contact lens by independent finishing laboratories to be an extension of the manufacturing process for an RGP contact lens. The manufacturer of the RGP contact lens is ultimately responsible for assuring that each finishing laboratory produces lenses that are essentially identical to the manufacturer's lens. In addition, the manufacturer is ultimately responsible for assuring that all quality assurance activities necessary to determine that a finished RGP contact lens meets specifications are appropriate, adequate, and correctly performed. The independent finishing laboratory is responsible for complying with those parts of the GMP for Medical Devices regulation which apply to the manufacturing operations he or she performs for the RGP contact lens manufacturer.

Requirements:

I. Implementation:

This procedure, to provide for the manufacturing and marketing of the finished lens by independent contact lens finishing laboratories, may be implemented by the RGP lens manufacturer after following the instructions below. In all cases, a sworn certification is required to be completed, signed, and dated by a responsible official of the company stating that the manufacturer will comply with all requirements set forth in this revised procedure; and will assume responsibility for ensuring the quality and traceability of the finished RGP lens to the lot or batch of material as identified by the manufacturer.

A. A manufacturer of a daily wear plastic RGP contact lens, who has a previously approved PMA/PMA supplement meeting all requirements set for in the May 9, 1985, policy entitled "New Procedures for Adding Lens Finishing Laboratories Through Supplements to Approved Premarket Approval Applications for Rigid Gas Permeable Contact Lenses," is not required to submit a 510(k). However, this procedure supersedes the May 9, 1985 policy. Therefore, the manufacturer is required to retain the following at his or her premises in the device master record and make it available to FDA upon request:

1. a completed sworn certification, as discussed above; and

2. all the documentation and information as outlined in Section II of this procedure.

B. A manufacturer who has an approved PMA/PMA supplement or an SE 510(k) for a daily wear RGP lens but has not received specific clearance from CDRH for adding finishing laboratories, should submit a 510(k) and obtain clearance. The 510(k) should contain the following:

1. either the necessary documentation and information as outlined in Section II of this procedure or authorization to reference an approved PMA/PMA supplement or SE 510(k) containing this information; and

2. a sworn certification, as discussed above.

C. A manufacturer, who has not received previous clearance for a daily wear plastic RGP contact lens and intends to implement this procedure providing for the manufacturing and marketing of the finished lens by independent contact lens finishing laboratories, should submit and obtain clearance for a complete 510(k) for an RGP contact lens as specified in the "PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES." The 510(k) should include the following:

1. either the necessary documentation and information as outlined in Section II of this procedure or authorization to reference an approved PMA/PMA supplement or SE 510(k) containing this information; and

2. a sworn certification, as discussed above.

NOTE: A LENS MANUFACTURER OF A DAILY WEAR PLASTIC RGP CONTACT LENS WHO CHOOSES TO DEVIATE FROM ANY PART OF THIS PROCEDURE SHOULD FIRST SUBMIT A NEW 510(K) AND RECEIVE AN SE DETERMINATION FROM CDRH.

II. Documentation:

A lens manufacturer with an approved PMA/PMA supplement or an SE 510(k) for a class II RGP contact lens should comply with the following:

A. The manufacturer should provide pertinent written information to each class II RGP contact lens finishing laboratory. This information should include, but is not limited to, the following:

1. complete range of specifications for the finished contact lens, and detailed process instructions for any manufacturing steps that require processing in a manner that is in any way unique to the material from which the lens is to be manufactured;

2. complete and accurate copies of all the labeling for distribution with the lens, which includes the cautionary statement, "Caution: Non-sterile. Clean and condition lenses prior to use," as accepted by CDRH in the PMA or 510(k); and

3. a detailed description of the following key quality assurance activities that CDRH requires the lens finishing laboratories to perform:

a. incoming material inspections;

b. acceptance/rejection criteria at each manufacturing step;

c. identity and specifications for each processing compound, such as sealing waxes and polishing compounds;

d. cleaning instructions and specifications for cleaning compounds;

e. final product acceptance criteria and test methods;

f. identity and specification for packaging and labeling materials;

g. microbiological requirements for finishing laboratories as outlined in the "MICROBIOLOGY" section of the "PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES" entitled "Microbiological Requirements for Hydrophobic Contact Lenses;"

h. maintenance of records, including device history records sufficient to ensure the traceability of any lens to the lot or batch of material, as identified by the material supplier, from which the lens was manufactured, and complete complaint files; and

i. continuing written audit procedures to be employed by an appropriately trained individual of the lens finishing laboratory in accordance with the definition in the current GMP regulation (21 CFR 820.3(b)) which states:

> "Audit" means a documented activity performed in accordance with written procedures on a periodic basis to verify, by examination and evaluation of objective evidence, compliance with those elements of the quality assurance program under review."

B. The manufacturer should have a written protocol by which he or she will evaluate the class II RGP contact lens finishing laboratories. The manufacturer should maintain the documentation for each contact lens finishing laboratory at his or her premises in the device master record, specifically identified. All documentation should be readily accessible and available to FDA upon request. All required evaluation, as specified below, should be completed prior to manufacturing and marketing by the finishing laboratory. The protocol should include the following:

1. Either an on-site inspection or a questionnaire to be completed by an appropriately trained individual of the laboratory and reviewed by the manufacturer.

2. If the finishing laboratory did not participate in the clinical testing of the lens that is the subject of the manufacturer's application, the finishing laboratory should prepare at least 10 lenses from at least 10 prescriptions provided by the lens manufacturer. A responsible official of the manufacturer will inspect the lenses to determine whether they meet the final product criteria of the lenses in the approved PMA/PMA supplement or SE 510(k).

3. Procedures whereby the manufacturer will verify that each lens finishing laboratory is in compliance with the lens manufacturer's standard operating procedures and FDA's current GMP Medical Device regulation; and that finished lenses sampled in accordance with the inspection sampling plan comply with the manufacturer's submitted lens specifications with respect to, but not limited to, design, labeled dimensions, powers, surface finish, edge finish, and microbiological requirements.

C. The manufacturer should have a written monitoring plan, for continued surveillance by the lens manufacturer over each finishing laboratory, to monitor audit procedures and ensure continued conformance of a finished lens to the specifications identified in the approved PMA/PMA supplement or SE 510(k).

D. The manufacturer should have a written plan for an adverse reaction reporting system to be established and maintained by the manufacturer, encompassing all cleared finishing laboratories and meeting all provisions of the Medical Device Reporting (MDR) regulation (21 CFR 803). The lens finishing laboratories should report all adverse reactions to the manufacturer within 10 days of becoming aware of such reactions.

E. The manufacturer should have two written suitably worded sworn declarations for each class II RGP contact lens finishing laboratory, which should be completed and signed prior to manufacturing and marketing by the finishing laboratory.

1. One declaration, to be completed and signed by a responsible official from each lens finishing laboratory, will state that, once the finishing laboratory begins to manufacture the lens, the finishing laboratory will comply with:

   a. the manufacturer's manufacturing process;
   b. all requirements of the Federal Food, Drug, and Cosmetic Act;
   c. the approved PMA or SE 510(k); and
   d. this procedure.

2. A second declaration, to be completed and signed by a responsible official of the manufacturer, will verify that the lens finishing laboratory has been evaluated in accordance with, and found to conform to, all provisions of the protocol described in Section II B above.

F. The manufacturer must maintain a list of the following information for each lens finishing laboratory that has been found by the manufacturer to have met all evaluation criteria and that have signed the declaration described above in Section II E 1 above:

1. name;
2. address;
3. name and title of the person at each finishing laboratory responsible for compliance with this procedure;
4. private label brand name, if applicable;
5. the date on which the addition of each class II RGP contact lens finishing laboratory was implemented; and
6. any changes in the above items.

THE MANUFACTURER MUST MAINTAIN ALL DOCUMENTATION AT HIS OR HER PREMISES IN THE DEVICE MASTER RECORD AND MAKE IT AVAILABLE TO FDA UPON REQUEST.

# COLOR ADDITIVES AND CONTACT LENSES

## Introduction:

FDA's responsibility for regulating color additives used in or on devices; (e.g., contact lenses) began on May 28, 1976, when the Medical Device Amendments became law. The Amendments clarified the coverage of the color additive provisions of the act, so that a color additive used in or on a device which comes in direct contact with the human body for a significant period of time is subject to regulation under section 721 of the act. Section 721(a) provides that such color additives shall be deemed unsafe unless the use is "listed" through issuance of a regulation under section 721(b).

CDRH believes that a contact lens that contains a color additive subject to section 721 of the act cannot be found SE in a 510(k) until the color additive listing has become effective. **If a 510(k) is submitted prior to the listing becoming effective, CDRH will refuse to accept the submission.** Listing of a color additive is accomplished by submitting a color additive petition (CAP) to the FDA's Center for Food Safety and Applied Nutrition (CFSAN) (refer to 21 CFR 71). Details for submission of a CAP are discussed in item I below. Item II contains guidance for use of listed colors in class II contact lenses.

## I. Color Additive Petition:

Generally, listing is a one-time occurrence for each color additive proposed for contact lens use. Once listed, the color additive may be used by any contact lens manufacturer for coloring any contact lens without additional listing requirements provided the manufacturer complies with the provisions of the regulation.

The guidance in this section entitled, "CHEMISTRY GUIDANCE FOR LISTING COLOR ADDITIVES IN CONTACT LENSES," was prepared by CFSAN and describes the information and data that should be provided in a CAP. A CAP should be submitted to:

Division of Petition Control (HFS-215)
Office of Premarket Approval
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

For additional information on requirements for submitting a CAP, please contact the Indirect Additives Branch at (202) 254-9511.

The listing process generally evaluates only the safety of a color additive in the quantities that may conceivably be used in contact lenses. Consequently, the 510(k) process will concern itself with the effect of the "listed" color additive on the safety and effectiveness of each lens material with an incorporated "listed" color additive. Therefore, a manufacturer is required to submit a 510(k) the first time he or she proposes to incorporate a "listed" color additive in a clear lens material in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect. The manufacturer's 510(k) submission should be complete as specified in the "PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES."

CHEMISTRY GUIDANCE FOR LISTING COLOR ADDITIVES IN CONTACT LENSES

The following information is requested of petitioners seeking clearance for color additives used in contact lenses. This guidance addresses only the issue of the color additive. Requirements for clearance of the colored lens material are discussed in Item II of this procedure and in the "MANUFACTURING/CHEMISTRY" section of the "PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES."

A. Identity, Composition, Properties, Specifications of Color Additive:

1. Chemical Name: Chemical names should conform where possible to the nomenclature adopted by Chemical Abstracts, or, if already regulated by FDA for other uses, the name used in current regulations. The Chemical Abstracts Registry number should be submitted for each color additive, if available. For assistance, contact Director of Nomenclature, Chemical Abstracts Service, P.O. Box 3012, Columbus, Ohio, 43210 or telephone (1-800) 848-6533.

2. Common and Trade Name: Common and/or trade names should not be the only means of identification of color additive materials. However, reference to common names should be included. If the color additive is listed in The Colour Index, the identifying number should be included. If a user is unsure of the identity of the color additive, he or she should contact the manufacturer as to the name and identity of the material he or she furnishes. If necessary, the manufacturer should be asked to provide to FDA identity information for proprietary substances.

3. Structural Information: The molecular formula, molecular weight and chemical structure should be presented for each color additive.

4. Method of Manufacture and Chemical Composition: Color additives conforming to the identity and specifications for a regulated color additive may simply be referenced to that regulation. Otherwise, the manufacture of the color additive should be outlined as follows:

   a. List of all substances employed in the synthesis and the amounts of concentrations of each employed.

   b. Equations for principal reactions as well as known or likely side reactions.

   c. Range of purity of color additive and means of determination.

   d. Identity and level of impurities and side products in color additive as determined by analysis or calculation.

5. Properties of Color Additive: Information should be provided on the chemical, physical and/or spectral properties of the color additive that will serve to identify and characterize the additive and differentiate it from other color additives. Information that may be of use could include, but is not restricted to, melting points, refractive index, solubilities, spectral curves, saponification values, acid values, etc. If specifications are proposed for the color additive, then analytical methods used to determine the specifications and validation data supporting their accuracy, precision, and specificity should be provided.

B. Amount of Color Additive Proposed for Use:

1. Typical as well as maximum likely use levels of the color additive in the lens should be reported.

2. The maximum weight of a typical lens should be estimated.

3. The typical and maximum weight of color additive for the lens should be estimated from (1) and (2).

C. Estimation of Color Additive Exposure:

In general, exposure to color additives may be estimated using the results of extraction studies conducted with the colored device. For contact lenses, however, a preliminary estimate of exposure should be based upon the worst case assumption that all of the available color additive will be extracted from the lenses in the course of 1 year. Estimates of worst case daily exposure should be calculated by dividing the maximum total weight of color additive per pair of lenses by 365 days.

Should extraction studies be recommended by FDA because this worst case estimate of color additive exposure is not supported by the available toxicity data, then the petitioner will need to determine the actual rate of color additive extraction. The tests should be conducted in such a manner that the limit of measure for color additive migration would permit estimates of color additive exposure which are significantly less than the estimate based upon complete extraction of color additive over the course of 1 year. The ability to develop lower estimates will be influenced by the sensitivity of the analytical method, the amount of resin extracted and the duration of the extraction experiment.

The extraction tests should be conducted at 37°C with a solvent that would simulate human tears and yet would permit sensitive analytical measurements. A period of at least 2 weeks is the recommended duration for such extraction experiments. At least three determinations of the amount of color additive extracted or the limit of measurement should be made. The method of color additive quantitation should be thoroughly described. The analytical findings should be validated by spiking the extracts with an equivalent amount of color additive and demonstrating adequate recoveries. A standard curve useful for determining such levels of color additive should be provided along with the raw data and sample chromatograms, etc. for all analyses. In the event that no color additive is detected, the petitioner should spike the extracts at the claimed limit of measurement and report data to show that a measurable signal above background results.

ADDENDUM

CHEMISTRY GUIDANCE FOR LISTING COLOR ADDITIVES IN CONTACT LENSES

A. Permanently listed color additives approved for eye area use in cosmetics will be approved for use as lens colors with no further testing required.

B. (1) Permanently listed color additives not approved for eye area use and (2) other color additives intended as colors in contact lenses will be evaluated on a case-by-case basis. Testing requirements will be dependent on the exposure levels and the degree of concern for potential toxicity of the color additive and its contaminants. Chemistry and available toxicology information will be considered in the determination.

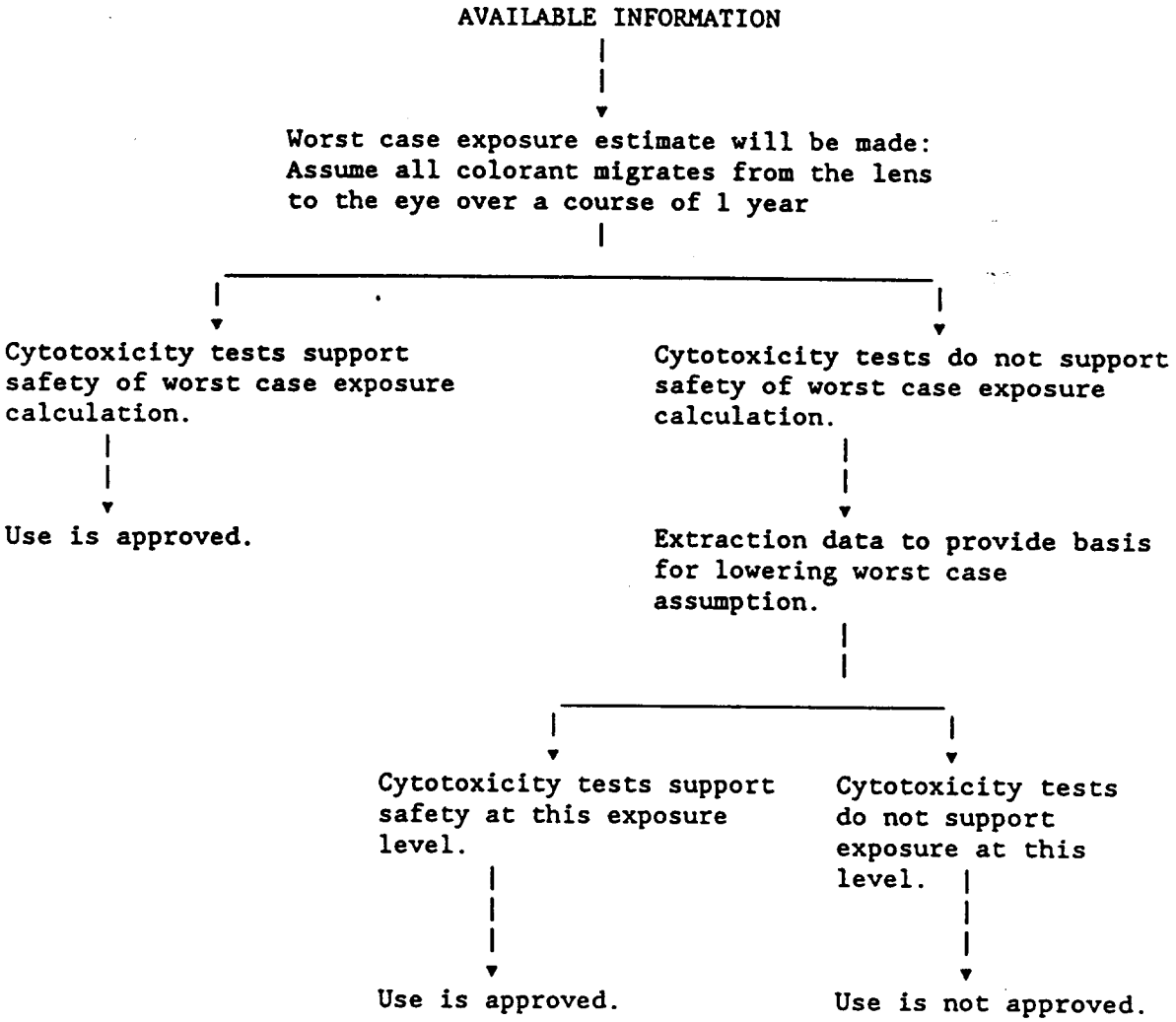
C. A color additive which has been demonstrated to be a carcinogen will not be approved.

D. Carcinogenic contaminants (1) in color additives which have been found to be negative in a carcinogenicity bioassay or (2) in color additives which have not been tested in a bioassay, will be subject to risk assessment. If the lifetime risk of cancer, based on a worst-case exposure estimate, is considered to be sufficiently low, use of the color additive may be approved.

E. The in vivo Three Week Ocular Irritation Test in Rabbits and the Guinea Pig Sensitization Test, as described in the "TOXICOLOGY" section, should be conducted with both colored and uncolored lenses.

F. A cytotoxicity test on the color additive (neat) and on extracts* of colored and uncolored lenses should be performed. This test should allow direct exposure of the cells to the tested color additive or lens extract to provide dose response information; the agar overlay test is, therefore, not recommended for this purpose. A 28-day repeated instillation ocular irritation test can be substituted for a cytotoxicity test.

*Extracts of the lens material are prepared in two types of solvents (polar and non-polar).




Note: A 28-day repeated instillation ocular irritation test with the neat dye and the lens extracts can be substituted for cytotoxicity tests.

II. Procedure for Incorporating "Listed" Color Additives in Contact Lenses:

A. Introduction:

CDRH has developed a procedure to allow a manufacturer, with a previously approved PMA/PMA supplement or an SE 510(k) for a daily wear plastic contact lens containing a "listed" color additive, to incorporate other "listed" color additives singularly or in combination to the lens material. The color additive proposed for use must be listed as safe for use in contact lenses in accordance with section 721 of the act, as amended (July 1993). The use of this procedure eliminates the need for submission and clearance of a new 510(k) for each colored lens, provided the manufacturer does not deviate from any part of this procedure and the requirements set forth in this procedure are met.

NOTE: This procedure applies only to incorporating the "listed" color additive in lenses having marketing clearance; it does not apply to any other manufacturing process change.

B. Objectives:

1. Manufacturer's Objective: To obtain clearance for an acceptable procedure to allow the use of additional "listed" color additives in a colored daily wear plastic contact lens.

2. CDRH's Objective: To ensure that the finished daily wear plastic contact lens containing "listed" color additives will meet the specifications of a previously approved PMA/PMA supplement or an SE 510(k).

C. Requirements:

1. Implementation:

This procedure, to incorporate other "listed" color additives singularly or in combination to the lens material, may be implemented after following the instructions below. A sworn certification is required and is to be completed, signed, and dated by a responsible official of the company, stating that the manufacturer will comply with all of the testing and documentation requirements set forth in this procedure and assume responsibility for ensuring the quality of the finished lenses.

* Note: The word "certification" applies to documentation in the 510(k), and should not be confused with "batch certification" as required by the color additive listing provisions.

a. The manufacturer, who has an approved PMA/PMA supplement or an SE 510(k) containing the manufacturing process by which a "listed" color additive was incorporated in the daily wear plastic contact lens material, should retain the following information at his or her premises in the device master record and make it available to FDA upon request:

(1) a sworn certification, as discussed above; and

(2) all documentation and information as outlined in Requirements, Item 2, of this procedure.

b. The manufacturer, who has an approved PMA/PMA supplement or an SE 510(k) for a clear version of a daily wear plastic contact lens and intends to incorporate a "listed" color additive in the lens material, should submit and obtain clearance for a 510(k) meeting all requirements as specified in the "PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES." The 510(k) should include a sworn certification, as discussed above.

c. The manufacturer, who does not have clearance for a daily wear plastic contact lens and intends to incorporate a "listed" color additive in the lens material, should submit and obtain clearance for a complete 510(k), as specified in the "PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES." The 510(k) should include a sworn certification, as discussed above.

NOTE: A LENS MANUFACTURER OF A DAILY WEAR PLASTIC CONTACT LENS WHO CHOOSES TO DEVIATE FROM ANY PART OF THIS PROCEDURE SHOULD FIRST SUBMIT A NEW 510(K) AND RECEIVE AN SE DETERMINATION FROM CDRH.

2. Documentation:

a. The manufacturer of a class II contact lens should document the changes of the "listed" color additives incorporated in the contact lens material, which were not previously included in the approved PMA/PMA supplement or SE 510(k). The manufacturer should maintain the documentation listed in items 2b (1)-(7) at his or her premises in the device master record, specifically identified. All documentation should be readily accessible and made available to FDA upon request. All required testing, as specified below, should be completed prior to marketing new colored contact lenses.

b. Documentation should include the following information:

(1) name and amount of the "listed" color additive or additives incorporated in the contact lens material not to exceed the minimum reasonably required to accomplish the intended coloring effect;

(2) date of incorporation of different color additive(s);

(3) verification that the manufacturing process (e.g., reactive or entrapment) by which the "listed" color additive is to be incorporated in the lens material is significantly unchanged (i.e., no change that would require submission of a new 510(k)) from the manufacturing process previously included in the approved PMA/PMA supplement or SE 510(k);

(4) measured visible light transmittance of the lens which should be 70% or greater in the visible range (380 - 780 nm);

(5) results from testing which demonstrate that the finished contact lens with "listed" color additives incorporated remains within original specifications;

(6) results from testing which demonstrate the parameters of the new colored contact lens will remain stable under the proposed storage conditions for the proposed expiration date (The establishment of an expiration date should be based on newly derived stability data developed in accordance with procedures established in the manufacturer's approved PMA/PMA supplement or SE 510(k), or in a new 510(k) in which the protocol has been cleared by CDRH); and

(7) labeling identical to that which was previously included in the approved PMA/PMA supplement or SE 510(k), and the revisions to correct those statements in the labeling that are no longer accurate (e.g., color additive names, lens parameters, and expiration date) as a result of making changes allowed by this procedure.

# PROCEDURE FOR IMPLEMENTING CHANGES IN PACKAGING MATERIALS

## Introduction:

CDRH has developed a procedure to allow a manufacturer with a previously approved PMA or an SE 510(k) for a daily wear plastic contact lens utilizing a specific packaging solution and packaging material, to make changes in those materials or solutions used in the final packaging of the lens. Although the 510(k) process allows a manufacturer to make insignificant changes without submitting a 510(k), changes in packaging, such as in the materials or solutions, could affect sterility and/or stability of the lens which could significantly affect the safety and effectiveness of the lens. The use of this procedure eliminates the need for submission and clearance of a new 510(k) for a change in packaging materials, provided the manufacturer does not deviate from any part of this procedure and the requirements set forth in this procedure are met.

## Objectives:

Manufacturer's Objective: To obtain clearance for an acceptable procedure to allow changes in materials or solutions used in the final packaging of the daily wear plastic lens by the holder of a previously approved PMA/PMA supplement or an SE 510(k).

CDRH's Objectives: To ensure compatibility of the contact lens with the lens storage solution, container, closure or other plastic components that are the subject of the change and that may come into direct contact with the contact lens; and to ensure that the changes in the packaging materials have not compromised the sterility or stability of the contact lens for the labeled expiration date.

CDRH believes that these objectives can be met by a manufacturer with an approved PMA or an SE 510(k) for any class II contact lens when he or she follows the requirements in this procedure. Therefore, a manufacturer with an approved PMA or an SE 510(k) for a class II contact lens may make changes in the contact lens packaging materials without prior CDRH clearance, provided all the requirements set forth in this procedure are met. This procedure applies to changes such as those listed below:

(1) types of buffers utilized in lens packaging solutions or addition of buffers to saline solutions (e.g., borate to phosphate buffer);

(2) closure materials for lens containers (e.g., S2000 silicone to X9711 silicone stopper);

(3) lens package container (e.g., glass to plastic); and

(4) labeling changes necessary to make the device labeling correspond to the new packaging and expiration dating. Note: This procedure does not apply to implementation of any other labeling change significantly affecting safety or effectiveness.

Requirements:

I. Implementation:

This procedure, to make changes in materials or solutions used in the final packaging of the lens, may be implemented after following the instructions below. A sworn certification is required and is to be completed, signed, and dated by a responsible official of the company, stating that the manufacturer: will comply with all testing and documentation requirements set forth in this procedure; will assume responsibility for ensuring the compatibility of the contact lens material with the storage solution, container, closure or other plastic components; and will assure that the changes in packaging will not compromise the sterility or stability of the finished class II contact lens.

A. The manufacturer, who has an approved PMA or an SE 510(k) for a daily wear plastic contact lens utilizing a specific packaging solution and packaging material, should retain the following information at his or her premises in the device master record and make it available to FDA upon request:

1. a sworn certification, as discussed above; and

2. all documentation and information as outlined in item II of this procedure.

B. The manufacturer, who has not received clearance for a daily wear plastic contact lens, should submit a complete 510(k) as specified in the "PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES." In addition, the 510(k) should include a sworn certification, as discussed above.

NOTE: A LENS MANUFACTURER OF A DAILY WEAR PLASTIC CONTACT LENS WHO CHOOSES TO DEVIATE FROM ANY PART OF THIS PROCEDURE SHOULD FIRST SUBMIT A NEW 510(K) AND RECEIVE AN SE DETERMINATION FROM CDRH BEFORE IMPLEMENTING THE CHANGE.

II. Documentation:

A. The manufacturer for a class II daily wear plastic contact lens should document the nature of all changes in contact lens packaging materials or solutions not previously submitted in the approved PMA or 510(k). The manufacturer should maintain the documentation listed in item B. 1-5 at his or her premises in the device master record, specifically identified. All documentation should be readily accessible and made available to FDA upon request. All required testing, as specified below, should be complete and should demonstrate fulfillment of the specifications in the approved PMA or SE 510(k) prior to marketing the device in the modified packaging.

B. Documentation should include the following information:

1. The lens containers, closures, or other components that are the subject of the change should be fully described as to their chemical composition, physical form, and source of supply. If a glass container is used, the type of glass should be stated in accordance with current USP classification. If a buffer has been added to the contact lens packaging solution or has been changed, the buffer should be described chemically in accordance with the current established nomenclature. The final specifications, including qualitative and quantitative formulas, for the packaging solution should be documented.

2. If a plastic container, other plastic component or closure (e.g., silicone elastomer) comes in direct contact with the lens or lens packaging solution, compatibility testing of the new plastic container, closure and other plastic components should be demonstrated by meeting the requirements of the most recent published version of the USP, as described in the section entitled, "Containers for Ophthalmics--Plastics (Biological Test Procedures)."

   Note: If any plastic container, component, or closure does not meet the USP requirements, a manufacturer should submit a new 510(k) with a justification for proposing the packaging change that does not meet USP requirements; and receive an SE determination from CDRH before using the new plastic in packaging.

3. Results from testing which demonstrate the sterility and stability parameters of the finished contact lens when packaged in the new lens packaging materials and stored under the proposed storage conditions for the proposed expiration date should be documented. The establishment of an expiration date should be based on newly derived sterility and stability data developed in accordance with procedures previously established in the manufacturer's approved PMA, SE 510(k), or in a new 510(k) in which the protocol has been cleared by CDRH.

4. The date on which the changes in contact lens packaging materials were implemented and all test data and information supporting the changes should be documented.

5. The revisions to correct those statements (including the expiration date) or diagrams in the labeling that are no longer accurately descriptive of the product or product line as a result of making changes allowed by this procedure should be documented.

End of Guidance