Table 6B Notes:

TITLE: Refractive Changes (Absolute Value) from Baseline to Final Visit

PURPOSE: To provide changes in refractive data in a concise format.

GENERAL:

Separate tables should be prepared and clearly identified for:

Completed Control Eyes (Table 6B1)
Completed Trial Eyes (Table 6B2)
Discontinued Control Eyes (Table 6B3)
Discontinued Trial Eyes (Table 6B4)

Number and percentage in the first section of Table 6B refer to the number of eyes in the diopter of change column for the corresponding row. Percentage should be calculated in accordance with the following formula:

$$\% \text{ at each diopter of change} = \frac{\text{\# of eyes at each diopter of change}}{\text{\# of total eyes}} \times 100$$

For each change that is greater than 1.00 diopter, the second section of Table 6B should be completed.

TABLE 6(B)
REFRACTIVE CHANGES (ABSOLUTE VALUE) FROM BASELINE
TO FINAL VISIT

Diopters	Total Eyes #	%
0.00 to 1.00		
1.12 to 1.50		
1.62 to 2.00		
(Continue as Needed)		

Mean Refractive Change _____ D.
Minimum Refractive Change _____ D.
Maximum Refractive Change _____ D.

LISTING OF REFRACTIVE CHANGES (ABSOLUTE VALUE) FROM BASELINE TO FINAL VISIT
FOR EYES THAT CHANGED MORE THAN 1 DIOPTER

Investigator	Patient	Eye	Baseline	Final Visit	Absolute Change	Reason
1.						
2.						
3.						

Table 7 Notes:

TITLE: Visual Acuity Results with Contact Lens at Final Visit

PURPOSE: To provide visual acuity (VA) data for the contact lens in a concise format.

GENERAL:

Separate tables should be prepared and clearly identified for:

Completed Control Eyes (Table 7A)
Completed Trial Eyes (Table 7B)
Discontinued Control Eyes (Table 7C)
Discontinued Trial Eyes (Table 7D)

In addition to the data on the table for the final visit, the data in the "Visual Acuity Summary" must be provided. The number of eyes that had a VA of 2 or more Snellen Lines worse than the initial best corrected VA must be provided for each visit, and an explanation must be provided for each instance in the second section of Table 7.

Number and percentage in each horizontal row of each VA column refer to the number of eyes in the best corrected column for the corresponding row. Percentage should be calculated in accordance with the formula on the table.

TABLE 7
VISUAL ACUITY RESULTS WITH CONTACT LENS
AT FINAL VISIT

Initial Best Corrected	Number of Eyes	20/15 # %	20/20 # %	20/25 # %	20/30 # %	20/40 ... # %	Not Reported # %	Totals # %
20/15	X X	X X						X X
20/20	X X	X X						X X
20/25	X X	X X						X X
20/30	X X	X X						X X
20/40	X X	X X						X X
(Continue as Needed)	X X	X X						X X
Totals	X X	X X						X X

$$\%\ \text{at each VA (or total)} = \frac{\#\ \text{of eyes at each VA (or total)}}{\#\ \text{of eyes at initial best corrected of corresponding row}} \times 100$$

Visual Acuity Summary:

eyes with initial best corrected VA of 20/30 or better _____.
eyes with final VA with lens of 20/30 or better _____.
eyes with final VA with lens within +/- 1 Snellen line of best corrected _____.
eyes with final VA with lens of worse than +/- 1 Snellen line of best corrected _____.

TABLE 7(cont.)
LISTING OF EYES THAT CHANGED 2 OR MORE SNELLEN LINES

Investigator	Patient	Eye	Initial VA	VA at Visit	Reason
1.					
2.					
3.					
etc.					

Table 8 Notes:

TITLE: Average Hours Worn per Visit

PURPOSE: To provide an accounting of wearing time by time in study.

GENERAL:

Separate tables should be prepared and clearly identified for:

Completed Control Eyes (Table 8A)
Completed Trial Eyes (Table 8B)
Discontinued Control Eyes (Table 8C)
Discontinued Trial Eyes (Table 8D)

Number and percentage refer to the number of eyes in the average daily wearing time column for the corresponding row. Percentage should be calculated in accordance with the following formula:

$$\% \text{ at each time} = \frac{\text{\# of eyes at each time}}{\text{\# of total eyes}} \times 100$$

TABLE 8
AVERAGE HOURS WORN

Daily wearing time (in hours)	Intermediate Visits 1		2		3		4		Unscheduled		Final Visit	
	#	%	#	%	#	%	#	%	#	%	#	%
0 to 4.0	X	X	X	X	X	X	X	X	X	X	X	X
4.1 to 6.0												
6.1 to 8.0												
8.1 to 10.0												
10.1 to 12.0												
12.1 to 14.0												
14.1 to 16.0												
16.1 to 18.0												
> 18.1												
Not reported												
Wearing time average/visit (hours/day)												

Table 9 Notes:

TITLE: Discontinued Eyes Tabulated by Completed Visits and Reasons for Discontinued with Incidence Rates

PURPOSE: To provide comprehensive data on all discontinued eyes with reasons for discontinuation, time in study, and incidence rates.

GENERAL:

Eyes known to have discontinued between scheduled visits should be listed in the "Unscheduled Visits" column.

Total discontinuations should be provided for each intermediate visit. Aggregate discontinuations and aggregate incidence rate should be calculated for each reason and for total discontinuations.

Aggregate incidence rates should be calculated in accordance with the formula shown on the table. It is recognized that this formula will result in some error because active and incomplete eyes are not taken into account. However, this error will be small unless the discontinuation rate, number of active eyes, or number of incomplete eyes is excessive. In such cases, submission of additional data and subsequent review may be required.

Note: More than one reason may be given for discontinuation. In such a case, note only the principal reason on the table and identify the additional reasons in a footnote to the table.

TABLE 9
DISCONTINUED EYES TABULATED BY COMPLETED VISITS
AND REASONS FOR DISCONTINUED WITH INCIDENCE RATES

REASONS FOR DISCONTINUATION	Eyes at (or after) Visit Completed INITIAL	Intermediate 1	2	3	4	Unsch.	Aggre. Disc.	%
Visual Acuity	C/T	C/T	C/T	C/T	C/T	C/T	C/T	%
Positive SLF								
Adverse Reaction								
Lens Positioning								
Discomfort								
Handling Problem								
Disinterest								
Lost-to-Follow-up								
None Given								
Other (Specify)								
Total	C/T	C/T	C/T	C/T	C/T	C/T	C/T	%

$$\% \text{ Incidence} = \frac{\text{Aggregate eyes discontinued per reason}}{\text{Total eyes completed + total eyes disc.}} \times 100$$

C = # control eyes
T = # trial eyes

Table 10 Notes:

TITLE: Lens Replacements by Visit

PURPOSE: To provide a tabulation of all lenses replaced during the study by reason for replacement.

GENERAL:

Separate tables should be prepared and clearly identified for:

Completed Patients (Table 10A)
Discontinued Patients (Table 10B)

Lenses replaced for visual acuity, pathology or other physiological reasons must be listed individually, with the specific reason for replacement and the visual acuity with the replacement lens.

Number and percentage refer to the number of eyes for each reason for replacement for the corresponding row. Percentage should be calculated in accordance with the following formula:

$$\% \text{ of eyes with lenses replaced} = \frac{\text{\# of eyes at each visit}}{\text{\# of total eyes}} \times 100$$

TABLE 10
LENS REPLACEMENTS BY VISIT

REASON FOR REPLACEMENT	INITIAL # %	Intermediate Visit 1 # %	2 # %	3 # %	4 # %	Unsched. # %	Total # %
Visual Acuity	C/T	C/T	C/T	C/T	C/T	C/T	C/T
Comfort							
Pathology							
Base Curve							
Diameter							
Lost							
Torn							
Lens Deposits							
Bad Edge							
Bad Surface							
Discoloration							
Other (Specify)							
Totals	C/T	C/T	C/T	C/T	C/T	C/T	C/T

C = # control eyes
T = # trial eyes

CLIN--APPENDIX D

TREND ANALYSIS PROFILE

The Trend Analysis Profile (TAP) is intended to assist in the identification of trends. The TAP provides the number of events (e.g., adverse reactions) that occur at each visit of the study as well as the total number of events occurring during the study. In a sense, it is similar to a life table analysis in that it may quickly indicate the interval of time from the entry of subjects into the trial until the occurrence of specific events (e.g., adverse reactions). It may also reveal data trends that would be difficult to glean from the clinical report; however, it is not intended to replace the clinical report or Summary of Safety and Effectiveness.

The following directions outline the appropriate methods for completing the TAP form. CDRH anticipates that the TAP form may evolve over time as CDRH and sponsors discover improved means of presenting trend data.

Item	Category	Instructions for completing TAP
1	Time in Study	This entry identifies how far the study has progressed; e.g., 1 week or 1 month into the study. (The data reported in a given column should represent only the data collected during that particular time interval. Only data in the Total column, at the far right of the table, are cumulative for the entire study.)
2	Total # of Eyes	This number includes the total number of eyes, either active or discontinued, that were examined during that time interval.
3	D/C Eyes	This number includes all the eyes discontinued during that time interval.
4	Average Wear Time	This number is the average wear time reported by all eyes, either active or discontinued, during that time interval.
5	All Adverse Reactions	Each adverse reaction should be recorded only at the onset of the event. Follow-up visits for that particular event should not be recorded here.
6	All Corneal Ulcers	This is a subset of the Adverse Reactions discussed in Item 5. For this entry, each ulcer should be recorded only at the onset in the same manner that adverse reactions were reported in Item 5.

7	All Iritis	This is a subset of the Adverse Reactions discussed in Item 5. For this entry, each iritis episode should be recorded only at the onset in the same manner that adverse reactions were reported in Item 5.
8	Total Reports Staining	This number includes all staining reports which occurred during that time interval. If there are multiple reports for one eye, each report should be counted in this category.
9	Staining Reports >Gr 2	This number includes all staining reports greater that grade 2, which occurred during that time interval. If there are multiple reports > grade 2 for one eye, each report should be counted in this category.
10	Total # of Eyes Reporting Staining:	This number includes the number of eyes that had staining reports one or more times during the study. Even if there are multiple reports for one eye, only one report should be counted.
11-13	Edema Categories	The instructions for completing the edema entries correspond exactly to the instructions for completing the staining categories (Items 8-10 above). Follow the instructions for Items 8-10 substituting the word "edema" for the word "staining."
14-16	Injection Categories	The instructions for completing the injection entries correspond exactly to the instructions for completing the staining categories (Items 8-10 above). Follow the instructions for Items 8-10 substituting the word "injection" for the word "staining."
17-19	Neovasc. Categories	The instructions for completing the neovascularization entries correspond exactly to the instructions for completing the staining categories (Items 8-10 above). Follow the instructions for Items 8-10 substituting "neovascularization" for the word "staining."
20	Total Visits	This includes the total number of visits occurring during this time interval.
21	Total Missed Visits	This includes the total number of missed visits during this time interval.

TREND ANALYSIS PROFILE (TAP)

SPONSOR/510(K) No. _____ TRADE NAME: _____

No. Eyes Enrolled: _____ Generic Indication _____

	VISIT NUMBER 1	2	3	4	5	6	TOTALS
TIME IN STUDY							
TOTAL # OF EYES							
D/C EYES							
AVERAGE WEAR TIME							
ALL ADVERSE REACTIONS							
ALL CORNEAL ULCERS							
ALL IRITIS							
TOTAL REPORTS STAINING							
STAINING REPORTS > GR 2							
TOTAL NUMBER OF EYES REPORTING STAINING							
TOTAL REPORTS EDEMA							
EDEMA REPORTS > GR 2							
TOTAL NUMBER OF EYES REPORTING EDEMA							
TOTAL REPORTS INJECTION							
INJECTION REPORTS > GR 2							
TOTAL NUMBER OF EYES REPORTING INJECTION							
TOTAL REPORTS NEOVASC.							
NEOVASC. REPORTS > GR 2							
TOTAL NUMBER OF EYES REPORTING NEOVASCULARIZATION							
TOTAL VISITS							
TOTAL MISSED VISITS							

CLIN-APPENDIX E

CULTURE PROCEDURES

Introduction:

During the clinical studies when cultures must be taken, the following procedures should be followed: If a clinical lesion is present, cultures should be made by scraping the lesion with a platinum spatula. If cultures of the cornea or corneal surface are required as determined by the judgment of the investigator, the lids, conjunctiva, and cornea should be cultured according to the procedure given in Brinser, John H. and Avery Weiss, "Laboratory Diagnosis in Ocular Disease," Chapter 1 in Duane's Clinical Ophthalmology, Volume 4, edited by William Tasman, Hagerstown, MD.: Harper and Row, 1992, and Gerbert C. Rebell and Richard K. Forster "Fungi of Keratomycoses," Manual of Clinical Microbiology, edited by Edwin H. Lenette, Earle H. Spaulding and Joseph P. Truant, American Society for Microbiology, Washington, D.C., 1980. Cultures should be made on blood agar, chocolate agar incubated in a candle jar or equivalent, and Sabouraud's dextrose agar containing 50 micrograms per ml of gentamicin or chloramphenicol. Cultures should be inoculated on the solid media directly from the patient and immediately placed under the atmospheric conditions for incubation. Use of transport holding media, thioglycollate, etc. is not recommended. All organisms should be identified to species to the level of competence of a good clinical microbiology laboratory employing the Minitek or API systems, or their equivalent, and meeting microbiology proficiency test standards. The number of colonies of each species isolated should be recorded approximately.

If, in the judgment of the investigator, cultures of the cornea or corneal surface are not required, cultures of the lids and quantitative cultures of the cul-de-sac should be obtained as follows:

I. Cul-de-sac Cultures

A. A sterile calcium alginate swab is moistened in sterile buffered solution or trypticase soy broth.

B. Obtain culture inoculum from cul-de-sac by holding lids open, asking the patient to look upward, and without touching the lids with the swab, place swab in cul-de-sac and rotate it 360° around the axis of the stick.

C. Drop swab into 2.5 ml of sterile phosphate buffered saline solution (Ph 7.2) containing 20% glycerol for immediate transport to the laboratory (maximum time 2 hours). The swab should be cut off just above the calcium alginate portion with sterile scissors and the cut portion allowed to drop into the tube of transport media. This will eliminate contamination of the sample with the stick.

D. Immediately vortex-mix and make 10^{-1} and 10^{-2} dilutions in sterile buffer.

E. Pass 1.0 ml of the remaining undiluted sample through a membrane filter and, using sterile forceps, place the membrane filter on a chocolate agar plate (CAP).

F. (1) From each of the well-mixed 10^{-1} and the 10^{-2} dilutions, pass 1.0 ml through membrane filters and, using sterile forceps, place each of these membrane filters on a chocolate agar plate.

(2) Secondly, from each of the 10^{-1} and the 10^{-2} dilutions, pass 1.0 ml through membrane filters and, using sterile forceps, place each of these membrane filters on a blood agar plate (BAP).

(3) Finally, from each of the 10^{-1} and the 10^{-2} dilutions, pass 1.0 ml through membrane filters and, using sterile forceps, place each of these membrane filters on a Sabouraud's dextrose agar (SAB) plate (containing antibiotics).

G. Incubate all chocolate agar plates in a CO_2 enriched atmosphere for 48 hours at 37°C. Incubate the blood agar plates aerobically (F.(2) above) and, if necessary, anaerobically (F.(4) above) for 48 hours at 37°C. Incubate the Sabouraud's dextrose agar plates (containing antibiotic) at ambient temperature (approximately 25°C) for 2 weeks.

H. Count all organisms, correcting for dilution, and identify all organisms to species to the current state-of-the-art attained by a competent clinical microbiology laboratory. Identify all isolates of Staphylococcus aureus by the coagulase test.

II. Lid Cultures

A. Moisten a sterile calcium alginate swab in sterile buffer or trypticase soy broth.

B. Obtain a culture inoculum from the margin of the lower lid by drawing the swab along the margin of the lid.

C. Place the swab in a minimum volume (0.5 ml) of sterile phosphate saline (Ph 7.2) containing 20% glycerol and immediately transport to the laboratory.

D. Plate the inoculum and streak out on blood agar (aerobic), chocolate agar (CO_2 atmosphere), and Sabouraud's dextrose agar with gentamicin or chloramphenicol. Alternatively, the inoculum may be inoculated directly from the patient to the solid media.

E. After 48 hours incubation identify the species isolated and the relative number of colonies of each present.

III. Lens Cultures

A. The lens is removed from the eye with the investigator's hand protected by a sterile glove (without talc). The lens is immersed in a dilute peptone solution or in a sterile phosphate buffered saline solution (Ph 7.2) containing 20% glycerol and agitated with a vortex mixer. The lens is retrieved with a sterile forceps. The vortexed solution can then be used for membrane filter counts and streaked onto plate media for identification of organisms, similar to the eye culture.

B. If the patient has an inflamed eye and is not wearing the lens when he comes in for examination, first the eye is cultured, then the lens from the case, then the solution in the case and the lens case.

In this instance, remove the lens with sterile forceps and culture as above.

IV. Lens Case Solutions

For purpose of evaluation it is necessary that a careful record be kept of lens case cultures in which the lens was not being worn but was still in the case and lens case cultures made after the lens had been removed and was being worn by the patient.

A. The entire volume of the solution should be cultured with a technique such as membrane filter.

B. If the fluid contains a preservative, the solution in the case should be mixed into an equal volume of trypticase soy broth containing Azolectin-Tween 80 (or phosphate buffer solution with Tween 80), allowed to stand for 20 minutes and then cultured by the membrane filter method. Other suitable methods of neutralization may be used (e.g., DE system or neutralization by dilution).

C. The membrane filter disk may be aseptically cut in two and half put on a blood agar plate and the other half on a Sabouraud's dextrose agar slant containing antibiotic.

V. Lens Case

A. The lens case should be rinsed with a non-ionic surfactant-containing diluent and the entire volume cultured to recover low numbers.

B. Culture as in IV A and C above.

ALTERNATE CULTURE PROCEDURE

I. Cul-de-sac Cultures

A. A sterile calcium alginate swab is moistened in sterile buffered solution or trypticase soy broth.

B. Obtain culture inoculum from cul-de-sac by holding lids open, asking the patient to look upward, and without touching the lids with the swab, place swab in cul-de-sac and rotate it 360° around the axis of the stick.

C. Drop swab into 2.5 ml of sterile phosphate buffered saline solution (pH 7.2) containing 20% glycerol for immediate transport to the laboratory (maximum time 2 hours). The swab should be cut off just above the calcium alginate portion with a sterile scissor and the cut portion allowed to drop into the tube of transport media. This will eliminate contamination of the sample with the stick.

D. Immediately vortex-mix and make 10^{-1} and 10^{-2} dilutions in sterile buffer.

E. Using a sterile pipette, syringe, or dropper, inoculate one plate each of blood agar, chocolate agar and a Sabouraud's dextrose agar slant with gentamicin or chloramphenicol, with one drop of the undiluted sample and streak out for isolation of colonies.

F. Pass the remaining undiluted sample, and the 10^{-1} and 10^{-2} dilutions through each of three membrane filters. Using a sharp sterile scalpel cut each of the filters into three or four pie-shaped sections and place them on the selection of culture media designated above, namely blood agar (aerobic), chocolate agar (CO_2 enriched atmosphere), Sabouraud's dextrose agar with gentamicin or chloramphenicol. Incubate the Sabouraud's agar slant at ambient temperature (27-30°C) for 2 weeks.

G. Alternatively, if membrane filtration apparatus is unavailable, the remaining undiluted sample and 1 ml of the 10^{-1} and 10^{-2} dilutions each should be plated to the 3 or 4 culture media as designated in F above and spread evenly over the agar surface.

H. Incubate all plate cultures for 48 hours and count and identify all organisms to species to the current state of the art attained by a competent clinical microbiology laboratory. Identify all isolates of Staphylococcus aureus by the coagulase test.

II. Lid Cultures

A. Moisten a sterile calcium alginate swab in sterile buffer or trypticase soy broth.

B. Obtain a culture inoculum from the margin of the lower lid by drawing the swab along the margin of the lid.

C. Place the swab in a minimum volume (0.5 ml.) of sterile phosphate saline (pH 7.2) containing 20% glycerol and immediately transport to the laboratory.

D. Plate the inoculum and streak out on blood agar (aerobic), chocolate agar (CO_2 atmosphere), and Sabouraud's dextrose agar with gentamicin or chloramphenicol. Alternatively, the inoculum may be inoculated directly from the patient to the solid media.

E. After 48 hours incubation identify the species isolated and the relative number of colonies of each present.

III. Lens Cultures

A. The lens is removed form the eye with the investigator's hand protected by a sterile glove (without talc). The lens is immersed in a dilute peptone solution or in a sterile phosphate buffered saline solution (pH 7.2) containing 20% glycerol and agitated with a vortex mixer. The lens is retrieved with a sterile forceps. The vortexed solution can then be used for membrane filter counts or streaked onto plate media for identification of organisms, similar to the eye culture.

B. If the patient has an inflamed eye and is not wearing the lens when he comes in for examination, first the eye is cultured, then the lens from the case, then the solution in the case and the lens case.

In this instance, remove the lens with sterile forceps and culture as above.

IV. Lens Case Solutions

For purpose of evaluation it is necessary that a careful record be kept of lens case cultures in which the lens was not being worn but was still in the case and lens case cultures made after the lens had been removed and was being worn by the patient.

A. The entire volume of the solution should be cultured with a technique such as membrane filter.

B. If the fluid contains a preservative, the solution in the case should be made into an equal volume of trypticase soy broth containing Azolectin-tween 80 (or phosphate buffer solution with tween 80), allowed to stand for 20 minutes and then cultured by the membrane filter method. Other suitable methods of neutralization may be used (e.g., DE system or neutralization by dilution).

C. The membrane filter disk may be aseptically cut in two and half put on a blood agar plate and the other half on a Sabouraud's dextrose agar slant containing antibiotic.

V. Lens Case

A. The lens case should be rinsed with a non-ionic surfactant-containing diluent and the entire volume cultured to recover low numbers.

B. Culture as in IV A and C above.

LABELING

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LABELING

I. Introduction:

This section of the guidance provides general information on the applicable regulations and requirements for labeling of contact lenses, what information needs to be submitted for review of a 510(k) for a daily wear plastic contact lens, and examples of specific labeling components designed to meet the requirements of the applicable labeling regulations.

Contact lenses are subject to the general labeling requirements for all medical devices outlined in 21 CFR 801. CDRH considers all contact lenses to be prescription devices and, therefore, restricts the device to sale by or on the order of a licensed eyecare practitioner. Labeling requirements for prescription devices are discussed in 21 CFR 801.109. UV-absorbing contact lenses are further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) of the act.

As discussed in the introduction of this guidance document, SMDA requires that appropriate regulatory safeguards be in effect when daily wear soft or daily wear nonhydrophilic (hydrophobic) plastic contact lenses are reclassified from class III to class II. CDRH considers adequate labeling to be an important safeguard (general control) for assuring that new daily wear plastic contact lenses are substantially equivalent in terms of safety and effectiveness to a legally marketed (predicate) lens.

II. Labeling Information Required in an Original 510(k) or 510(k) for a Modification:

Under 21 CFR 807.87(e), a 510(k) applicant is required to submit proposed labels, labeling, and advertisements sufficient to describe the device (composition), its intended use (i.e., indications for use), and the directions for its use. This basic information is required before CDRH can render a substantial equivalence determination for either an original 510(k) or for a 510(k) that includes modifications (e.g., changes in device description, intended use, or directions for use) if the modification significantly affects safety or effectiveness of the device. In addition changes such as (1) adding or deleting a contraindication or significant warning or precaution and (2) revising labeling to provide for disposable wear are considered modifications that requires the submission of 510(k)s.

III. Examples of Labeling Modifications That do not Require Submission of a 510(k):

Examples of labeling modifications that do not require submission of a 510(k) include: (1) updating labeling to include adding the monovision fitting technique to the labeling of a single vision contact lens to manage presbyopia using the language in the Practitioners Fitting and Information Guide and Patient Instructions examples, and (2) adding language to the labeling to allow lenses to be prescribed in a frequent replacement program.

IV. Regulatory Guidance:

Information that generally accompanies the sale and distribution of a contact lens can include, but is not limited to, such printed matter as a Package Insert, a Practitioner Fitting and Information Guide, Patient Instructions, and Container Labeling. CDRH considers such printed matter to be labeling as described in 21 CFR 801.109(2)(d), which also provides general guidance as to the type of information that should be included in the contact lens labeling.

Because labeling is not approved when 510(k) clearance is granted, the manufacturer should be advised that once the device is marketed, he or she is required to label the device in accordance with applicable regulations which include, among other things, prohibition against misbranding and including false and misleading information in the labeling. In order to avoid violating the labeling regulations, applicants should scrutinize their labeling in draft for words or phrases that are exaggerated, potentially ambiguous, or subjective as well as unsubstantiated statements, claims, or puffery. Such words or phrases in labeling may be considered false or misleading, and if marketed with false or misleading claims, could cause the manufacturer to be subject to regulatory action. CDRH urges applicants to carefully adhere to pertinent labeling regulations and to maintain their labeling in draft form until a substantial equivalence letter is received.

Pertinent Labeling Regulations:

- Definitions of "label" and "labeling" (Sections 201(k) and 201(m) of the Federal Food, Drug, and Cosmetic Act (the act)).

- Information required in a premarket notification submission pertaining to labeling (21 CFR 807.87(e)).

- General Labeling Provisions, Prescription Device Labeling (21 CFR 801 and 801.109) and (for UV-Absorbing Lenses, Restrictive Device Regulation, 520(e) of the act under authority of section 515(d)(1)(B)(ii) of the act).

- Explanation of what causes a device to be misbranded and false and misleading labeling (Section 502 of the Act, 21 CFR 801.6, 807.39, and 807.97).

- Warning required by the Clean Air Act and the FDA notice published in the Federal Register on June 29, 1993 (FR 58 34812).

Refer to Labeling--Appendices A, B, C, and D for examples of (1) a Package Insert, (2) a Professional Fitting and Information Guide, (3) Patient Instructions, and (4) Container Labeling that are designed to incorporate the required elements of applicable labeling regulations. These examples may be used as guidance in preparing your labeling, but should be modified, as needed, so that they are applicable to specific lens materials, procedures, wearing schedules (e.g., disposable), etc. Marginal instructions are included in the examples, and you should refer to the key at the beginning of the examples for explanations of items in each example. Some specific items to consider in developing your labeling include:

1. Manufacturers are not required to duplicate the same information in the Professional Fitting and Information Guide that is in the Package Insert if the Package Insert is printed in the back of the Professional Fitting and Information Guide, provided adequate references to the Package Insert are included in the Professional Fitting and Information Guide. However, the Patient Instructions should contain the items in the example (Appendix C).

2. Manufacturers who already have approval to market a lens for extended wear may include a daily wear indication for approved daily wear lenses in the extended wear labeling as long as all required elements are included in the labeling.

3. Lenses made from the same generic material that incorporate different design configurations may be included in the same labeling provided information applicable to specific designs is complete. Different generic materials should not be combined in the same labeling because it could make the labeling long and cumbersome and misleading to users.

4. Separate Patient Instructions will be required for daily wear single-use disposable contact lenses and those lenses that are to be cleaned and disinfected according to a conventional wear schedule or part of a planned replacement program. Manufacturers may use the Patient Instructions example to prepare disposable lens labeling, but should modify these instructions, as needed, to allow for disposable wear.

The following references may be consulted for further guidance:

1. Labeling Regulatory Requirements for Medical Devices. This publication discusses such areas as advertising material considered labeling, what is false and misleading labeling, adequate directions for use, and prescription device requirements as well as providing examples of ways that device manufacturers can comply with labeling requirements. Copies of this publication can be obtained by calling DSMA (telephone number in Introduction section).

2. Device Labeling Guidance #G91-1 (Office of Device Evaluation Blue Book Memorandum). This guidance provides detailed interpretations of applicable labeling regulations, and can be obtained by calling the DOD Freedom of Information (FOI) Technician at (301) 594-2205 or from DSMA (telephone number in Introduction section).

3. What You Need to Know About Safe Contact Lens Wear. This brochure was developed in cooperation with professional eyecare associations, contact lens trade associations, and representatives from Canada and FDA. It provides general guidance to wearers of all types of contact lenses (e.g., soft (hydrophilic), rigid gas permeable, and conventional hard lenses) and wear schedules including disposable wear, extended wear and daily wear. This brochure was not designed to contain all of the elements in the labeling regulations; however, it may be useful in developing your labeling. The brochure is available through your professional association.

4. Human Factors Principles of Medical Device Labeling. This guidance pertains to labeling for all medical devices. It contains basic principles for the effective design of instruction booklets for medical device use. Along with the principles are selected examples (graphics, cleaning steps, etc.) abstracted from a generic model booklet. These examples do not contain all elements required by 21 CFR 801.109, but they embody human factors principles and may be used, along with the labeling example, as a guide in writing your Patient Instructions. This guidance is available by contacting DSMA (telephone number above).

5. Labeling Suggestions for Ultraviolet Light (UV)-Absorbing Contact Lenses, prepared in draft on September 16, 1987 (Appendix E).

PACKAGE INSERT

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.

Checklist:

[Note: Please check to make sure that the following areas are present in your package insert:]

HEADING (Package Insert)
IMPORTANT (Read Carefully, Etc.)
CAUTION (Federal Law Prohibits Dispensing Without a Prescription or Most Recent Statement Required by Regulation)
WARNING (Statement Required by Environmental Protection Agency (EPA))
TRADE NAME AND OTHER DESCRIPTIVE INFORMATION
DESCRIPTION
ACTIONS
INDICATIONS (USES)
CONTRAINDICATIONS (REASONS NOT TO USE)
WARNINGS
PRECAUTIONS
ADVERSE REACTIONS
FITTING
PREPARING AN RGP LENS FOR FITTING (If Applicable)
WEARING SCHEDULE
LENS CARE DIRECTIONS
- Basic Instructions
- Heat (Thermal) Disinfection (If Applicable)
- Emergency (Alternate) Method for Heat (Thermal) Disinfection (If Applicable)
- Chemical (Not Heat) Disinfection (If Applicable)
- Lens Deposits and Use of Enzymatic Cleaning Procedure (If Applicable)
- Lens Case Cleaning and Maintenance (If Applicable)
- Care for a Dried Out (Dehydrated) [Dry] Lens (If Applicable)
- Care for a Sticking (Nonmoving) Lens

EMERGENCIES
HOW SUPPLIED
REPORTING OF ADVERSE REACTIONS

Example:

IMPORTANT - Please read carefully and keep this information for future use. This package insert is intended for the eyecare practitioner, but should be made available to patients upon request. The eyecare practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTION: Federal Law Prohibits Dispensing Without a Prescription (or use 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 for this product, pursuant to EPA regulation.]

TRADE NAME (TN)
(fill in generic name)

[Soft (Hydrophilic)] [Rigid Gas Permeable] [Silicone] Contact Lenses

[Spherical] [Aspherical] [Other, specify] Lenses for:
[(Myopia)]
[(Hyperopia)]
[Presbyopia]
[Not-aphakic] (Aphakia)]
[Astigmatic (Toric) Lenses to Correct Astigmatism]
[Include Other Applicable Intended Use]

DESCRIPTION:

The TN (generic name) [Silicone] [Rigid Gas Permeable] [Soft (Hydrophilic)] Contact Lens is available as a [spherical] [aspherical] [bifocal] lens [and as an astigmatic (toric) lens]. The lens material, (generic), is a copolymer of [include description of material including color additive and/or UV-absorber, if applicable]. The TN Contact Lens is a [hemispherical shell] [specify] of the following dimensions:

- Diameter: Approximately [#] mm
- Center Thickness, for Low Minus Lens: [#] mm
  for Plus Lens: [#] mm
- Base Curve: [#] mm to [#] mm
- Powers: -[#] Diopters to +[#] Diopters
  [For Bifocal] Bifocal Add Powers: [#] to [#] Diopters
  Bifocal Add Power Diameters: [#] to [#] mm
  [For Toric]: Axis and Power

The physical/optical properties of the lens are:

- Specific Gravity:
- Refractive Index:
- Light Transmittance [Clear and Tinted (List Separately)]:
- Surface Character [Hydrophilic/Hydrophobic]:
- Wetting Angle (CLMA method for RGP lens only)
- Water [Content] [Absorption]:
- Oxygen Permeability:*
- [Any additional Physical Parameters that apply to TN Contact Lens]

*[method for determination of oxygen permeability]

ACTIONS:

[In its hydrated state, the]/[The] TN Contact Lens when placed on the cornea acts as a refracting medium to focus light rays on the retina. [Include the following sentence if the lens is a toric lens: The (toric) lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.]

INDICATIONS (USES):

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 non-diseased 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].

[Include if applicable] Eyecare practitioners may prescribe the lens for [either single-use disposable wear] [or for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement (see WEARING SCHEDULE)]. When prescribed for frequent/replacement wear, the lens may be disinfected using a [either a] [heat] [or] [chemical] disinfection system.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the TN Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the TN Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated
- [Include additional contraindications as appropriate]

WARNINGS:

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eyecare practitioner's direction and all labeling instructions for proper use of 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 patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eyecare practitioner.

PRECAUTIONS:

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

[Add next statement if light transmittance of a tinted lens is 70% or less in the visible range (380 - 780 nm]

- Patients may experience a reduction in visibility while wearing this lens in conditions of low illumination.

Special Precautions for Eyecare Practitioners:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

[Include next item for aspheric lenses for presbyopia]

- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

[Include next item only if lens is indicated for aphakic persons]

- Aphakic patients should not be fitted with TN Contact Lenses until the determination is made that the eye has healed completely.

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

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.

- Before leaving the eyecare practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

[Include next item for rigid gas permeable contact lenses]

- [Include a statement appropriate to lens regarding use of fluorescein]

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

[Precautions pertaining to cleaning and disinfection are not applicable to daily wear disposable lenses]

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.

  [Include next two items if lens is a soft (hydrophilic) contact lens]

  - Never use solutions recommended for conventional hard contact lenses only.

  - Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.

[Include next item if lens is a rigid gas permeable lens]

- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.

- Always use fresh unexpired lens care solutions.

- Always follow directions in the package inserts for the use of contact lens solutions.

- Use only a [heat (thermal)] [chemical (not heat)] lens care system. Use of a [heat (thermal)] [chemical (not heat)] care system can [specify damage] the TN Contact Lenses.

- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

- Always keep the lenses completely immersed in the recommended storage solution when the 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]. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if lens surface does become dried out.

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.

- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Carefully follow the handling, insertion, removal, cleaning disinfecting, storing and wearing instructions in the Patient Instructions for the TN Contact Lens and those prescribed by the eyecare practitioner.

- Never wear lenses beyond the period recommended by the eyecare practitioner.

- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.

[Include next item if applicable; modify as needed]

- Always discard disposable lenses and lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eyecare practitioner.
- Always contact the eyecare practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS:

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Feeling that something is in the eye such as a foreign body or scratched area
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)

- Dry eyes
- [Additional information as appropriate]

If the patient notices any of the above, he or she should be instructed to:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. [Discard the lens (for disposable lens)] Place the lens in the storage case and contact the eyecare practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should [discard the lens and replace it with a new one (for disposable)] thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult the eyecare practitioner.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING:

Conventional methods of fitting contact lenses [apply] [do not apply] to TN (generic name) Contact Lenses. For a detailed description of the fitting techniques, refer to the TN Professional Fitting and Information Guide, copies of which are available from:

Manufacturer's Name
Address
Toll Free Telephone Number (if Available)

[ADD FOR RGP LENSES] PREPARING AN RGP LENS FOR FITTING:

[Include applicable information]

WEARING SCHEDULE:

The wearing and replacement schedules should be determined by the eyecare practitioner. Patients tend to overwear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

[Include this paragraph if applicable] [Company Name] recommends that the lens be discarded and replaced with a new lens every [#] [weeks/other]. However, the eyecare practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

The TN Contact Lenses are indicated for daily wear. The maximum suggested wearing time for these lenses is:

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

Studies have not been completed to show that the TN Contact Lens is safe to wear during sleep.

LENS CARE DIRECTIONS:

[This section is not applicable for daily wear disposable lenses. The labeling should state that the patient should always have a spare pair of lenses with him or her at all times]

Eyecare practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

General Lens Care (To First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

- 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.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme (as recommended by the eyecare practitioner) and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

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

  [Option 2] The lens care products listed below are recommended by [manufacturer] for use with the TN Contact Lens. Eyecare practitioners may recommend alternate products that are appropriate for the patient's use with his or her lens.

Lens Care Table:

Product Purpose to:	Lens Care System	
	Heat (Thermal)	Chemical (Not Heat)
Clean		
Rinse		
Disinfect		
Store		
Lubricate/Rewet		
Enzyme [not applicable for disposable lenses]		

*_____is a trade mark of (Manufacturer).
_____, _____, _____, 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, and 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 the manufacturer and/or the eyecare practitioner.

- 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, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses.

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

- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

[Include next two items for rigid gas permeable lenses and other materials if appropriate]

- TN Contact Lenses cannot be heat (thermally) disinfected.
- Disposable and lenses prescribed in a frequent replacement program should be thrown away after the recommended wearing period prescribed by the eyecare practitioner.

[Include additional information as appropriate]

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

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

- **After cleaning** and thoroughly rinsing contact lenses with recommended solutions, prepare the empty lens storage case. **To keep the lenses wet during disinfection;** use the solution that is recommended by the lens manufacturer and/or the eyecare practitioner.
- Wet the lens chambers (sections) with fresh saline solution.
- Put each lens into its correct chamber.
- Fill the chamber of the case to the line with fresh saline solution. Completely cover the lenses.
- Tightly close the top on each chamber of the lens storage case.
- Put the lens storage case into the disinfection unit and follow the disinfection unit manufacturer's directions for operating the unit (turning the unit on, assuring that it works, and leaving it on for a sufficient time to disinfect the lenses).
- Before reinsertion of the lenses, no rinsing is necessary unless the eyecare practitioner recommends rinsing.

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

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

- If a heat disinfection unit is not available, place the tightly closed storage container which contains the lenses into a pan of already boiling water. [Leave the closed lens case in the pan of boiling water for at least 10 minutes. (Above an altitude of 7,000 feet, boil for at least 15 minutes.)] Be careful not to allow the water in the pan to boil away. Remove the pan from the heat and allow it to cool for 30 minutes to complete the disinfection of the lens.

Note: Use of heat disinfection unit should be resumed as soon as possible.

- Leave the lenses in the unopened storage case until ready to put on the eyes.

- Before reinsertion of the lenses, no rinsing is necessary unless the eyecare practitioner recommends rinsing.

[Include if Applicable] Chemical (Not Heat) Disinfection:

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

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.

- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eyecare practitioner.

- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.

- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.

- Do not heat the disinfection solution and lenses.

- Leave the lenses in the unopened storage case until ready to put on the eyes.

- Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

[INCLUDE IF ENZYME CLEANING IS RECOMMENDED] LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:

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

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE:

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

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.

[INCLUDE FOR SOFT (HYDROPHILIC) CONTACT LENS OR WHEN APPLICABLE] CARE FOR A [DRIED OUT (DEHYDRATED)] [DRY] LENS:

[Include applicable information for specific lens materials]

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

CARE FOR A STICKING [NONMOVING] LENS:

If the lens sticks [(stops moving)] [(cannot be removed)], the patient should be instructed to apply [#] of drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after [#] minutes, the patient should immediately consult the eyecare practitioner.

EMERGENCIES:

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

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.

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 (Distributor's) Name
Address
1-800 [include number]

Printed (month/year)

To Part 5 of Document