OCT 19 2004 K040839

510(k) SUMMARY

COMPLETE® BLINK-N-CLEAN® Lens Drops

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

Paul J. Nowacki
Manager
Regulatory Affairs
Advanced Medical Optics
1700 E. St. Andrew Place
Santa Ana, CA 92799-5162

Phone: (714) 247-8601
Fax: (714) 247-8677
EMail: paul.nowacki@amo-inc.com

Summary Prepared: September 30, 2004

(a)(2) **Device Trade Name:** COMPLETE® BLINK-N-CLEAN® Lens Drops

Device Common Name: Soft (Hydrophilic) and Rigid Gas Permeable Contact Lens Solution

Device Classification/Panel: Class II (Special Controls)/Ophthalmic Device

Device Classification Names: Accessories, Soft Lens Products (LPN) Products, Contact Lens Care, Rigid Gas Permeable (MRC)

(a)(3) **Identification of Predicate Device:** COMPLETE® BLINK-N-CLEAN® Lens Drops is the same as the currently-marketed lens drops and substantially equivalent to other lubricating and rewetting drop products.

(a)(4) **Device Description:** COMPLETE® BLINK-N-CLEAN® Lens Drops is a sterile, isotonic, buffered, solution containing lubricants, preservatives, buffers, surfactants, ancillary ingredients, and purified water.

The product is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use):** COMPLETE® BLINK-N-CLEAN® Lens Drops is indicated to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses, as well as rigid gas permeable lenses before application and during wear.

(a)(6) **Comparison of Technological Characteristics:** The technological characteristics of the product remain the same.

510(k) SUMMARY
COMPLETE® BLINK-N-CLEAN® Lens Drops
March 2004

(b)(1) **Discussion of Nonclinical Studies:**

COMPLETE®BLINK-N-CLEAN® Lens Drops was evaluated for compatibility with silicone acrylate lenses and fluorosilicone acrylate rigid gas permeable (RGP) lenses during thirty (30) regimen cycles. Average changes in diameter, power and base curve for the test lenses were within established acceptance criteria, with test lenses showing a trend comparable to that of the controls. In addition, visual observations did not show evidence of surface deposits, discoloration and/or deformities. Based on these results, COMPLETE® BLINK-N-CLEAN® Lens Drops is compatible with all RGP contact lenses.

In addition, a study for quantifying surface protein accumulation on human-worn contact lenses and subsequent protein removal in simulated in-eye use of lens rewetter products has been conducted. The results show that COMPLETE® BLINK-N-CLEAN® Lens Drops removal significant amount of protein than the predicate devices.

Other preclinical safety and efficacy criteria were established in P910075/S7.

(b)(2) **Clinical:**

Clinical safety and acceptability of COMPLETE® BLINK-N-CLEAN® Lens Drops was established in 910075/S7.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** The safety, efficacy and performance of COMPLETE® BLINK-N-CLEAN® Lens Drops is substantially equivalent to other contact lens care lubricating and rewetting drops currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2004

Advanced Medical Optics
c/o Mr. Paul Nowacki
Manager, World Regulatory Affairs and Medical Compliance
1700 E. St. Andrew Place
P.O. Box 25162
Santa Ana, CA 92799-5162

Re: K040839
Trade/Device Name: Complete® Blink-N-Clean® Lens Drops
Regulation Number: 21 CFR 886.5918; 21 CFR 886.5928
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC; LPN
Dated: August 13, 2004
Received: August 17, 2004

Dear Mr. Nowacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER:
(IF KNOWN): _____

DEVICE NAME: COMPLETE® BLINK-N-CLEAN® Lens Drops

INDICATIONS FOR USE:

- COMPLETE® BLINK-N-CLEAN® Lens Drops is indicated to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses, as well as rigid gas permeable lenses before application and during wear.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K040839

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 3/5/09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K040839 / A2

To: Division Director: CP / DUNCD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: _____

Date: _____

905

K040839 /A2

ADVANCED MEDICAL OPTICS

March 3, 2009

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: Transfer of Rights to Premarket Notifications (510(k)s) from Advanced Medical Optics, Inc. to Abbott Medical Optics Inc.

This is to inform you that Abbott Laboratories (Abbott) has completed its acquisition of Advanced Medical Optics, Inc. Effective February 26, 2009, our name has changed to Abbott Medical Optics Inc.

Advanced Medical Optics, Inc. hereby releases rights to the attached list of 510(k)s (Attachment 1) to Abbott Medical Optics Inc.

Please contact me at 714/247-8866, or Jeanne Isaacs, Regulatory Affairs Manager, with any questions.

Sincerely,

Richard J. DeRisio
Corporate Vice President
Global Public Policy and Regulatory Affairs

FDA CDRH DMC

MAR - 5 2009

Received

ATTACHMENT 1

PREMARKET NOTIFICATIONS (510(k)s)

510(K)	Device Name
K760684	Vitreous Aspirating and Cutting Instrument (TAC)
K792096	2 FR Kelman Chamber Maintainer
K813500	Gould I/A Handpiece and accessories
K820223	OMS Quartz Infusion Contact Lens
K820680	Disposable Tubing Sets OPO-1, -2, -3, -4
K821051	LIQUIFILM® Wetting Solution
K821052	SOAKARE® Contact Lens Soaking Solution
K821054	TOTAL® Hard Contact lens Solution
K821055	BLINK-N-CLEAN® Contact Lens Solution
K821496	Disposable Irrigation/Aspiration System OPO-5
K822706	PRE-SERT® Contact Lens Cushioning Solution
K822707	CLEAN-N-SOAK® Contact Lens Cleaning and Soaking Solution
K823222	Intraocular Lens Glide
K832235A	OPO-16 Disposable Vitrectomy Handpiece
K833405	Medical Optics Irrigation/Aspiration Kit
K840695	AISP Phaco Kits OPOSL19, OPOSL21
K841072	Irrigation/Aspiration Tubing Sets OPO-13, -14, -15
K843041	Heslin Disposable Tubing Set OPO-9
K843342	LENSKEEPER® Lens Carrying Case
K844373	OMS Ultra Phaco Products
K844374	Vitreous Aspiration & Cutting Instrument
K844448	OMS/Gonvers Retinal Perforator
K851262 K851263 K851264	Mono and Binocular Indirect Ophthalmoscope
K854225	4Plus Surgical System, Sensory V, Sensory V160
K864003	Phaco Folder IOL Forceps
K861642	LENSKEEPER® Contact Lens Carrying Case
K861643	STYLEKEEPER® Contact Lens Carrying Case
K863569	BKS 1000™
K864003	AMO® Phaco-Folder™ Intraocular Lens Forceps
K864065	BKS-2 Disposable Vacuum Tubing Pack
K870807	BKS-1000™ Refractive Set
K872312	Ophthalmic Surgical System Model 3000
K874543	OPO32 Irrigation Sleeve
K881987	DURACLEAN® Daily Cleaner
K884251	ALLERGAN® Lens Case
K893199	AMO® Phaco-Injector™ Intraocular Lens Implant Instrument (Prodigy)
K893880	AMO® Collagen Shields
K904909	Vitrectomy System Vitrophage YPR 2001
K905129	Baerveldt Glaucoma Implant

ATTACHMENT 1

PREMARKET NOTIFICATIONS (510(k)s)

510(K)	Device Name
K911998	Multitome Model 1000 Vitrectomy Driving System
K924235	AMO® Elite™ Phacoemulsification System Products
K924235A	AMO® Prestige™ Phacoemulsification System Products
K925254	AMO® Flex-Tip™ Disposable Handpiece OPO38
K930320	AMO® PhacoFlex Insertion Instrument PIC-I, PIH-I
K935003	AMO® IV Pole OM770101P2
K935223	AMO® Opsys Phaco System
K935226	OMS Programmable IV Pole or PIVP2
K941603	AMO® PhacoFlex Inserter Disposable Cartridge PIC-II
K946054	AMO® OMS Diplomax™ Phaco System
K950218	Slimline Phaco Handpiece
K951462	AMO® Profinesse III® Ultrasonic Handpiece System
K955455	Baerveldt Pars Plana Glaucoma Implant
K961242	AMO® PhacoFlex II Insertion System
K962402	AMO® Prestige® Day Pack
K971186	Modified AMO® Diplomax™ and AMO® Opsys® consoles
K980775	COMPLETE® Solution (Upgrade A Protein Removal)
K981116	AMO® Sovereign Cataract Extraction System
K981168	COMPLETE® Solution (Upgrade B)
K983150	COMPLETE® (Upgrade B Lubricating & Rewetting Drops)
K984383	ULTRACARE® Neutralizing Tablets (Coating Change)
K992028	REFRESH CONTACTS L&R Solution
K993153	ILS 600C Laser Keratome
K000164	COMPLETE® Solution (Conditioning Claim)
K001211	Modified 600C Keratome
K002890	600C Laser Keratome
K003109	Blink-N-Clean Lens Drops
K003252	COMPLETE® Solution (No Rub-Frequent Replacement)
K003638	Mojave Cataract Extraction System
K010223	TOTALCARE Conditioning & Soaking Solution
K013479	COMPLETE® Solution (No Rub-Conventional)
K013941	Pulsion FS Laser Keratome
K014202	COMPLETE® Solution (Upgrade B Without HPMC)
K024166	COMPLETE C MPS (9451X)
K030092	COMPLETE BC MPS (8941X)
K031126	IntraLase Laser
K031960	FS Laser
K032030	Blink CL Lubricant Eye Drops (9464X)
K040839	COMPLETE A Blink-N-Clean Lens Drops (8772X)
K041893	FS Laser
K042562	LensPlus Rewetting Drops (7317X)
K050494	COMPLETE Moisture Plus MP Disindecting Solition

ATTACHMENT 1

PREMARKET NOTIFICATIONS (510(k)s)

510(K)	Device Name
K050648	Sovereign High Vacuum Pack
K053396	COMPLETE D MPS (9560X)
K060366	AMO Ophthalmic Surgical System (Sterling Signature System)
K060372	FS Laser
K063682	FS Laser (smaller version)
K061399	ULTRACARE Cleaning & Disinfecting Solution-Neutralizing system
K073404	iFS Laser
K081545	1VIPR30
K081681	Vitrectomy Cutter and Sleeve

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

Richard J. DeRisio
Advanced Medical Optics
1700 E. St. Andrew Place
Santa Ana, CA 92705

Re: See Enclosed List

Dear Mr. DeRisio:

We have reviewed your letter dated March 3, 2009, stating that the rights to the above referenced premarket notifications (510(k)s) has been transferred. Transfer of 510(k) rights alone does not require submission of a new 510(k) under 21 CFR 807.81(a)(3). Consequently, we cannot change the name of the original 510(k) submitter in our database. Please note, as per 21 CFR 807.85(b), a firm may not **both** manufacture and distribute a device under their own name without having their own 510(k).

We suggest that information showing the transfer of the 510(k)s and their current ownership should be maintained in the company's files for review by an FDA investigator. You may contact the Center for Devices and Radiological Health's Office of Compliance at (240) 276-0100 if you have any questions on what information we expect to be maintained in your files.

If you have any other questions regarding this letter, please contact the 510(k) Staff at (240) 276-4040.

Sincerely yours,

Julie Stuart

Julie "Brandi" Stuart
Consumer Safety Officer
Premarket Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

K040839/A1

AMO™
ADVANCED MEDICAL OPTICS

September 24, 2004

510k Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: **510(k) K040839**
COMPLETE® BLINK-N-CLEAN® Lens Drops

TO WHOM IT MAY CONCERN:

Duplicate copies of the amendment to the above-referenced 510(k) are enclosed. This amendment is a response to the questions and requests arised by the FAD regarding the supplement we sent to the FDA on August 13, 2004. Further to our telephone conversation among Jim Saviola, OD (FDA), Jimmy Chen, PhD (FDA), Paul Nowacki (AMO) and Peter XU (AMO) on September 9, 2004 and a follow-up discussion between Jim Saviola, OD (FDA) and Paul Nowacki (AMO) on September 23, 2004, we revised the draft labeling of the 510(k) K040839 in accordance with the FDA's requests. The final draft labeling is enclosed.

If you have further questions regarding this, please contact me at Phone: (714)-247-8601 Fax: (714) 247-8677, Email: paul.nowacki@amo-inc.com or Peter XU (714) 247-8592 Fax: (714) 247-8677, Email: peter.xu@amo-inc.com

Sincerely,

Paul Nowacki

Paul Nowacki
Manger
Worldwide Regulatory Affairs and Medical Compliance

SK 24

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(j)]

I certify that, in my capacity as Director, Regulatory Affairs of Advanced Medical Optics, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Paul Nowacki
(Signature)

Paul Nowacki
(Typed Name)

September 24, 2004
(Date)

K040839
*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.
Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

30

ATTACHMENT

help prevent and remove protein bai ld-up

ALL COPY REVERSES TO WHITE UNLESS OTHERWISE SPECIFIED

011824

V-CODES PRINTS 100% BLACK (TYPICAL)

PANEL BACKGROUND PRINTS PROCESS CYAN W/TYPE REV. TO WHITE

CARTON BACKGROUND PRINTS GRADATION FROM 100% PMS 072 TO 80% PROCESS CYAN (TYPICAL)

TYPE & ® PRINT PMS 109: DROPSHADOW PRINTS BLACK (TYPICAL)

Helps keep lenses Clean while you wear Them.

TYPE & UNDERLINE PRINT PMS 109

COMPLETE® ICON & ® PRINT PMS 109 DROPSHADOW PRINTS BLACK

UPC BAR CODE PRINTS 100% BLACK ON WHITE BACKGROUND

PANEL BCKGRND PRINTS PROCESS CYAN & SHADOW PRINTS PMS 072 FROM SUPPLIED .PSD FILE; TYPE REV. TO WHITE WITH PMS 072 DROPSHADOW

removes

Keep

and RGP

TYPE ON DUST FLAP AND BOTTOM PANEL PRINTS PMS 072 ON WHITE BCKGD

63766US10M
8772X

LOT/EXP.:

011824

AMO
COMPLETE
Blink-N-Clean
LENS DROPS

For Soft Contact Lens

DIRECTIONS:

Distributed by:
Advanced Medical Optics, Inc.
Santa Ana, CA 92705, U.S.A.
1-800-347-5005
©2003 AMO, Inc.

No. 92825

COMPLETE®
Blink-N-Clean®
LENS DROPS

Helps remove protein and prevent buildup during lens wear

0.7 fl oz (20 mL) STERILE

CONTENTS: COMPLETE® Blink-N-Clean®

DO NOT USE.

PRECAUTIONS:

- Keep out of the reach of children.

WARNING: SEE PACKAGE INSERT FOR IMPORTANT SAFETY INFORMATION.

AMO
COMPLETE
Blink-N-Clean
LENS DROPS

USE ONLY IF IMPRINTED OVERWRAP ON BOTTLE IS INTACT

AMO
COMPLETE
Blink-N-Clean
LENS DROPS

Helps clean lenses while you wear them

COMPLETE® Blink-N-Clean® Lens Drops are doctor recommended for use with all types of soft contact lenses

0.7 fl oz (20 mL) STERILE

AMO WORLDWIDE SPECIFICATIONS
DRAWING NUMBER: 0166601
FORMAT: N/A
ARTWORK IS ACTUAL SIZE
DROP KEYLINES AND CALLOUTS BEFORE PROCESSING
COPY IS SHOWN AT 100%
PLATFORM: MAC - ILLUSTRATOR 8.0

INKS: PMS 186 | PMS 072 | BLACK | PROCESS CYAN | COATING(S)

011824

CARTON RTE
(MARCHESINI FOLD)
1-7/8" X 1-1/16" X 3-25/32"

0166601

AMO ADVANCED MEDICAL OPTICS
Worldwide Specifications
Labeling and Packaging

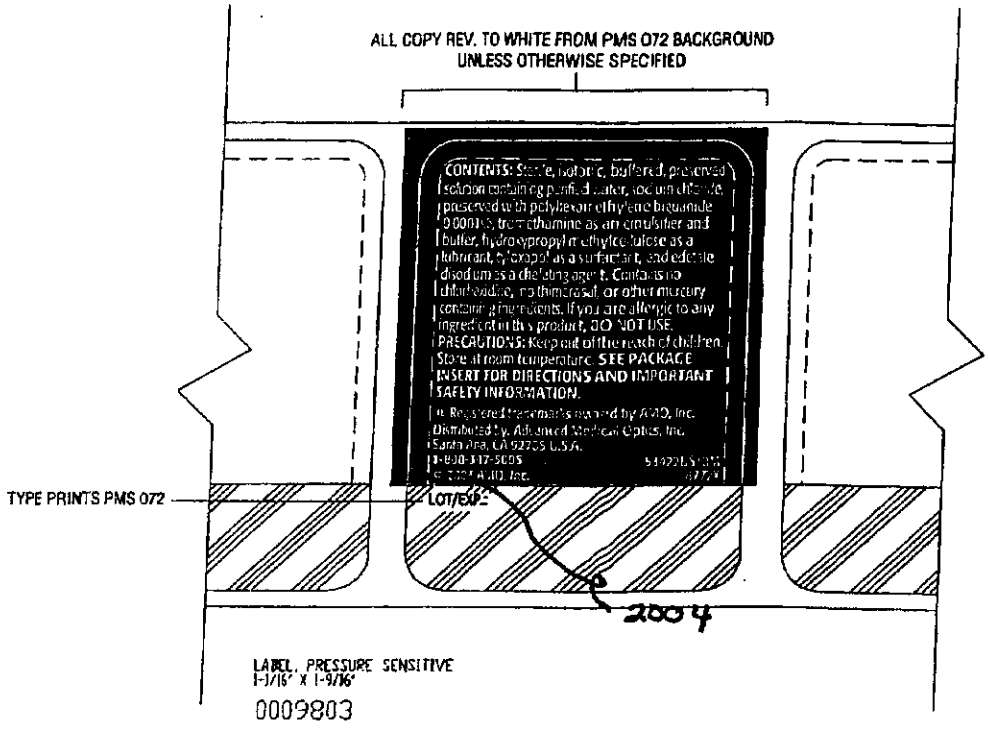
ARTWORK SPECIFICATIONS

PART #: 63766US10M DRAWING #: 0166601

	FINAL APPROVAL	DATE
WW Labeling/Packaging Coordinator	G. Ramos	7/9/03
Marketing	D. Mitz	7/14/03
Regulatory Affairs Labeling Compliance	A. Brunk	7/10/03

YOUR SIGNATURE IS REQUIRED.
If signatures are NOT present, this document is NOT valid.

32



AMO WORLDWIDE SPECIFICATIONS
DRAWING NUMBER: 0009803
FORMAT: N/A
ARTWORK IS ACTUAL SIZE DROP KEYLINES AND CALLOUTS BEFORE PROCESSING COPY IS SHOWN AT100% PLATFORM: MAC - ILLUSTRATOR 8.0

INK	
PMS 072	COATING(S)

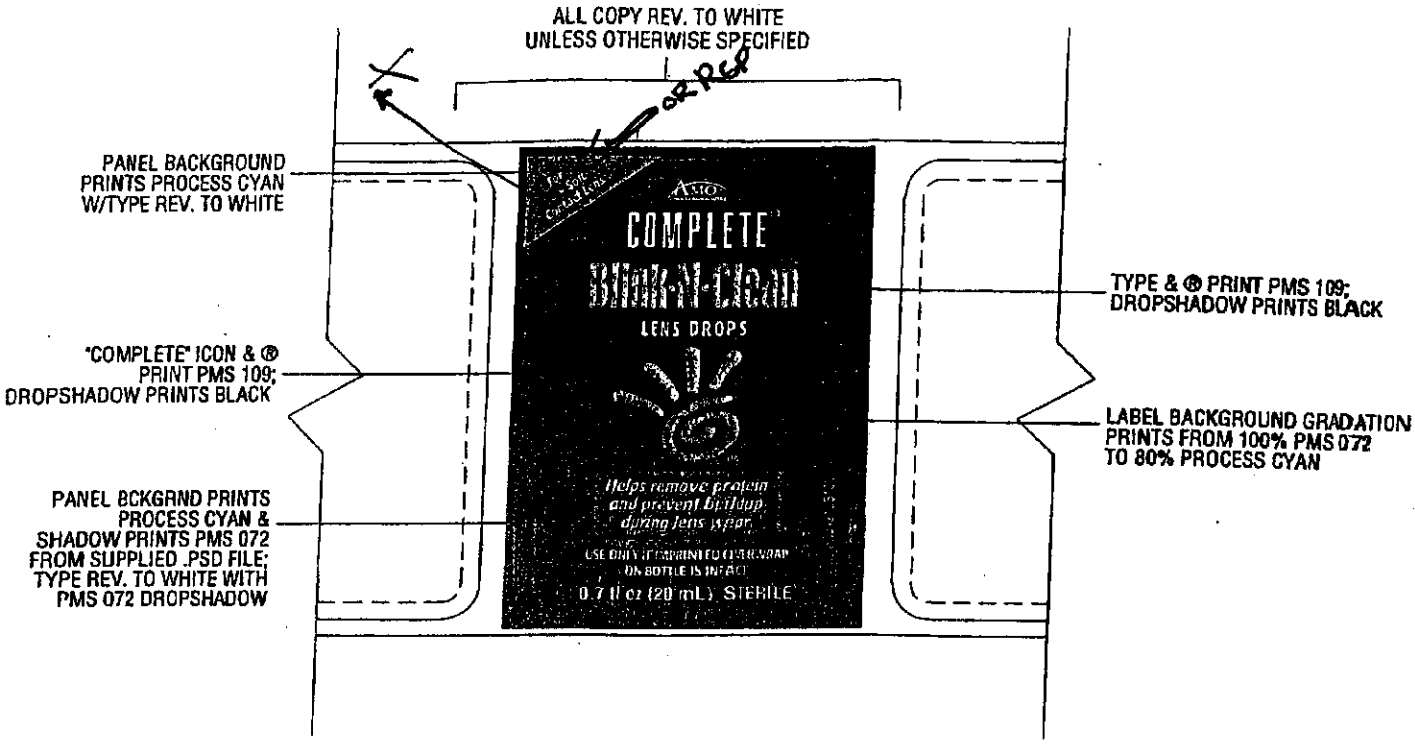
AMO ADVANCED MEDICAL OPTICS — Worldwide Manufacturing Support
Labeling and Packaging

ARTWORK SPECIFICATIONS

PART #: 53422US10M **DRAWING #:** 9803

	FINAL APPROVAL	DATE
WW Labeling/Packaging Coordinator		7/1/03
Marketing		7/7/03
Regulatory Affairs Labeling Compliance		7/10/03

YOUR SIGNATURE IS REQUIRED.
If signatures are NOT present, this document is NOT valid.



LABEL, PRESSURE SENSITIVE
1-1/16" X 1-9/16"

0009804

AMO WORLDWIDE SPECIFICATIONS
DRAWING NUMBER: 0009804 **FORMAT: N/A**
ARTWORK IS ACTUAL SIZE DROP KEYLINES AND CALLOUTS BEFORE PROCESSING COPY IS SHOWN AT 150% PLATFORM: MAC - ILLUSTRATOR 8.0

	PMS 109	PMS 072	BLACK	PROCESS CYAN	COATING(S)
1A					

AMO ADVANCED MEDICAL OPTICS — Worldwide Specifications Labeling and Packaging

ARTWORK SPECIFICATIONS

PART #: 53421US10M DRAWING #: 0009804

	FINAL APPROVAL	DATE
WW Labeling/Packaging Coordinator	L. Demos	6/27/03
Marketing	L. Imus	7/7/03
Regulatory Affairs Labeling Compliance	D. Krisak	7/16/03

YOUR SIGNATURE IS REQUIRED.
If signatures are NOT present, this document is NOT valid.

AMO™
ADVANCED MEDICAL OPTICS

Important - Please read carefully and keep this package insert for future reference.

COMPLETE® Blink-N-Clean® Lens Drops

For use with soft (hydrophilic) contact lenses, including disposable lenses and extended wear lenses, and RGP contact lenses.

DESCRIPTION:
COMPLETE® Blink-N-Clean® Lens Drops is a sterile, isotonic, buffered, preserved solution. This aqueous formulation includes purified water, sodium chloride, preserved with polyhexamethylene biguanide 0.0001%, tromethamine as an emulsifier and buffer, hydroxypropyl methylcellulose as a lubricant, tyloxapol as a surfactant, and edetate disodium as a chelating agent. This preparation contains no chlorhexidine, no thimerosal and no other mercury containing ingredients.

ACTIONS:
COMPLETE® Blink-N-Clean® Lens Drops lubricates and rewets lenses, helps prevent protein film build-up, helps to remove particulate material that may cause irritation and/or discomfort. Use **COMPLETE® Blink-N-Clean®** Lens Drops to promote lens cleanliness during wear, to rewet lenses before insertion and lubricate lenses during wear to moisten and reduce lens friction against the cornea. When wearing extended wear lenses, use **COMPLETE® Blink-N-Clean®** Lens Drops to moisten lenses before retiring and upon awakening.

INDICATIONS:
COMPLETE® Blink-N-Clean® Lens Drops is indicated for use to lubricate and rewet soft ~~(hydrophilic) contact lenses~~, disposable and extended wear lenses, daily wear and RGP contact lenses.

CONTRAINDICATIONS (REASONS NOT TO USE):
If you are allergic to any ingredient in **COMPLETE® Blink-N-Clean®** Lens Drops, do not use this product.

WARNINGS:
PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens case. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION.**

Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care practitioner.

Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have

AMO WORLDWIDE SPECIFICATIONS
DRAWING NUMBER: 5101
FORMAT: N/A

ARTWORK IS ACTUAL SIZE
ALL COPY PRINTS100% BLACK UNLESS OTHERWISE SPECIFIED
DROPS KEYLINES AND COLOR CALLOUTS BEFORE PROCESSING
COPY IS SHOWN AT 80% OF ACTUAL SIZE

PLATFORM: MAC - QUARKXPRESS 4.0

INSERT, PENCIL FOLD
4-1/2" X 7"
0005101 A

INK BLACK

also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement.

Studies have also shown that smokers had a higher incidence of adverse reactions.

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

To avoid contamination, do not touch the dropper tip of the bottle to any surface. Replace cap after using.

PRECAUTIONS:
Keep bottle tightly closed when not in use. Store at room temperature. Use before the expiration date marked on the bottle and carton. Keep out of the reach of children.

ADVERSE REACTIONS (POSSIBLE PROBLEMS) AND WHAT TO DO:
The following may occur:

- Eyes stinging, burning, or itching
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (visual acuity)
- Blurred vision
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above, IMMEDIATELY remove and examine your lenses.

If a lens appears to be damaged, do not reapply; consult your eye care practitioner. If the problem stops and the lenses appear to be undamaged, follow the "Directions" below, before reapplying the lens.

If the problem continues, IMMEDIATELY remove your lenses, discontinue use of all lens care products that contact the eye, and consult your eye care practitioner.

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

DIRECTIONS:
To help prevent and remove protein build-up, To lubricate and rewet your lenses and ~~to relieve minor irritation, discomfort, dryness, blurring and itchiness~~, apply one or two drops to each eye, ~~up to~~ four times per day, then blink several times.

If you require more frequent in-the-eye use of **COMPLETE® Blink-N-Clean®** Lens Drops to maintain comfortable lens wear, this may signify a condition that should be evaluated by your eye care practitioner.

HOW SUPPLIED:
COMPLETE® Blink-N-Clean® Lens Drops is supplied in sterile 20 mL plastic bottles. The bottles are marked with the lot number and expiration date.

~~January~~ Revised ~~July 2003~~ April 2004

Distributed by:
Advanced Medical Optics, Inc.
Santa Ana, CA 92705 U.S.A.

July 2004 September 2004
~~71656US10M~~ C
8772X

AMO ADVANCED MEDICAL OPTICS — Worldwide Specifications *Labeling and Packaging*

ARTWORK SPECIFICATIONS

PART #: 71656US10M *DRAWING #:* 5101

	FINAL APPROVAL	DATE
WW Labeling/Packaging Coordinator		7/1/03
Marketing		7/7/03
Regulatory Affairs Labeling Compliance		7/10/03
LCR Requestor		

YOUR SIGNATURE IS REQUIRED.
If signatures are NOT present, this document is NOT valid.

FDA Telephone Contact

Date: September 9, 2004

Product: Blink-N-Clean

Application # K040839

FDA Participants: Jim Saviola, OD, Jimmy Chen, PhD

AMO Participants: Paul Nowacki, Peter Xu

Discussion

(b)(4) Confidential and Proprietary Information

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2004

Advanced Medical Optics
c/o Mr. Paul Nowacki
Manager, World Regulatory Affairs and Medical Compliance
1700 E. St. Andrew Place
P.O. Box 25162
Santa Ana, CA 92799-5162

Re: K040839
Trade/Device Name: Complete® Blink-N-Clean® Lens Drops
Regulation Number: 21 CFR 886.5918; 21 CFR 886.5928
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC; LPN
Dated: August 13, 2004
Received: August 17, 2004

Dear Mr. Nowacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

1

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER:
(IF KNOWN): _____

DEVICE NAME: COMPLETE® BLINK-N-CLEAN® Lens Drops

INDICATIONS FOR USE:

- COMPLETE® BLINK-N-CLEAN® Lens Drops is indicated to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses, as well as rigid gas permeable lenses before application and during wear.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K040839

DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ 401)
9200 Corporate Blvd
Rockville, Maryland 20850

August 17, 2004

ADVANCED MEDICAL OPTICS, INC.
1700 E. ST. ANDREW PLACE
P.O. BOX 25162
SANTA ANA, CA 92799
ATTN: PAUL J. NOWACKI

510(k) Number: K040839
Product: COMPLETE BLINK-N-CLEAN LENS DROPS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 15, 2004

ADVANCED MEDICAL OPTICS, INC.
1700 E. ST. ANDREW PLACE
P.O. BOX 25162
SANTA ANA, CA 92799
ATTN: PAUL J. NOWACKI

510(k) Number: K040839
Product: COMPLETE
BLINK-N-CLEAN
LENS DROPS

Extended Until: 16-AUG-2004

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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AMO™
ADVANCED MEDICAL OPTICS

July 13, 2004

Document Mail Center (HFZ-401)
Office of Device and Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard.
Rockville, MD 20805

RE: **510K#: K040839**
Product: COMPLETE® BLINK-N-CLEAN® LENS DROPS

TO WHOM IT MAY CONCERN:

We are requesting an extension of 30 days to respond your letter of June 15, 2004 regarding our 510K submission, K040839.

Please feel free to contact me if you have any questions. Thank you.

Sincerely,

Paul Nowacki

Paul Nowacki
Manager
Worldwide Regulatory Affairs and Medical Compliance
Phone: 714-247-8601
Fax: 714-247-8677

SK25

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 15, 2004

ADVANCED MEDICAL OPTICS, INC.
1700 E. ST. ANDREW PLACE
P.O. BOX 25162
SANTA ANA, CA 92799
ATTN: PAUL J. NOWACKI

510(k) Number: K040839
Product: COMPLETE
BLINK-N-CLEAN
LENS DROPS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 31, 2004

ADVANCED MEDICAL OPTICS, INC.
1700 E. ST. ANDREW PLACE
P.O. BOX 25162
SANTA ANA, CA 92799
ATTN: PAUL J. NOWACKI

510(k) Number: K040839
Received: 31-MAR-2004
Product: COMPLETE
BLINK-N-CLEAN LENS
DROPS

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

1C040839

Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Confidential and Proprietary Information
Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

FDA/CDRH/OCE/DID 2004 MAR 31 A 11:36

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

ADVANCED MEDICAL OPTICS, INC.
1700 E. ST. ANDREWS PLACE
SANTA ANA, CA 92799-5162

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
330986820

2. CONTACT NAME
ART DAL CORSO

2.1 E-MAIL ADDRESS
art.dalcorso@amo-inc.com

2.2 TELEPHONE NUMBER (Include Area Code)
714-247-8592

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
714-247-8677

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:

- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologics License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:

- ☑ Original Application

Supplement Types:

- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- ☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- ☐ This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

OP II

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

- ☐ YES
- ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b) (4)

SK 17

Form FDA 3601 (08/2003)

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CDRH SUBMISSION COVER SHEET

COMPLETE®
BLINK-N-CLEAN®
Lens Drops

ABBREVIATED
510(k) NOTIFICATION

CDRH Submission Cover Sheet

Date of submission: March 30, 2004

FDA Document Number: K040839

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
❒ Original submission ❒ Modular submission ❒ Amendment ❒ Report ❒ Report Amendment	❒ Regular ❒ Special ❒ Panel Track ❒ 30-day Supplement ❒ 30-day Notice ❒ 135-day Supplement ❒ Real-time Review ❒ Amendment to PMA Supplement	❒ Presubmission summary ❒ Original PDP ❒ Notice of intent to start clinical trials ❒ Intention to submit Notice of Completion ❒ Amendment to PDP ❒ Report	■ Original submission ❒ Traditional ❒ Special ■ Abbreviated ❒ Additional information ❒ Traditional ❒ Special ❒ Abbreviated	❒ Pre-IDE meeting ❒ Pre-PMA meeting ❒ Pre-PDP meeting ❒ 180-day meeting ❒ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
❒ Original submission ❒ Amendment ❒ Supplement	❒ Original submission ❒ Amendment ❒ Supplement ❒ Report	❒ Original submission ❒ Additional information	❒ Original submission ❒ Additional information	Describe submission:

Section B — Applicant or Sponsor

Company/Institution name: Advanced Medical Optics, Inc.		Establishment registration number: 2020664
Division name (if applicable) N/A		Phone number (include area code): (714) 247-8609
Street address: 1700 E. St. Andrew Place, P.O. Box 25162		FAX number (include area code): (714) 247-8677
City: Santa Ana	State/Province: California 92799-5162	Country: USA
Contact name: Paul J. Nowacki		
Contact title: Manager, Regulatory Affairs		Contact e-mail address: paul.nowacki@amo-inc.com

Section C — Submission correspondent (if different from above)

Company/Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code):
Street address:		FAX number (include area code):
City:	State/Province:	Country:
Contact name:		
Contact title:		Contact e-mail address:

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Section D1 Reason for Submission – PMA, PDP, or HDE

- ❒ New device
- ❒ Withdrawal
- ❒ Additional or expanded indications
- ❒ Licensing agreement
- ❒ Change in design, component, or specification:
  - ❒ Software
- ❒ Color Additive
  - ❒ Material
  - ❒ Specifications
- ❒ Other (specify below)
- ❒ Location change:
  - ❒ Manufacturer
  - ❒ Sterilizer
  - ❒ Packager
  - ❒ Distributor
- ❒ Process change:
  - ❒ Manufacturing
  - ❒ Sterilization
  - ❒ Packaging
  - ❒ Other (specify below)
- ❒ Labeling change:
  - ❒ Indications
  - ❒ Instructions
  - ❒ Performance characteristics
- ❒ Shelf life
- ❒ Trade name
- ❒ Other (specify below)
- ❒ Report submissions:
  - ❒ Annual or periodic
  - ❒ Post-approval study
  - ❒ Adverse reaction
  - ❒ Device defect
  - ❒ Amendment
- ❒ Response to FDA correspondence:
  - ❒ Request for applicant hold
  - ❒ Request for removal of applicant hold
  - ❒ Request for extension
  - ❒ Request to remove or add manufacturing site
- ❒ Change in ownership
- ❒ Change in correspondent
- ❒ Other reason (specify):

Section D2 Reason for Submission – IDE

- ❒ New device
- ❒ Addition of institution
- ❒ Expansion/extension of study
- ❒ IRB certification
- ❒ Request hearing
- ❒ Request waiver
- ❒ Termination of study
- ❒ Withdrawal of application
- ❒ Unanticipated adverse effect
- ❒ Notification of emergency use
- ❒ Compassionate use request
- ❒ Treatment IDE
- ❒ Continuing availability request
- ❒ Change in:
  - ❒ Correspondent
  - ❒ Design
  - ❒ Informed consent
  - ❒ Manufacturer
  - ❒ Manufacturing process
  - ❒ Protocol - feasibility
  - ❒ Protocol - other
  - ❒ Sponsor
- ❒ Response to FDA letter concerning:
  - ❒ Conditional approval
  - ❒ Deemed approved
  - ❒ Deficient final report
  - ❒ Deficient progress report
  - ❒ Deficient investigator report
  - ❒ Disapproval
  - ❒ Request extension of time to respond to FDA
  - ❒ Request meeting
- ❒ Report Submission:
  - ❒ Current investigator
  - ❒ Annual progress
  - ❒ Site waiver limit reached
  - ❒ Final
- ❒ Other reason (specify):

Section D3 Reason for Submission – 510(k)

- ❒ New device
- ❒ Addition or expanded indications
- ■ Other reason (specify):
- ❒ Change in technology
- ❒ Change in design
- ❒ Change in materials
- ❒ Change in manufacturing process

Additional rigid gas permeable lens labeling claim

Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial Equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: ■ 510(k) summary attached ❒ 510(k) statement
1 LPN	2 MRC	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 PMA P910075/S7	1 COMPLETE® BLINK-N-CLEAN® Lens Drops	1 Advanced Medical Optics, Inc.
2	2	2
3	3	3
4	4	4

Section F — Product Information – Applicable to All Applications

Common or usual or classification name: LPN, Accessories, Soft Lens Products
MRC, Products, Contact Lens Care, Rigid Gas Permeable

Trade or proprietary or model name	Model number
1 COMPLETE® BLINK-N-CLEAN® Lens Drops	N/A
2	
3	
4	

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ■ Laboratory testing ❒ Animal trials ❒ Human trials

Section G — Product Classification – Applicable to All Applications

Product code:	C.F.R. section	Device class:
LPN MRC	21 CFR §886.5918 & 886.5928 (Reclassified July 7, 1997)	❒ Class I ■ Class II ❒ Class III ❒ Unclassified

Classification panel:
Ophthalmic Device Panel

Indications (from labeling):
COMPLETE® BLINK-N-CLEAN® Lens Drops is indicated to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses, as well as rigid gas permeable lenses before application and during wear.

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[redacted]	FDA Document Number:

Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

■ Original ❒ Add ❒ Delete	FDA establishment registration number: 8020862	■ Manufacturer ❒ Contract manufacturer ❒ Contract sterilizer ❒ Repackager/relabeler

(b)(4) Confidential and Proprietary Information

[redacted]

❒ Original ❒ Add ❒ Delete	FDA establishment registration number:	❒ Manufacturer ❒ Contract manufacturer ❒ Contract sterilizer ❒ Repackager/relabeler

Company/Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		Fax number (include area code):	
City:	State/Province:	Country:	ZIP/Postal Code:
Contact name:			
Contact title:		Contact e-mail address:	

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ABBREVIATED PREMARKET NOTIFICATION 510(K)

COMPLETE® BLINK-N-CLEAN® Lens Drops

AMO
ADVANCED MEDICAL OPTICS

March 30, 2004

510k Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: Abbreviated 510(k): COMPLETE® BLINK-N-CLEAN® Lens Drops
Rigid Gas Permeable (RGP) Lens Claim

TO WHOM IT MAY CONCERN:

(b)(4) Confidential and Proprietary Information

[redacted]

We ask that the existence of this 510(k) be kept confidential for at least 90 days since the intent to market with the claim covered by this 510(k) has been kept confidential and no disclosures have been made. FDA will be immediately notified of any disclosure of intent to market.

To the best of my knowledge, all data and information submitted in this premarket notification are truthful and accurate; no material fact has been omitted. An FDA Truthful and Accurate Statement form can be found in Section 8.

Sincerely,

Paul J. Nowacki

Paul J. Nowacki
Manager
Regulatory Affairs

Phone: 714-247-8601
Fax: 714-247-8677
EMail: paul.nowacki@amo-inc.com

510(K) NOTIFICATION
TABLE OF CONTENTS

COMPLETE® BLINK-N-CLEAN® Lens Drops

Section	Content
1	510(k) Summary
2	Lens Compatibility Test Report
3	Draft Labeling
4	Indications for Use
5	Truthful and Accurate Statement

AMO
ADVANCED MEDICAL OPTICS

510(k) SUMMARY

COMPLETE® BLINK-N-CLEAN® Lens Drops

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

Paul J. Nowacki
Manager
Regulatory Affairs
Advanced Medical Optics
1700 E. St. Andrew Place
Santa Ana, CA 92799-5162

Phone: (714) 247-8601
Fax: (714) 247-8677
EMail: paul.nowacki@amo-inc.com

Summary Prepared: March 2004

(a)(2) **Device Trade Name:** COMPLETE® BLINK-N-CLEAN® Lens Drops

Device Common Name: Soft (Hydrophilic) and Rigid Gas Permeable Contact Lens Solution

Device Classification/Panel: Class II (Special Controls)/Ophthalmic Device

Device Classification Names: Accessories, Soft Lens Products (LPN) Products, Contact Lens Care, Rigid Gas Permeable (MRC)

(a)(3) **Identification of Predicate Device:** COMPLETE® BLINK-N-CLEAN® Lens Drops is the same as the currently-marketed lens drops and substantially equivalent to other lubricating and rewetting drop products.

(a)(4) **Device Description:** COMPLETE® BLINK-N-CLEAN® Lens Drops is a sterile, isotonic, buffered, solution containing lubricants, preservatives, buffers, surfactants, ancillary ingredients, and purified water.

The product is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use):** COMPLETE® BLINK-N-CLEAN® Lens Drops is indicated to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses, as well as rigid gas permeable lenses before application and during wear.

(a)(6) **Comparison of Technological Characteristics:** The technological characteristics of the product remain the same.

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510(k) SUMMARY
COMPLETE® BLINK-N-CLEAN® Lens Drops
March 2004

(b)(1) **Discussion of Nonclinical Studies:**

COMPLETE® BLINK-N-CLEAN® Lens Drops was evaluated for compatibility with silicone acrylate lenses and fluorosilicone acrylate rigid gas permeable (RGP) lenses during thirty (30) regimen cycles. Average changes in diameter, power and base curve for the test lenses were within established acceptance criteria, with test lenses showing a trend comparable to that of the controls. In addition, visual observations did not show evidence of surface deposits, discoloration and/or deformities. Based on these results, BLINK-N-CLEAN® Lens Drops is compatible with all RGP contact lenses.

Other preclinical safety and efficacy criteria were established in P910075/S7.

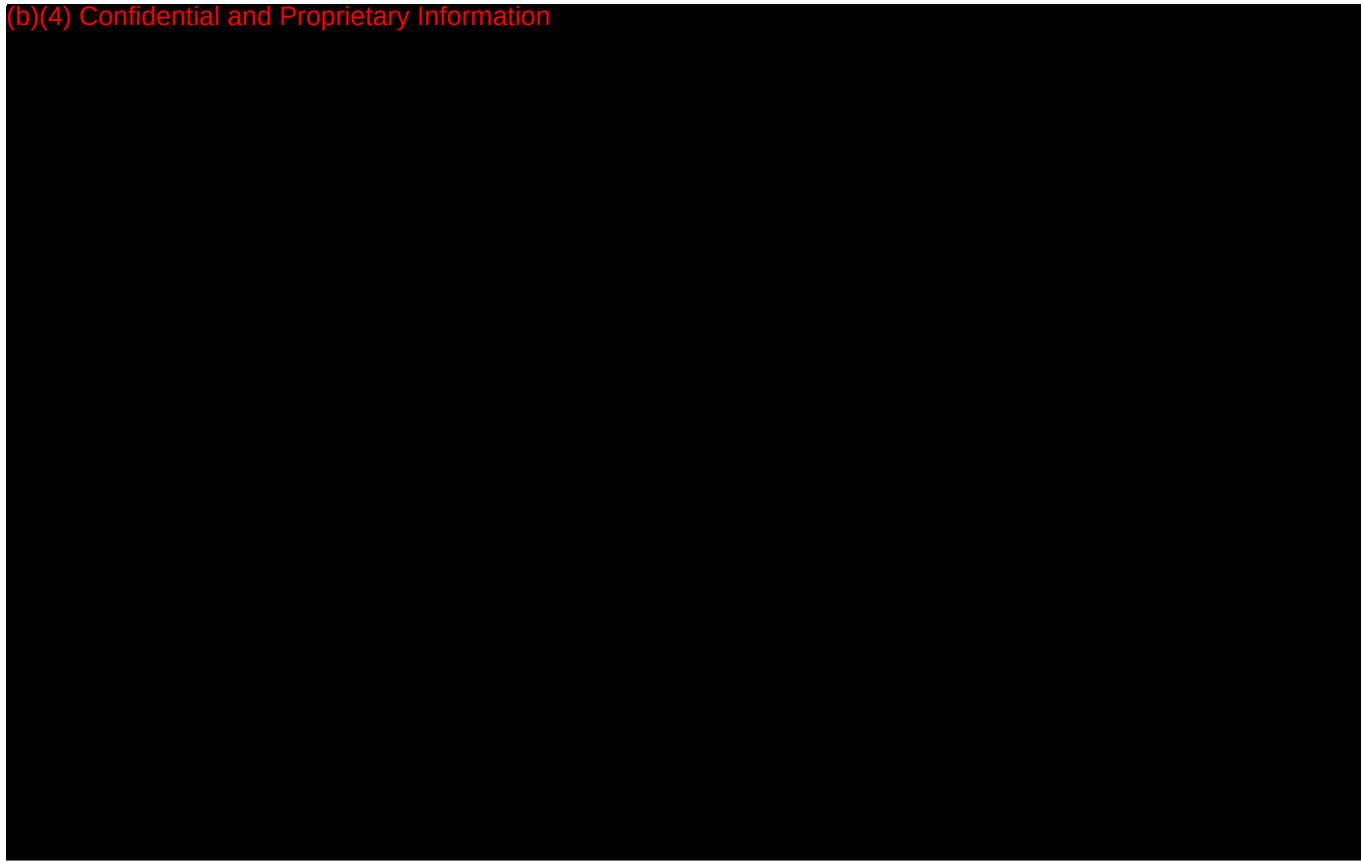
(b)(2) **Clinical:**

Clinical safety and acceptability of COMPLETE® BLINK-N-CLEAN® Lens Drops was established in 910075/S7.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:**
The safety, efficacy and performance of COMPLETE® BLINK-N-CLEAN® Lens Drops is substantially equivalent to other contact lens care lubricating and rewetting drops currently on the market.

LENS COMPATIBILITY

(b)(4) Confidential and Proprietary Information



ADVANCED MEDICAL OPTICS

(b)(4) Confidential and Proprietary Information

Lens Compatibility Study of Blink-N-Clean® Lens Drops (8772X) with RGP Contact Lenses for Regulatory Registration

Technical Report No.: 2477

ISSUED: Date of Last Signatory

(b)(4) Confidential and Proprietary Information

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3.0 MATERIALS/EQUIPMENT..... 4
4.0 PROCEDURES..... 4
5.0 RESULTS..... 4
6.0 DISCUSSION..... 4
7.0 CONCLUSION..... 4
8.0 REFERENCES..... 4
9.0 APPENDICES..... 5

(b)(4) Confidential and Proprietary Information - Technical Report

(b)(4) Confidential and Proprietary Information - Technical Report

(b)(4) Confidential and Proprietary Information - Technical Report

(b)(4) Confidential and Proprietary Information - Technical Report

(b)(4) Confidential and Proprietary Information - Technical Report

(b)(4) Confidential and Proprietary Information - Technical Report

Attachment I

Protocol for the Compatibility Study of Blink-N-Clean® Lens Drops, 8772X, with RGP Contact Lenses for Regulatory Registration

November 2003

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ADVANCED MEDICAL OPTICS

(b)(4) Confidential and Proprietary Information

Protocol for the Compatibility Study of Blink-N-Clean® Lens Drops, 8772X, with RGP Contact Lenses for Regulatory Registration

ISSUED: Date of Last Signature

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

Draft Labeling

COMPLETE®
BLINK-N-CLEAN®
Lens Drops

AMO™
ADVANCED MEDICAL OPTICS

Important - Please read carefully and keep this package insert for future reference.

COMPLETE® Blink-N-Clean® Lens Drops

For use with soft (hydrophilic) contact lenses, including disposable lenses and extended wear lenses.

DESCRIPTION:
COMPLETE® Blink-N-Clean® Lens Drops is a sterile, isotonic, buffered, preserved solution. This aqueous formulation includes purified water, sodium chloride, preserved with polyhexamethylene biguanide 0.0001%, tromethamine as an emulsifier and buffer, hydroxypropyl methylcellulose as a lubricant, tyloxapol as a surfactant, and edetate disodium as a chelating agent. This preparation contains no chlorhexidine, no thimerosal and no other mercury containing ingredients.

ACTIONS:
COMPLETE® Blink-N-Clean® Lens Drops lubricates and rewets lenses, helps prevent protein film build-up, helps to remove particulate material that may cause irritation and/or discomfort. Use **COMPLETE® Blink-N-Clean®** Lens Drops to promote lens cleanliness during wear, to rewet lenses before insertion and lubricate lenses during wear to moisten and reduce lens friction against the cornea. When wearing extended wear lenses, use **COMPLETE® Blink-N-Clean®** Lens Drops to moisten lenses before retiring and upon awakening.

INDICATIONS:
COMPLETE® Blink-N-Clean® Lens Drops is indicated for use to lubricate and rewet soft ~~(hydrophilic) contact lenses~~, disposable and extended wear lenses, daily wear ; and RGP contact lenses.

CONTRAINDICATIONS (REASONS NOT TO USE):
If you are allergic to any ingredient in **COMPLETE® Blink-N-Clean®** Lens Drops, do not use this product.

WARNINGS:
PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens case. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION.**

Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care practitioner.

Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have

AMO WORLDWIDE SPECIFICATIONS
DRAWING NUMBER: 5101
FORMAT: N/A

ARTWORK IS ACTUAL SIZE
ALL COPY PRINTS100% BLACK UNLESS OTHERWISE SPECIFIED
DROPS KEYLINES AND COLOR CALLOUTS BEFORE PROCESSING
COPY IS SHOWN AT 80% OF ACTUAL SIZE

PLATFORM: MAC - QUARKXPRESS 4.0

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4-12 X 7
0805101 A

INK BLACK

104

also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement.

Studies have also shown that smokers had a higher incidence of adverse reactions.

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

To avoid contamination, do not touch the dropper tip of the bottle to any surface. Replace cap after using.

PRECAUTIONS:
Keep bottle tightly closed when not in use. Store at room temperature. Use before the expiration date marked on the bottle and carton. Keep out of the reach of children.

ADVERSE REACTIONS (POSSIBLE PROBLEMS) AND WHAT TO DO:
The following may occur:

- Eyes stinging, burning, or itching
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (visual acuity)
- Blurred vision
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above, IMMEDIATELY remove and examine your lenses.

If a lens appears to be damaged, do not reapply; consult your eye care practitioner. If the problem stops and the lenses appear to be undamaged, follow the "Directions" below, before reapplying the lens.

If the problem continues, IMMEDIATELY remove your lenses, discontinue use of all lens care products that contact the eye, and consult your eye care practitioner.

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

DIRECTIONS:
To lubricate and rewet your lenses and to relieve minor irritation, discomfort, dryness, blurring and itchiness, apply one or two drops to each eye, up to four times per day, then blink several times.

If you require more frequent in-the-eye use of **COMPLETE® Blink-N-Clean®** Lens Drops to maintain comfortable lens wear, this may signify a condition that should be evaluated by your eye care practitioner.

HOW SUPPLIED:
COMPLETE® Blink-N-Clean® Lens Drops is supplied in sterile 20 mL plastic bottles. The bottles are marked with the lot number and expiration date.

Revised ~~July 2003~~ March, April 2004

Distributed by:
Advanced Medical Optics, Inc.
Santa Ana, CA 92705 U.S.A.

71656US~~10M~~
8772X

AMO ADVANCED MEDICAL OPTICS — Worldwide Specifications *Labeling and Packaging*

ARTWORK SPECIFICATIONS

PART #: 71656US10M *DRAWING #:* 5101

	FINAL APPROVAL	DATE
WW Labeling/Packaging Coordinator		7/1/03
Marketing		7/7/03
Regulatory Affairs Labeling Compliance		7/10/03
LCR Requestor		

YOUR SIGNATURE IS REQUIRED.
If signatures are NOT present, this document is NOT valid.

105

LABEL, PRESSURE SENSITIVE
1-1/16" X 1-9/16"

0009804

AMO WORLDWIDE SPECIFICATIONS
DRAWING NUMBER: 0009804
FORMAT: N/A
ARTWORK IS ACTUAL SIZE DROP KEYLINES AND CALLOUTS BEFORE PROCESSING COPY IS SHOWN AT150% PLATFORM: MAC - ILLUSTRATOR 8.0

IN	PMS 109	PMS 072	BLACK	PROCESS CYAN	COATING(S)

AMO ADVANCED MEDICAL OPTICS

Worldwide Specifications
Labeling and Packaging

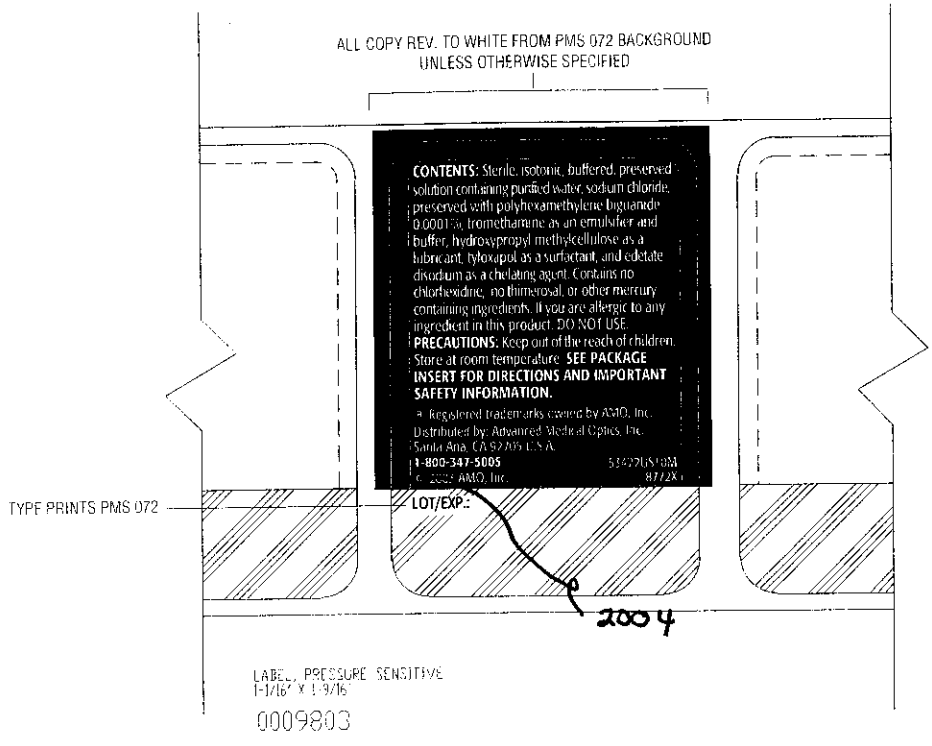
ARTWORK SPECIFICATIONS

PART #: **53421US10M** ***DRAWING #:*** **0009804**

	FINAL APPROVAL	DATE
WWLabeling/Packaging Coordinator	L. Ramos	6/27/03
Marketing	L. Mue	7/7/03
Regulatory Affairs Labeling Compliance	[illegible]	7/16/03

YOUR SIGNATURE IS REQUIRED.
If signatures are NOT present, this document is NOT valid.

106



AMO WORLDWIDE SPECIFICATIONS
DRAWING NUMBER: 0009803 **FORMAT: N/A**
ARTWORK IS ACTUAL SIZE DROP KEYLINES AND CALLOUTS BEFORE PROCESSING COPY IS SHOWN AT100% PLATFORM: MAC - ILLUSTRATOR 8.0

INK	PMS 072	COATING(S)

AMO ADVANCED MEDICAL OPTICS — Worldwide Manufacturing Support
Labeling and Packaging

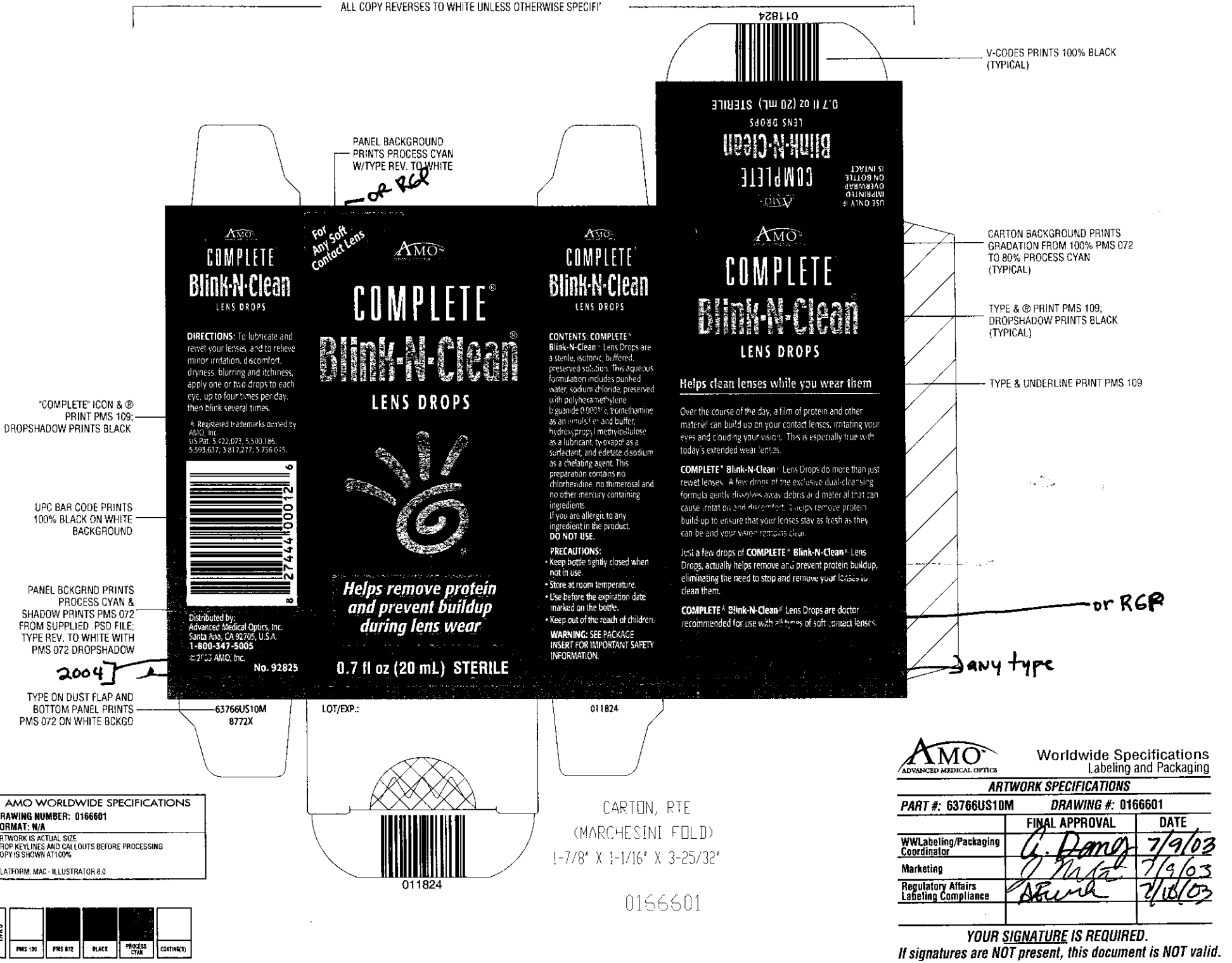
ARTWORK SPECIFICATIONS

PART #: **53422US10M** ***DRAWING #:*** **9803**

	FINAL APPROVAL	DATE
WW Labeling/Packaging Coordinator		7/1/03
Marketing		7/7/03
Regulatory Affairs Labeling Compliance		7/10/03

YOUR SIGNATURE IS REQUIRED.
If signatures are NOT present, this document is NOT valid.

107



AMO WORLDWIDE SPECIFICATIONS
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FORMAT: N/A
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PLATFORM: MAC - ILLUSTRATOR 8.0

INKS	PMS 109	PMS 072	BLACK	PROCESS CYAN	COATING(S)

AMO ADVANCED MEDICAL OPTICS

Worldwide Specifications
Labeling and Packaging

ARTWORK SPECIFICATIONS

PART #: **63766US10M** ***DRAWING #:*** **0166601**

	FINAL APPROVAL	DATE
WWLabeling/Packaging Coordinator	G. Dang	7/9/03
Marketing	J. Nate	7/9/03
Regulatory Affairs Labeling Compliance	A Brunk	7/10/03

YOUR SIGNATURE IS REQUIRED.
If signatures are NOT present, this document is NOT valid.

Indications for Use

COMPLETE®
BLINK-N-CLEAN®
Lens Drops

510(k) NUMBER:
(IF KNOWN): _____

DEVICE NAME: COMPLETE® BLINK-N-CLEAN® Lens Drops

INDICATIONS FOR USE:

- COMPLETE® BLINK-N-CLEAN® Lens Drops is indicated to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses, as well as rigid gas permeable lenses before application and during wear.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

_____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109 (Optional Format 1-2-96)

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PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(j)]

I certify that, in my capacity as Vice President, Worldwide Regulatory Affairs, Advanced Medical Optics, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Paul J. Nowacki
(Signature)

Paul J. Nowacki
(Typed Name)

March 30, 2004
(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

111

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Teng M. Chen

Subject: 510(k) Number K040839/S001

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☐ YES	☒ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☒ YES	☐ NO

Truthful and Accurate Statement ☐ Requested ☐ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 day

Predicate Product Code with class: MRC LPN Class II Ophthalmic

Additional Product Code(s) with panel (optional): 21 CFR 886.5918 and 21 CFR 886.5928

Review: [signature] 1583 10/18/04
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] 10/18/04
(Division Director) (Date)

Revised:4/2/03

Chen, Tzeng M.

From: XU, Peter [Peter.XU@amo-inc.com]
Sent: Monday, October 04, 2004 1:59 PM
To: Chen, Tzeng M.
Cc: Nowacki, Paul; Schaub, Pam
Subject: RE: B-N-C Labeling Changes

Hello Dr. Chen,

Further to our conversations this morning, please review the attached labeling. Please call me if we need to make further changes.
Regards,
Peter Xu

-----Original Message-----
From: Chen, Tzeng M. [mailto:TMC@CDRH.FDA.GOV]
Sent: Friday, October 01, 2004 11:36 AM
To: Nowacki, Paul
Cc: XU, Peter
Subject: RE: B-N-C Labeling Changes

Paul,

We have two items:

(b)(4) Confidential and Proprietary Information

[redacted]

19

(b)(4) Confidential and Proprietary Information

[redacted]

In addition, 510(K) Summary should be revised to reflect additional data submitted in the supplement.

Jim Saviola, OD
CAPT US PHS
Chief VEDB/DOED
301-594-1744

-----Original Message-----
From: Nowacki, Paul [mailto:Paul.Nowacki@amo-inc.com]
Sent: Thursday, September 16, 2004 4:45 PM
To: Jim Saviola; tzeng.chen@fda.hhs.gov
Cc: Funk, Avery; XU, Peter; Schaub, Pam
Subject: FW: B-N-C Labeling Changes
Importance: High

Dear Jim and Jimmy,

The first attachment contains the Blink-N-Clean® labeling incorporating your requested changes. Our Marketing group (Richard Scott) agreed to your changes! Unfortunately, the blue box with white letters did not scan very well. It is more legible on screen if you magnify the image.

Because the scanned labeling is not the best quality, I have also attached our internal memo regarding our teleconference on 9 Sep 04.

Let me what are the next steps.

Thanks,

Paul

21

and RGP

help prevent and remove Protein build-up

E ICON & G
NT PMS 109
NTS BLACK

ODE PRINTS
K ON WHITE
CKGROUND

ND PRINTS
ESS CYAN &
TS PMS 072
D PSD FILE:
WHITE WITH
OPSHADOW

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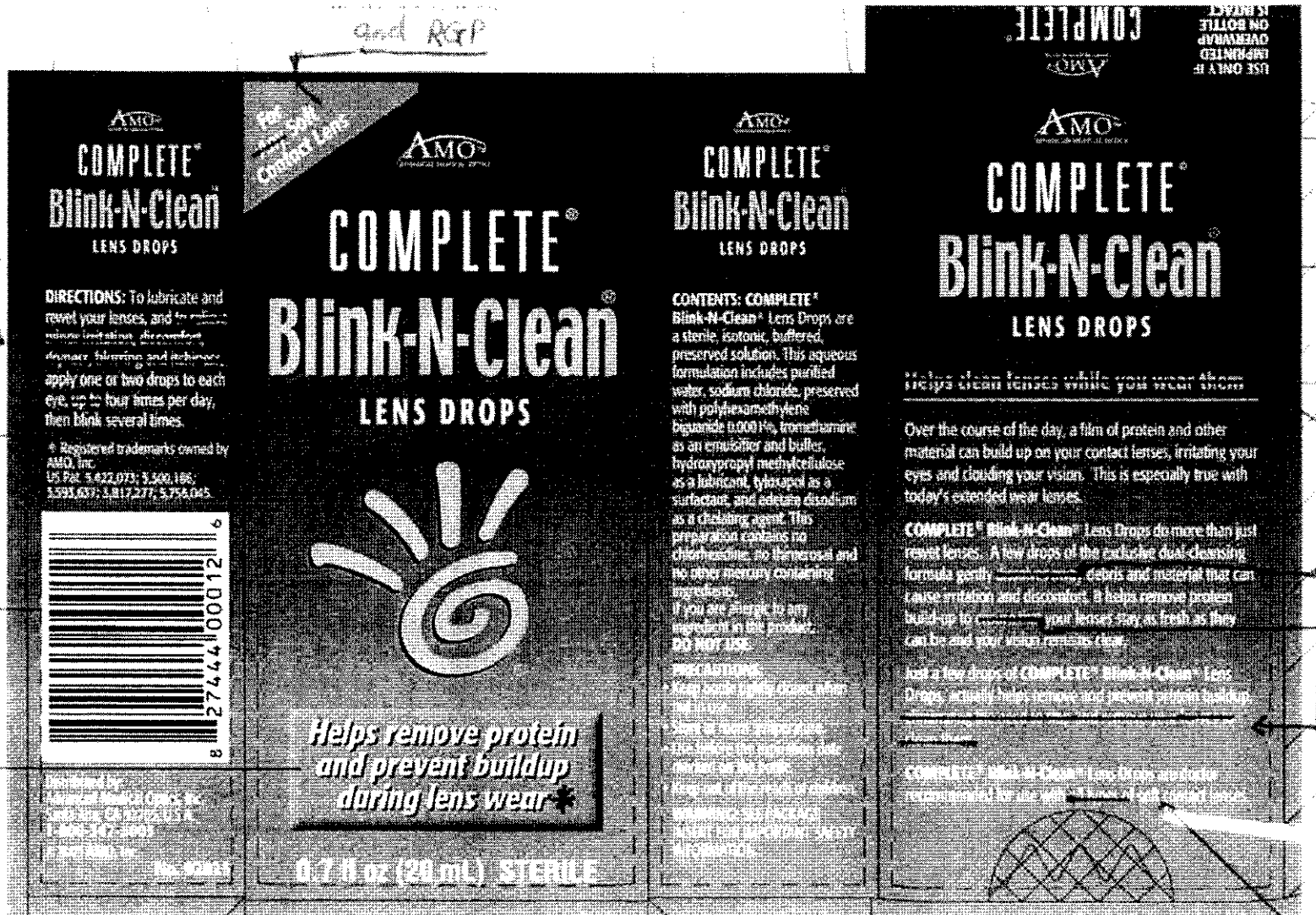

Help keep lens clean while wear them

Removes

Keep

It is not a substitute for the cleaning disinfecting solution when you remove your lenses.

and RGP

22

510(k) SUMMARY

COMPLETE® BLINK-N-CLEAN® Lens Drops

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

Paul J. Nowacki
Manager
Regulatory Affairs
Advanced Medical Optics
1700 E. St. Andrew Place
Santa Ana, CA 92799-5162

Phone: (714) 247-8601
Fax: (714) 247-8677
EMail: paul.nowacki@amo-inc.com

Summary Prepared: September 30, 2004

(a)(2) **Device Trade Name:** COMPLETE® BLINK-N-CLEAN® Lens Drops

Device Common Name: Soft (Hydrophilic) and Rigid Gas Permeable Contact Lens Solution

Device Classification/Panel: Class II (Special Controls)/Ophthalmic Device

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(a)(6) **Comparison of Technological Characteristics:** The technological characteristics of the product remain the same.

510(k) SUMMARY
COMPLETE® BLINK-N-CLEAN® Lens Drops
March 2004

(b)(1) **Discussion of Nonclinical Studies:**

COMPLETE®BLINK-N-CLEAN® Lens Drops was evaluated for compatibility with silicone acrylate lenses and fluorosilicone acrylate rigid gas permeable (RGP) lenses during thirty (30) regimen cycles. Average changes in diameter, power and base curve for the test lenses were within established acceptance criteria, with test lenses showing a trend comparable to that of the controls. In addition, visual observations did not show evidence of surface deposits, discoloration and/or deformities. Based on these results, COMPLETE® BLINK-N-CLEAN® Lens Drops is compatible with all RGP contact lenses.

In addition, a study for quantifying surface protein accumulation on human-worn contact lenses and subsequent protein removal in simulated in-eye use of lens rewetter products has been conducted. The results show that COMPLETE® BLINK-N-CLEAN® Lens Drops removal significant amount of protein than the predicate devices.

Other preclinical safety and efficacy criteria were established in P910075/S7.

(b)(2) **Clinical:**

Clinical safety and acceptability of COMPLETE® BLINK-N-CLEAN® Lens Drops was established in 910075/S7.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** The safety, efficacy and performance of COMPLETE® BLINK-N-CLEAN® Lens Drops is substantially equivalent to other contact lens care lubricating and rewetting drops currently on the market.

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Chen, Tzeng M.

To: Nowacki, Paul
Cc: peter.xu@amo-inc.com
Subject: RE: B-N-C Labeling Changes

Paul,

We have two items:

(b)(4) Confidential and Proprietary Information

[redacted]

25

(b)(4) Confidential and Proprietary Information

In addition, 510(K) Summary should be revised to reflect additional data submitted in the supplement.

Jim Saviola, OD
CAPT US PHS
Chief VEDB/DOED
301-594-1744

-----Original Message-----
From: Nowacki, Paul [mailto:Paul.Nowacki@amo-inc.com]
Sent: Thursday, September 16, 2004 4:45 PM
To: Jim Saviola; tzeng.chen@fda.hhs.gov
Cc: Funk, Avery; XU, Peter; Schaub, Pam
Subject: FW: B-N-C Labeling Changes
Importance: High

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Because the scanned labeling is not the best quality, I have also attached our internal memo regarding our teleconference on 9 Sep 04.

Let me what are the next steps.

Thanks,

Paul

26

Telephone Memo

Date: September 9, 2004

Product: Blink-N-Clean

Application: K040839

Between FDA Jim Saviola, OD
Tzeng M. Chen, Ph.D.

And AMO Paul Nowacki
Peter Xu

FDA initiated a call to AMO representatives to discuss the following carton labeling issues for K040839:

(b)(4) Confidential and Proprietary Information

[redacted]

27

(b)(4) Confidential and Proprietary Information

[redacted]

Yzeng M. Chen, Ph.D.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Document #: K040839 and K040839/S001

Reviewer: Team Leader/Chemist

Division/Branch: DOED/VEDB

Device Name: Complete Brink-N-Clean Lens Drops

Product To Which Compared (510(K) Number If Known): Alcon Clerz Plus Lubricating & Rewetting Drops (K984573)

		YES	NO	
1.	Is Product A Device	x		If **NO** = Stop
2.	Is Device Subject To 510(k)?	x		If **NO** = Stop
3.	Same Indication Statement?	x		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5.	Same Technological Characteristics?		x	If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?		x	If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?	x		If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?				If **NO** = Request Data
11. Data Demonstrate Equivalence?		x		Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

Complete [R] Brink-N-Clean [R] Lens Drops is indicated for use to lubricate and rewet soft disposal and extended wear lenses; and RGP contact lenses.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement.

Is the device life-supporting or life sustaining? No
Is the device implanted (short-term or long-term)? No
Does the device design use software? No
Is the device sterile? Yes
Is the device for single use? No
Is the device over-the-counter or prescription use? Over the counter
Does the device contain drug or biological product as a component? No
Is this device a kit? No
Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

[redacted]

Tzeng M. Chen, Ph.D. 10/4/04

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device: NA

2. Explain why not subject to 510(k); NA

3. How does the new indication differ from the predicate device's indication: NA

4. Explain why there is or is not a new effect or safety or effectiveness issue: NA

5. Describe the new technological characteristics: Different chemical formula for the subject device, compared to the predicate device.

6. Explain how new characteristics could or could not affect safety or effectiveness: NA

7. Explain how descriptive characteristics are not precise enough: NA

8. Explain new types of safety or effectiveness questions raised or why the questions are not new: NA

9. Explain why existing scientific methods can not be used: NA

10. Explain what performance data is needed: NA

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: Based on solution compatibility and in-vitro cleaning effectiveness for the human worn lenses, substantial equivalence is recommended.

ATTACH ADDITIONAL SUPPORTING INFORMATION

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K040839

Standard Organization No:
or
Standard Identification No:
or
CDRH Internal Reference No:

Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products, issued May 1, 1997.

Declaration of Conformity Elements:		
Any Adaptations Applied	(yes)	no
Any Requirements Not Applicable	yes	(no)
Any Deviations Applied	yes	(no)
Any Differences in Device Tested and Finished Product	yes	(no)
*Is There a Third Party or Test Lab Involved	yes	(no)

Was there another standard used in the review of this submission? yes (no)

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

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Indications for Use

510(k) NUMBER:
(IF KNOWN): _____

DEVICE NAME: COMPLETE® BLINK-N-CLEAN® Lens Drops

INDICATIONS FOR USE:

- COMPLETE® BLINK-N-CLEAN® Lens Drops is indicated to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses, as well as rigid gas permeable lenses before application and during wear.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K040839

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes? N/A		
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K040839

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box):**

☐ Special 510(k) - Do Sections 1 and 2

☒ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	NA	
Class III Certification and Summary. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA	
510(k) Kit Certification ***	NA	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)	✓	
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]	NA	

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For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.	NA	
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.	NA	
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.	NA	
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.	NA	

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	✓	
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:	NA	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No

Reviewer: [signature]

Concurrence by Review Branch: [signature]

Date: 8/27/04

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) TZENG M. CHEN

Subject: 510(k) Number K040839

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☐ YES	☒ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☒ YES	☐ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices NA

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ N

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

MRC Class II Ophthalmic 21 CFR 886.5918 and 21 CFR 886.5928
LPN

Review: [signature] (Branch Chief) VSDR (Branch Code) 6/14/04 (Date)

Final Review: [signature] for DSD (Division Director) 6/14/04 (Date)

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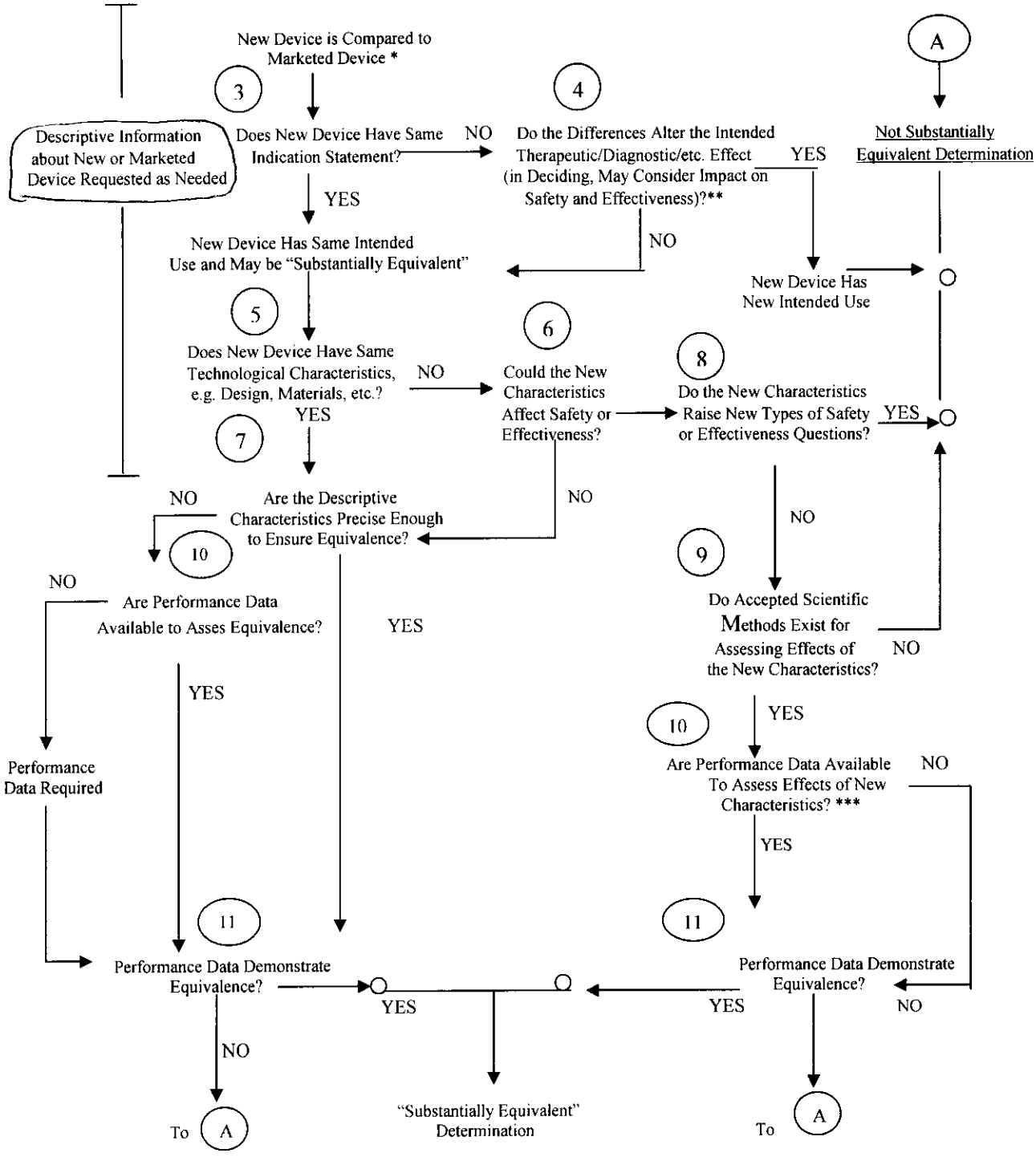
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	4267
CONNECTION TEL	917142478677
SUBADDRESS	
CONNECTION ID	
ST. TIME	06/10 15:50
USAGE T	00'57
PGS.	2
RESULT	OK

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CDRH
Division of Ophthalmic and Ear, Nose and Throat Devices

9200 Corporate Boulevard
Rockville, MD 20850
FAX NO. 301 480-4201
or 301 827-4601
PHONE NO. 301 594-2205

Date: June 10, 2004 Time: 3.50 PM

To: Paul Nowacki Fax #: 714-247-8677

Organization: AMO

From: Tzeng M. Chen

Department: DOED/VEDB

Subject: K040839

No. of Pages (Including cover sheet): 2

Comments:

☐ As Requested ☐ FYI ☐ Read and Destroy

☒ Response Needed ☐ Signature ☐ Circulate

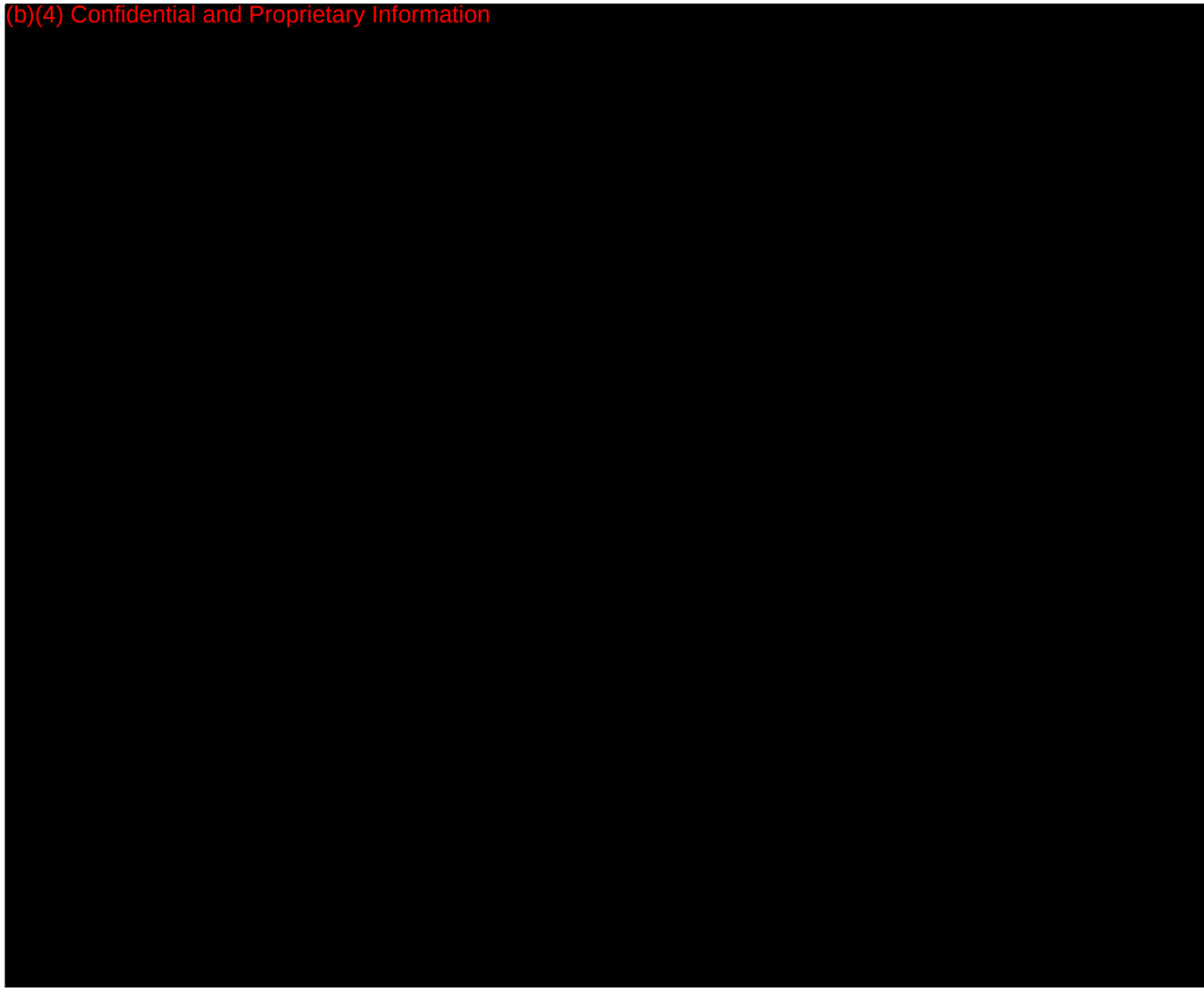
☐ For Correction ☐ Investigate ☐ File

LD

RE: Deficiencies for "Complete Blink-N-Clean Lens Drops" (K040839)

The following deficiencies were noted during the review:

(b)(4) Confidential and Proprietary Information



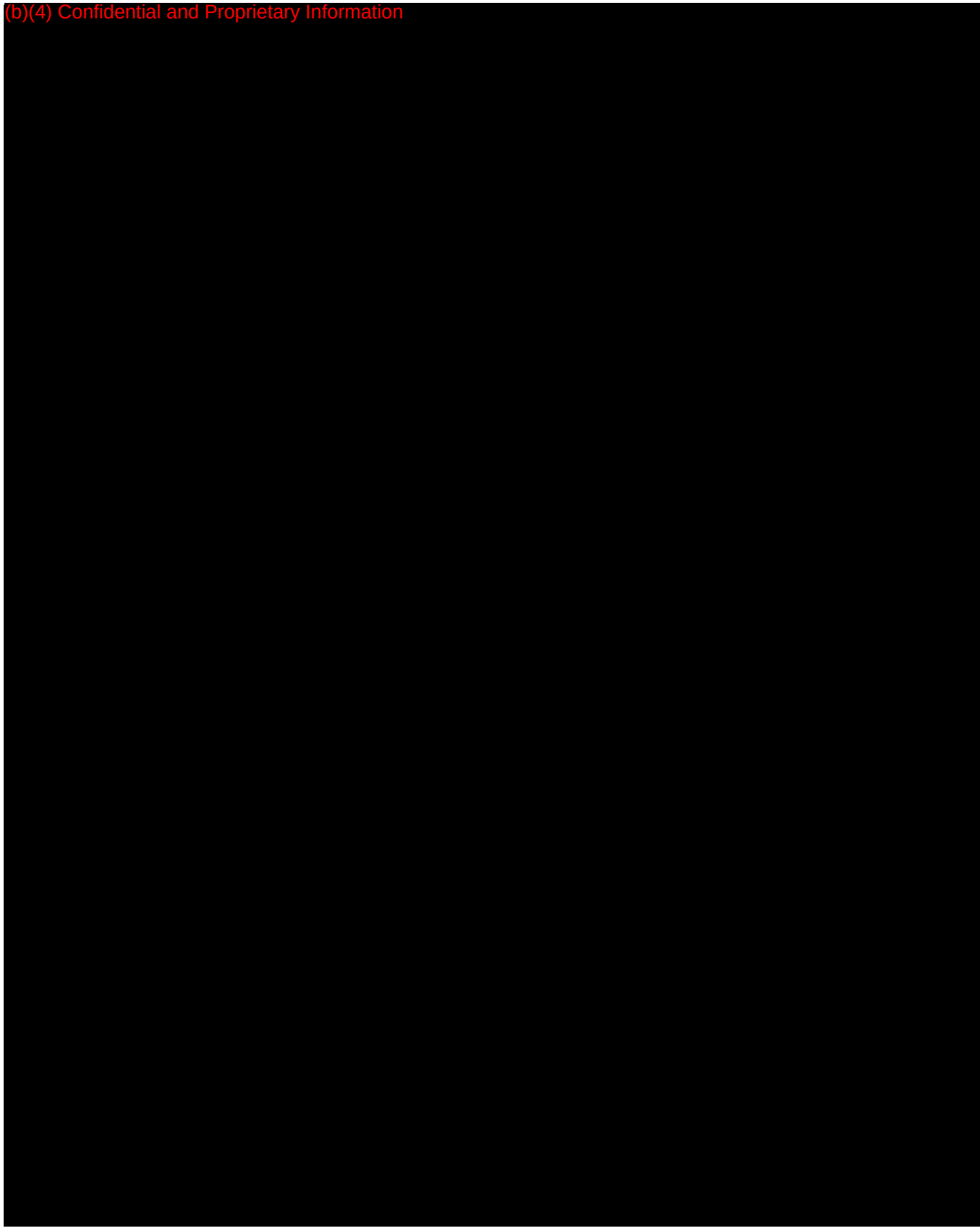
This submission will be on hold pending additional information.

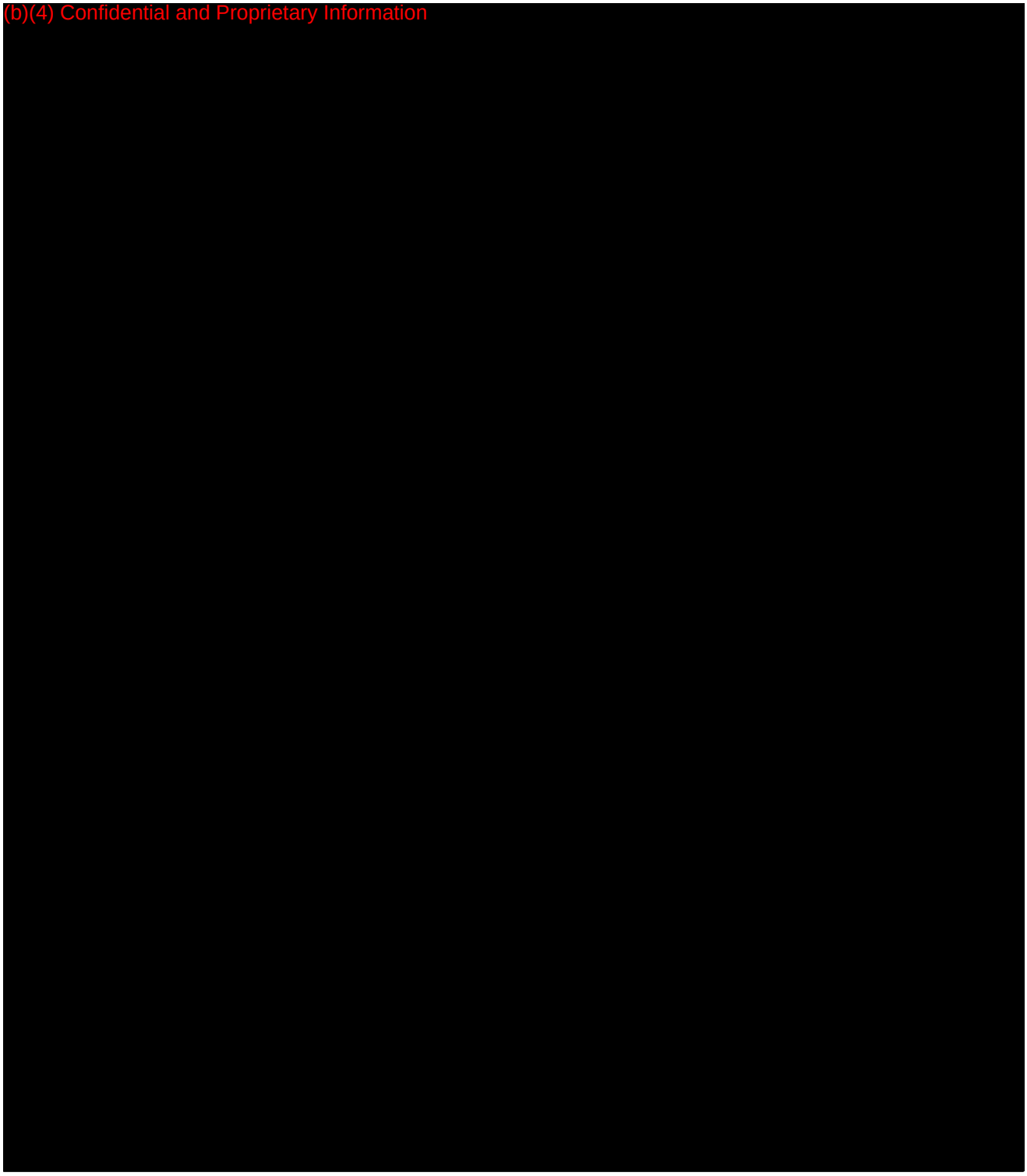
Tzeng M. Chen, Ph.D. 6/10/2004

b(

Team Leader Review for Complete-N-Clean Lens Drops, submitted by AMO (K040839)

(b)(4) Confidential and Proprietary Information





Recommendation

The following deficiencies were recommended to convey to the sponsor:

(b)(4) Confidential and Proprietary Information

[redacted]

This submission will be on hold pending additional information.

Tzeng M. Chen, Ph.D. 5/10/04

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Chen, Tzeng M.

From: Saviola, James
Sent: Monday, April 19, 2004 4:58 PM
To: Swann, Ronald L.
Cc: Chen, Tzeng M.; Whipple, David M.
Subject: FW: (b)(4) Confidential and Proprietary Information

Ron,

(b) (5)

[redacted]

Jim Saviola, OD
CAPT US PHS
Chief VEDB/DOED
301-594-1744

-----Original Message-----
From: Chen, Tzeng M.
Sent: Wednesday, April 14, 2004 1:49 PM
To: Swann, Ronald L.
Subject: (b)(4) Confidential and Proprietary Information

Dear Ron:

(b) (5)

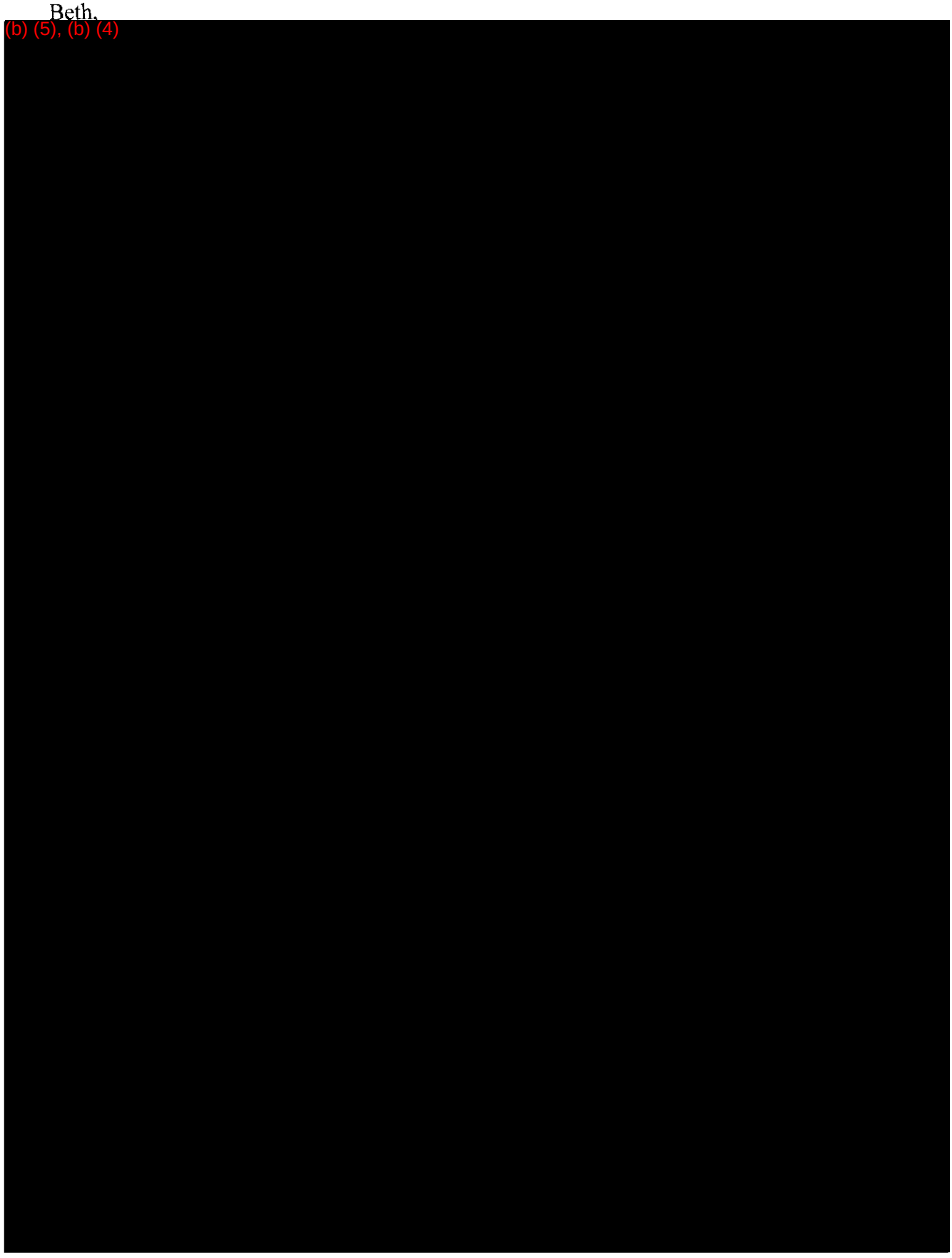
[redacted]

(b) (5)

[redacted]

Beth,

(b) (5), (b) (4)



(b) (5), (b) (4)

[redacted]

(b) (4), (b) (5)

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Mr. Paul J. Nowacki
Manager, Regulatory Affairs
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92623-9534

Re: K003109
Trade Name: COMPLETE[R] brand Lubricating and Rewetting Drops
Regulatory Class: II
Product Code: 86LPN
Dated: October 3, 2000
Received: October 4, 2000

Dear Mr. Nowacki:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Current Labeling

ALLERGAN

Important - Please read carefully and keep this package insert for future reference.

COMPLETE® brand
Lubricating and Rewetting Drops

For use with soft (hydrophilic) contact lenses, including disposable lenses

DESCRIPTION:
COMPLETE® brand Lubricating and Rewetting Drops is a sterile, isotonic, buffered, preserved solution. This aqueous formulation includes purified water, sodium chloride, preserved with polyhexamethylene biguanide 0.0001%, buffered with tromethamine, hydroxypropyl methylcellulose as a lubricant, tyloxapol as a surfactant, and edetate disodium as a chelating agent. This preparation contains no chlorhexidine, no thimerosal and no other mercury containing ingredients.

ACTIONS:
COMPLETE® brand Lubricating and Rewetting Drops has been formulated for use with soft (hydrophilic) contact lenses to rewet lenses before insertion and lubricate lenses during wear to moisten and reduce lens friction against the cornea. It also relieves minor irritation, discomfort, dryness, blurring and itchiness which may occur while wearing your lenses.

INDICATIONS:
COMPLETE® brand Lubricating and Rewetting Drops is indicated for use to lubricate and rewet soft (hydrophilic) contact lenses before application and during lens wear.

CONTRAINDICATIONS (REASONS NOT TO USE):
If you are allergic to any ingredient in **COMPLETE®** brand Lubricating and Rewetting Drops, do not use this product.

WARNINGS:
PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens case. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION.**

Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care practitioner.

Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement.

Studies have also shown that smokers had a higher incidence of adverse reactions.

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

To avoid contamination, do not touch the dropper tip of the bottle to any surface. Replace cap after using.

PRECAUTIONS:
Keep bottle tightly closed when not in use. Store at room temperature. Use before the expiration date marked on the bottle and carton. Keep out of the reach of children.

ADVERSE REACTIONS (POSSIBLE PROBLEMS) AND WHAT TO DO:
The following may occur:

- Eyes stinging, burning, or itching
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (visual acuity)
- Blurred vision
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above, IMMEDIATELY remove and examine your lenses.

If a lens appears to be damaged, do not reapply; consult your eye care practitioner. If the problem stops and the lenses appear to be undamaged, follow the "Directions" below, before reapplying the lens.

If the problem continues, IMMEDIATELY remove your lenses, discontinue use of all lens care products that contact the eye, and consult your eye care practitioner.

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

DIRECTIONS:
To lubricate and rewet your lenses and to relieve minor irritation, discomfort, dryness, blurring and itchiness, apply one or two drops to each eye, up to four times per day, then blink several times.

If you require more frequent in-the-eye use of **COMPLETE®** brand Lubricating and Rewetting Drops to maintain comfortable lens wear, this may signify a condition that should be evaluated by your eye care practitioner.

HOW SUPPLIED:
COMPLETE® brand Lubricating and Rewetting Drops is supplied in sterile 1/2 fl oz plastic bottles. The bottles are marked with the lot number and expiration date.

Revised November 1999

ALLERGAN
Irvine, CA 92612 U.S.A.

71331US10E

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K040839

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	NA	
Class III Certification and Summary. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA	
510(k) Kit Certification ***	NA	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

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	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)	✓	
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓ ✓	
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:	NA	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ **Yes** ____ **No**
Reviewer: Tzong M. Chen
Concurrence by Review Branch: J Sanch

Date: 6/14/07

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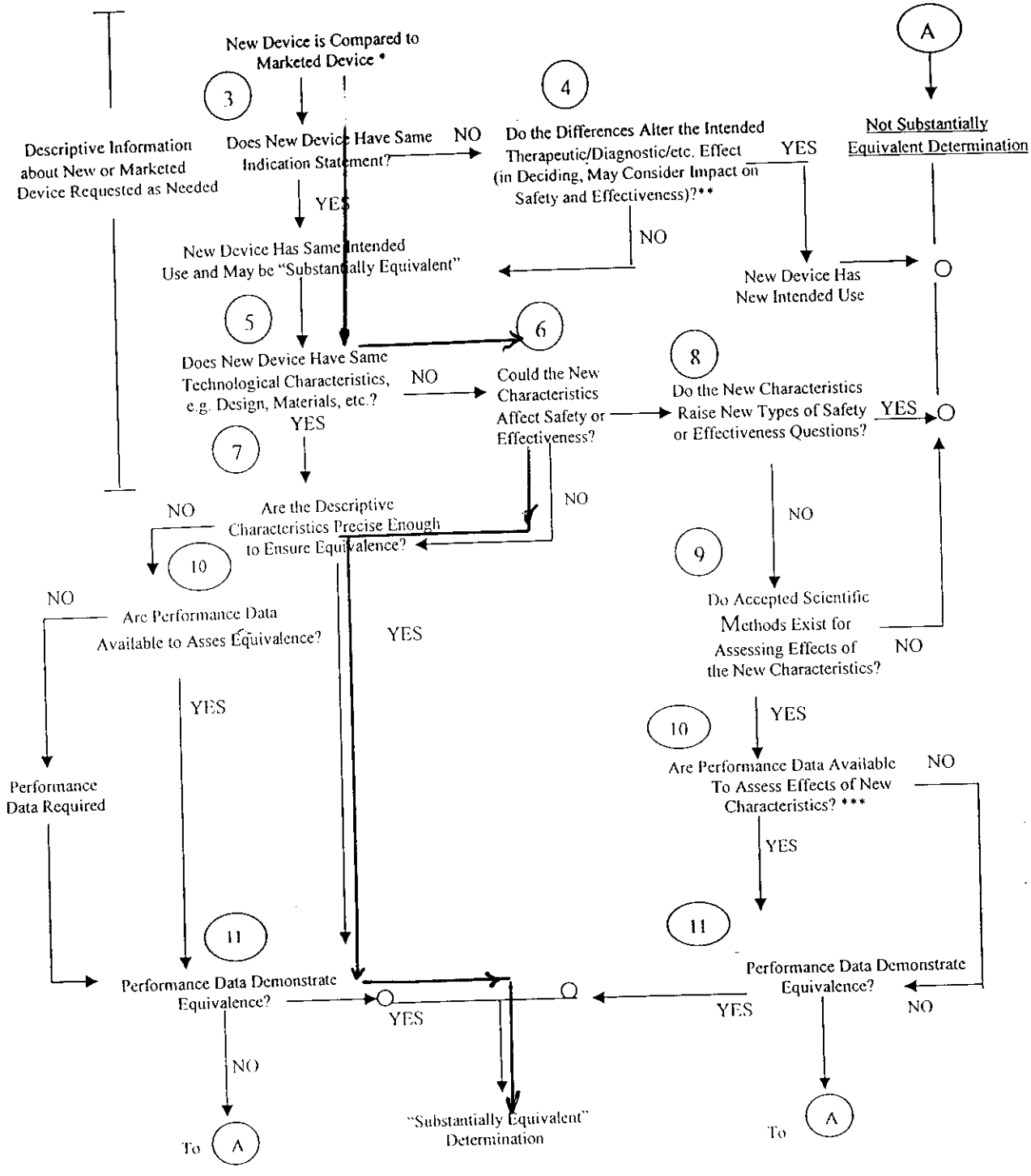
The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes? NA 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?	✓ ✓	 ✓
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✓

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

K040839 | 5001

AMO™
ADVANCED MEDICAL OPTICS

August 13, 2004

510k Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: **510(k) K040839**
COMPLETE® BLINK-N-CLEAN® Lens Drops

TO WHOM IT MAY CONCERN:

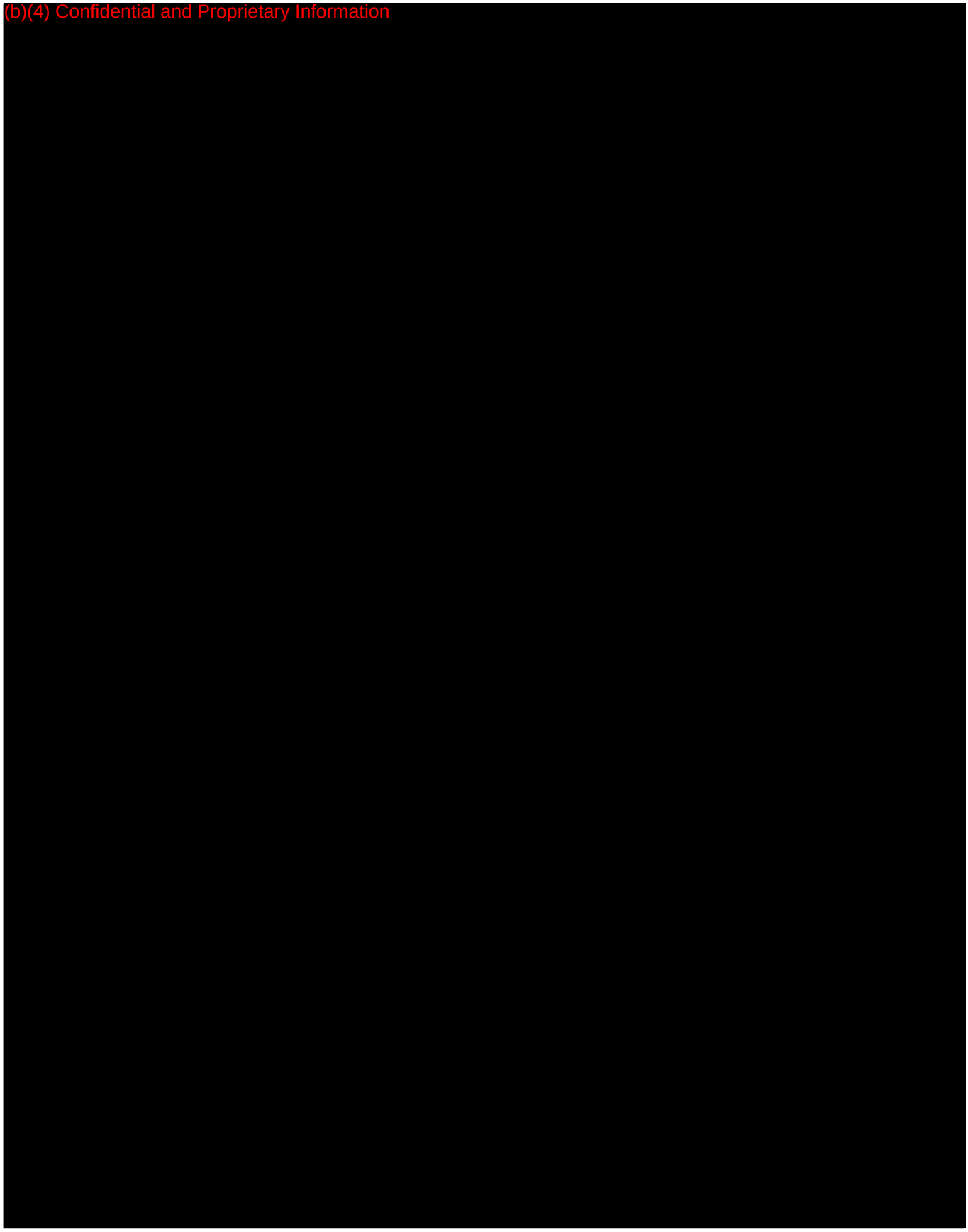
Duplicate copies of a supplement to the above-referenced 510(k) are enclosed. This supplement is a response to a June 21, 2004, FDA deficiency letter from FDA's reviewer Dr. Jimmy Chen. The questions and our response are as follows:

(b)(4) Confidential and Proprietary Information

[redacted]

1700 E. St. Andrew Place, P.O. Box 25162, Santa Ana, California, USA 92799-5162 Tel: (714) 247-8200

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

[redacted]

Please contact us with additional questions or comments.

Sincerely,

Paul Nowacki

Paul Nowacki

Manger
Worldwide Regulatory Affairs and Medical Compliance
Phone: (714) 247-8601
Fax: (714) 247-8677

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(j)]

I certify that, in my capacity as Director, Regulatory Affairs of Advanced Medical Optics, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Paul Nowacki
(Signature)

Paul Nowacki
(Typed Name)

August, 2004
(Date)

K040839
*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.
Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

ATTACHMENT I

0874 0874 0874 0874

AMO™ ADVANCED MEDICAL OPTICS

Important - Please read carefully and keep this package insert for future reference.

COMPLETE® Blink-N-Clean® Lens Drops

For use with soft (hydrophilic) contact lenses, including disposable lenses and extended wear lenses, and RGP contact lenses.

DESCRIPTION:
COMPLETE® Blink-N-Clean® Lens Drops is a sterile, isotonic, buffered, preserved solution. This aqueous formulation includes purified water, sodium chloride, preserved with polyhexamethylene biguanide 0.0001%, tromethamine as an emulsifier and buffer, hydroxypropyl methylcellulose as a lubricant, tyloxapol as a surfactant, and edetate disodium as a chelating agent. This preparation contains no chlorhexidine, no thimerosal and no other mercury containing ingredients.

ACTIONS:
COMPLETE® Blink-N-Clean® Lens Drops lubricates and rewets lenses, helps prevent protein film build-up, helps to remove particulate material that may cause irritation and/or discomfort. Use **COMPLETE® Blink-N-Clean®** Lens Drops to promote lens cleanliness during wear, to rewet lenses before insertion and lubricate lenses during wear to moisten and reduce lens friction against the cornea. When wearing extended wear lenses, use **COMPLETE® Blink-N-Clean®** Lens Drops to moisten lenses before retiring and upon awakening.

INDICATIONS:
COMPLETE® Blink-N-Clean® Lens Drops is indicated for use to lubricate and rewet soft ~~(hydrophilic) contact lenses~~, disposable and extended wear lenses, daily wear and RGP contact lenses.

CONTRAINDICATIONS (REASONS NOT TO USE):
If you are allergic to any ingredient in **COMPLETE® Blink-N-Clean®** Lens Drops, do not use this product.

WARNINGS:
PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens case. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION.**

Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care practitioner.

Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have

SECTION 4 SECTION 5

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43

also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement.

Studies have also shown that smokers had a higher incidence of adverse reactions.

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

To avoid contamination, do not touch the dropper tip of the bottle to any surface. Replace cap after using.

PRECAUTIONS:
Keep bottle tightly closed when not in use. Store at room temperature. Use before the expiration date marked on the bottle and carton. Keep out of the reach of children.

ADVERSE REACTIONS (POSSIBLE PROBLEMS) AND WHAT TO DO:
The following may occur:

- Eyes stinging, burning, or itching
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (visual acuity)
- Blurred vision
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above, IMMEDIATELY remove and examine your lenses.

If a lens appears to be damaged, do not reapply; consult your eye care practitioner. If the problem stops and the lenses appear to be undamaged, follow the "Directions" below, before reapplying the lens.

If the problem continues, IMMEDIATELY remove your lenses, discontinue use of all lens care products that contact the eye, and consult your eye care practitioner.

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

DIRECTIONS:
To lubricate and rewet your lenses and to relieve minor irritation, discomfort, dryness, blurring and itchiness, apply one or two drops to each eye, up to four times per day, then blink several times.

If you require more frequent in-the-eye use of **COMPLETE® Blink-N-Clean®** Lens Drops to maintain comfortable lens wear, this may signify a condition that should be evaluated by your eye care practitioner.

HOW SUPPLIED:
COMPLETE® Blink-N-Clean® Lens Drops is supplied in sterile 20 mL plastic bottles. The bottles are marked with the lot number and expiration date.

Revised ~~July 2003~~ April 2004
July 2004

Distributed by:
Advanced Medical Optics, Inc.
Santa Ana, CA 92705 U.S.A.

71656US~~10M~~
8772X

AMO ADVANCED MEDICAL OPTICS
Worldwide Specifications
Labeling and Packaging

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ATTACHMENT II

46

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or RGB

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"COMPLETE" ICON & ® PRINT PMS 109; DROPSHADOW PRINTS BLACK

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PANEL BCKGRND PRINTS PROCESS CYAN & SHADOW PRINTS PMS 072 FROM SUPPLIED .PSD FILE; TYPE REV. TO WHITE WITH PMS 072 DROPSHADOW

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any type

AMO
COMPLETE®
Blink-N-Clean®
LENS DROPS

For Any Soft Contact Lens

DIRECTIONS: To lubricate and rewet your lenses, and to relieve minor irritation, discomfort, dryness, blurring and itchiness, apply one or two drops to each eye, up to four times per day, then blink several times.

® Registered trademarks owned by AMO, Inc.
US Pat. 5,422,073; 5,580,186; 5,593,637; 3,817,277; 5,756,045.

27444 00012 6

Distributed by
Advanced Medical Optics, Inc.
Santa Ana, CA 92705 U.S.A.
1-800-347-5005
AMO, Inc.

No. 92825

Helps remove protein and prevent buildup during lens wear

0.7 fl oz (20 mL) STERILE

CONTENTS: COMPLETE® Blink-N-Clean® Lens Drops are a sterile, isotonic, buffered, preserved solution. This aqueous formulation includes purified water, sodium chloride, preserved with polyhexamethylene biguanide 0.0001%, tromethamine as an emulsifier and buffer, hydroxypropyl methylcellulose as a lubricant, tyloxapol as a surfactant, and edetate disodium as a chelating agent. This preparation contains no chlorhexidine, no thimerosal and no other mercury containing ingredients.
If you are allergic to any ingredient in the product, DO NOT USE.

PRECAUTIONS:
- Keep bottle tightly closed when not in use.
- Store at room temperature.
- Use before the expiration date marked on the bottle.
- Keep out of the reach of children.

WARNING: SEE PACKAGE INSERT FOR IMPORTANT SAFETY INFORMATION.

AMO
COMPLETE®
Blink-N-Clean®
LENS DROPS

Helps clean lenses while you wear them

Over the course of the day, a film of protein and other material can build up on your contact lenses, irritating your eyes and clouding your vision. This is especially true with today's extended wear lenses.

COMPLETE® Blink-N-Clean® Lens Drops do more than just rewet lenses. A few drops of the exclusive dual-cleansing formula gently dissolves away debris and material that can cause irritation and discomfort. It helps remove protein build-up to ensure that your lenses stay as fresh as they can be and your vision remains clear.

Just a few drops of COMPLETE® Blink-N-Clean® Lens Drops, actually helps remove and prevent protein buildup, eliminating the need to stop and remove your lenses to clean them.

COMPLETE® Blink-N-Clean® Lens Drops are doctor recommended for use with all types of soft contact lenses.

USE ONLY IF IMPRINTED OVERWRAP ON BOTTLE IS INTACT

AMO
COMPLETE®
Blink-N-Clean®
LENS DROPS
0.7 fl oz (20 mL) STERILE

011824

CARTON, RTE
(MARCHESINI FOLD)
1-7/8" X 1-1/16" X 3-25/32"

0166601

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Regulatory Affairs Labeling Compliance	A. Ward	7/10/03

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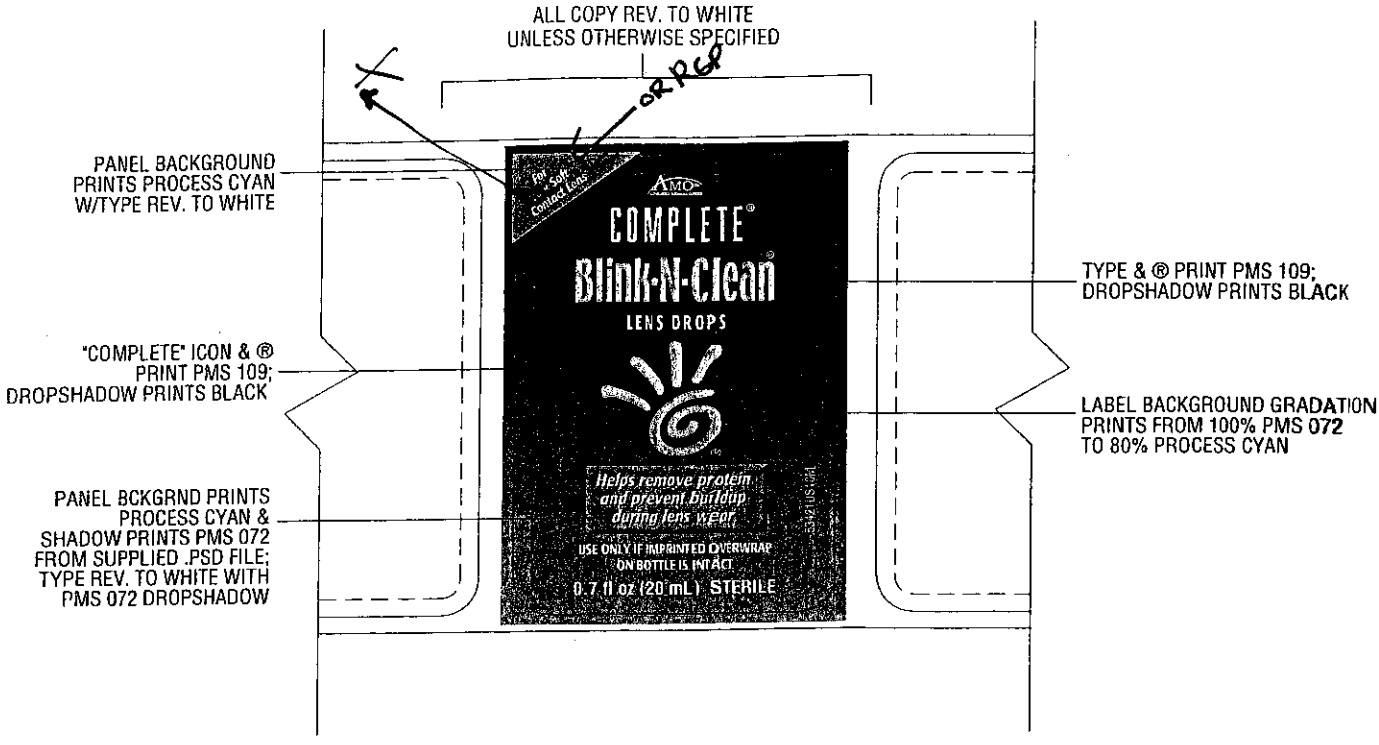

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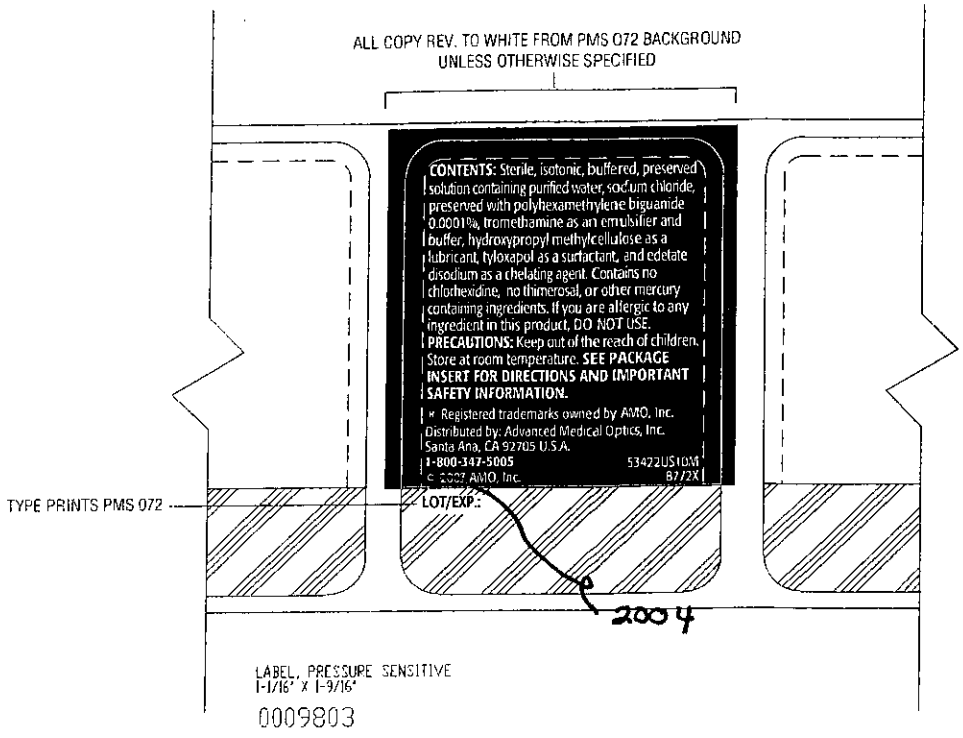

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AMO ADVANCED MEDICAL OPTICS — Worldwide Manufacturing Support
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ATTACHMENT III

SPECTROSCOPIC METHODS FOR QUANTIFYING SURFACE PROTEIN ACCUMULATION ON HUMAN-WORN CONTACT LENSES AND SUBSEQUENT PROTEIN REMOVAL IN SIMULATED IN-EYE USE OF LENS REWETTER PRODUCTS

WC Prather, CH Powell, JG Vehige
Consumer Eye Care R&D, Allergan, Inc., Irvine, Calif.

ABSTRACT

Purpose: In-eye rewetters have recently been claimed to remove protein from contact lenses in situ, but substantiating this removal is technically challenging. Complementary spectroscopic techniques (Attenuated total reflectance [ATR]-Fourier transform infrared [FTIR] and ultraviolet [UV]) provide a means to quantify surface accumulation and removal to such a degree that comparisons can be made regarding the efficacy of in-eye rewetters on the removal of surface and near-surface proteins.

Methods: The ATR-FTIR method measured surface protein at 3 localized points (3 mm^2 x 1 micron deep) on human-worn hydrogel and silicone-hydrogel lenses. After simulated in-eye cleaning with either a saline solution or a rewetting product, a second FTIR analysis probed the degree of reduction in the surface protein signal. Each simulated in-eye treatment solution was then analyzed by UV spectrophotometry, where tear proteins show distinct absorption bands. The short treatment with a rewetter removes only surface and near-surface proteins.

Results: There was a reduction of 1% to 10% in the protein infrared (IR) signal with both types of hydrogel lenses. With the silicone-hydrogel lenses, however, a rewetter containing sorbic acid showed an artificial increase in protein signal. No statistical differences in protein signal reduction were seen between the rewetting products tested. The UV experiment indicated a statistically significant difference in protein removal between rewetter products with both lens materials. Products with a highly UV-absorbing ingredient gave anomalous results.

Conclusions: FTIR and UV spectroscopies are complementary techniques for substantiating small levels of protein accumulation and removal. FTIR spectroscopy measures surface protein, but precision is affected by the need to subtract spectral contributions from the polymer and water. UV spectrophotometry measures total protein removal with a higher degree of precision than the FTIR methodology, resulting in higher statistical confidence when comparing efficacy of protein-removal products. This method, however, is inappropriate for products containing highly UV-absorbing ingredients.

BACKGROUND AND INTRODUCTION

Substantiating the removal of protein from contact lenses using in-eye lens rewetters is technically challenging. This research looks at the use of spectroscopic techniques to provide a means of quantifying lens surface protein accumulation and removal. This technique can be used to make comparisons regarding the efficacy of in-eye rewetters on the removal of surface and near-surface proteins, with some limitations.

Two spectroscopic techniques were used in this study with the idea that their complementary results would be correlatable.[1] FTIR spectroscopy, which has been used to measure the surface structure and composition of contact lenses,[2,3] measured surface proteins (to about 1 micron in depth) on human-worn lenses. This is essentially a nondestructive process that measures localized areas (about 2 mm in diameter) on the lens surface.[4] UV spectrophotometry has been used to evaluate protein deposits on contact lenses[5] and similar to its use in this study, quantities of protein removed from lenses after soaking.[6]

METHODS

Study Samples

Human-worn Group 4 hydrogel lenses (etafilcon A) and Group 3 silicone-hydrogel lenses (balafilcon A) were harvested following a collection protocol at 3 optometric offices. Lenses worn for 15 to 60 days were shipped overnight to Allergan where they were kept refrigerated in sterile saline until used in the study. For purposes of the experiment, one set of human-worn lenses was considered a single sample. Each lens was cut in half to produce 4 replicates per sample.

Solutions Tested

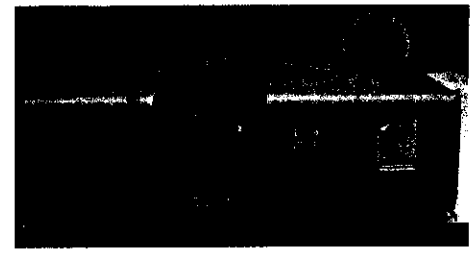
The following solutions were used in the FTIR and/or UV analysis of protein removal:

Solution	Product Name	FTIR Analysis	UV Analysis
S1	Allergan's COMPLETE® BLINK-N-CLEAN®	Yes	Yes
S2	Alcon's CLERZ® Plus	Yes	Yes
S3	Allergan's LENS PLUS®	Yes	Yes
S4	Bausch & Lomb's Sensitive Eyes®	Yes	No

FTIR Spectroscopy

FTIR spectroscopy was used to measure removal of surface proteins from human-worn hydrogel and silicone-hydrogel contact lenses (Figure 1). Baseline measurements of ~3 mm² by ~1 micron deep at each of 3 points on each lens half were made following an established pattern. Preliminary data indicated that 3 measurements per lens were sufficient to control for within-lens variation.[7] Each lens half was then cleaned using 1 of 4 test solutions. In-eye cleaning was simulated by placing 50 microliters (equivalent of 1 drop) of the solution on the anterior surface of a lens half. The lens half was then swiped back and forth in a contact lens case for 10 seconds using rubber-tipped forceps, followed by a rinse with 1 milliliter of sterile saline for 5 seconds. The lens half was then run through the FTIR spectroscopic process again in approximately the same 3 points to acquire postcleaning lens surface spectra.

Figure 1. Nicolet FTIR spectrometer



Each lens half was analyzed by FTIR at 3 points on the lens' anterior surface, approximately 1 mm from its periphery.

UV Spectrophotometry

The UV spectrophotometer was used to quantify the total amount of surface and near-surface protein recovered in fluids used in the simulated in-eye cleaning step (Figure 2). Like the previous experiment, a pair of lenses was considered a single sample. Each lens was cut in half, and each half was cleaned with solutions S1, S2, or S3 using the same process as for the FTIR experiment. The lens itself was then discarded (if not used in the FTIR analysis), and the resultant final rinse solution was analyzed by UV spectrophotometry. Data were collected in absorbance units and then converted to micrograms of protein. Baseline correction was performed to enhance the precision of the UV analysis.

Figure 2. Uvikon 943 spectrophotometer

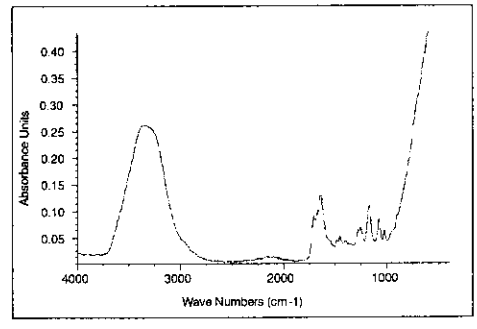
Postcleaning rinse solutions were analyzed for protein levels using a UV spectrophotometer.

RESULTS

FTIR Spectroscopy

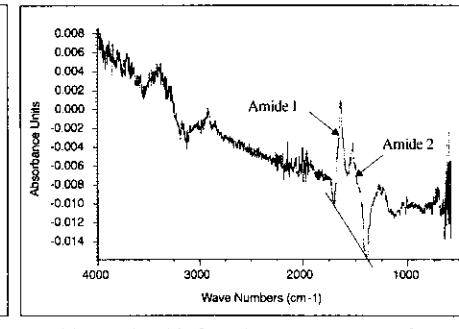
Figure 3 shows an example of an infrared spectrum of a human-worn Group 4 contact lens. The spectral signature of the surface proteins was obtained by the subtraction of both the lens polymer and water (Figure 4).

Figure 3. Contact Lens FTIR Spectrum



Example of an infrared spectrum of a human-worn contact lens.

Figure 4. Modified Contact Lens FTIR Spectrum



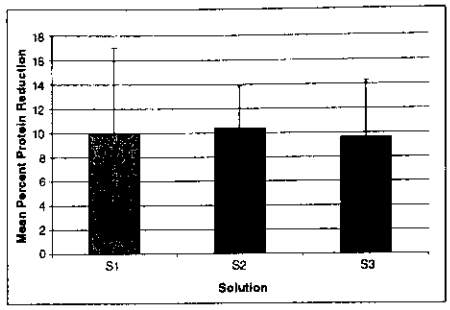
Amide 1 and amide 2 peaks on a spectrum of a contact lens surface minus the polymer and water.

Figure 4 illustrates the protein peaks representing the proteins sorbed to a particular lens surface. After adjusting the baseline, the magnitude of adsorption of 2 proteins was quantified. These proteins were identified as amide 1, found at approximately wave number 1640 and amide 2, found at approximately wave number 1550. Based on this process, the average protein adsorption after the cleaning step was subtracted from the average protein adsorption prior to the cleaning step to obtain the percentage of reduction in protein signal on a particular lens after it was cleaned. For comparison of the protein-removal abilities of the various solutions, amide 2 was used as the comparator. The protein peak of amide 1 overlaps with water, making it difficult to isolate spectrally, and renders measurement of the amide 1 peak more difficult and subjective.

When assessing protein removal in hydrogel lenses using FTIR spectroscopy, 3 of the solutions tested resulted in about 10-percent reduction of the protein signal (Figure 5). Solution S4 resulted in an anomalous increase in the protein signal. This finding is assumed

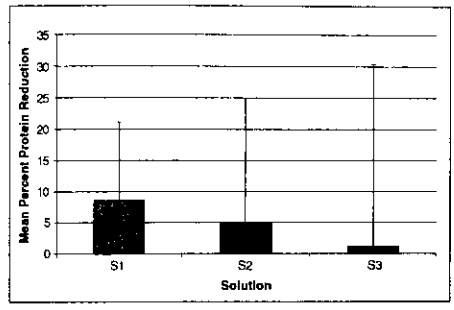
to be the result of the effects of boric and sorbic acid that influenced (enhanced) the FTIR signal of the lens surface proteins. Of the 3 remaining solutions, there was no significant difference in the reduction of surface proteins ($F = 0.072$, $P = .930$). When comparing the same 3 solutions' protein-removal abilities for silicone-hydrogel lenses, the results are slightly different (Figure 6). There is still no statistical difference between solutions with respect to protein reduction ($F = 0.422$, $P = .658$); however, the low means and high variances resulted from the large number of negative values in the results. Because there is no difference in the precleaning spectra between Group 3 and Group 4 lenses (Figure 7, $t = 1.32$, $P = .10$), the results of the solution comparison for Group 3 lenses suggest that the removal of protein from these types of lenses is poor or that the FTIR spectroscopic technique when using silicone-hydrogel lenses may need to be revised.

Figure 5. Protein Reduction on Group 4 Hydrogel Lenses



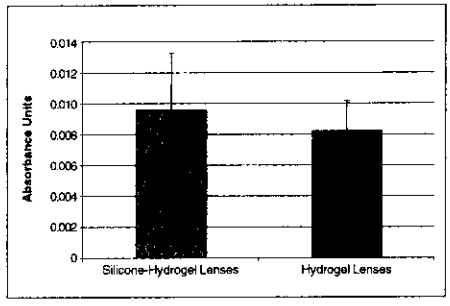
Solutions S1, S2, and S3 removed approximately 10% of measured surface protein from Group 4 hydrogel lenses. There was no difference between solutions ($F = 0.072$, $P = .930$).

Figure 6. Protein Reduction on Group 3 Silicone-Hydrogel Lenses



Solutions S1, S2, and S3 removed from 1% to 8% of measured surface protein from Group 3 silicone/hydrogel lenses. There was no difference between solutions ($F = 0.422$, $P = .658$).

Figure 7. Precleaning Amide 2 Protein Levels

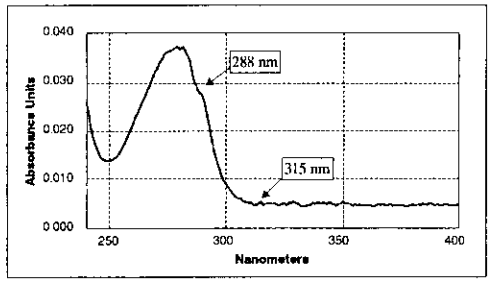


Baseline surface protein levels are similar between Group 4 hydrogel and Group 3 silicone-hydrogel lens materials ($t = 1.32$, $P = .10$).

UV Spectrophotometry

Figure 8 illustrates a typical UV spectrum of the resultant solution following a lens cleaning. To control for any effect of the cleaning solution components enhancing the peak, the absorbance data point collected for each spectrum was the difference in absorbance values at 288 nanometers (nm) and 315 nm, which is the difference between the absorbance at the characteristic absorption shoulder for lysozyme (288 nm) and the baseline (315 nm).[8] Baseline correction enhanced the precision of the UV analysis.

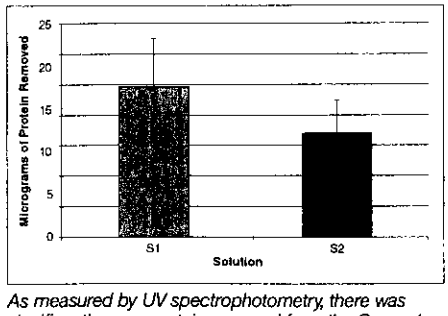
Figure 8. UV Spectrum of Postcleaning Rinse Solution



UV spectrophotometric assessment of protein was evaluated between 288 nm and 315 nm.

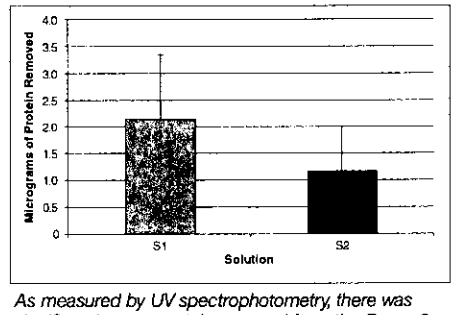
For the UV portion of the experiment, only solutions S1 and S2 were considered in the analysis. Data from lenses cleaned with solution S3 were not included (due to artifacts secondary to its aerosol packaging). Figure 9 compares the protein removed from hydrogel lenses using solutions S1 and S2. The results indicate that solution S1 removed a significantly larger amount of protein from the lens than did solution S2 ($t = 2.544$, $P = .011$). For silicone-hydrogel lenses, the results are similar (Figure 10); solution S1 removed a significantly larger amount of protein than solution S2 ($t = 2.228$, $P = .019$), but the degree of protein removal from silicone-hydrogel lenses is less than that from hydrogel lenses. This may result from the cleaners removing protein from hydrogel lenses residing beyond the measurement depth of FTIR analysis or protein being sorbed to hydrogel lenses may be more easily extracted relative to silicone-hydrogel lenses.and without HPMC and examines the tear physiology of patients wearing soft contact lenses soaked in HPMC and non-HPMC solutions.

Figure 9. Protein Removal in Group 4 Hydrogel Lenses



As measured by UV spectrophotometry, there was significantly more protein removed from the Group 4 hydrogel lenses cleaned with solution S1 than with solution S2 ($t = 2.544$, $P = .011$).

Figure 10. Protein Removal in Group 3 Silicone-Hydrogel Lenses



As measured by UV spectrophotometry, there was significantly more protein removed from the Group 3 silicone-hydrogel lenses cleaned with solution S1 than with solution S2 ($t = 2.228$, $P = .019$).

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CONCLUSIONS

FTIR and UV spectroscopies are complementary techniques for substantiating small levels of protein accumulation and removal, particularly when assessing hydrogel lenses. Higher levels of surface protein removal from hydrogel lenses (10% as compared to 1% to 8% in silicone-hydrogel lenses) assessed by FTIR spectroscopy are corroborated by high levels of protein removal from hydrogel lenses (again, relative to silicone-hydrogel lenses) assessed using UV spectrophotometry. Both techniques suggest that protein is more easily removed from hydrogel lenses than from silicone-hydrogel lenses.

UV spectrophotometry measures total protein removal with a higher degree of precision than the FTIR methodology. FTIR spectroscopy was able to measure protein removal from human-worn contact lenses but was unable to detect differences between the cleaning abilities of the solutions. The UV spectrophotometer, however, was able to collect data that resulted in the ability to statistically differentiate between the efficacy of protein-removal solutions.

An alternate hypothesis for the above discrepancy between FTIR and UV measures of protein removal may be that the protein detected in UV analysis is being removed from regions of the lens beyond FTIR detection.

There are clear limitations to the FTIR technique. Precision is affected by the need to subtract spectral contributions from the polymer and water. FTIR is a good technique for measuring surface proteins in hydrogel lenses and may be for silicone-hydrogel lenses as well. Because of the large variance seen in the silicone-hydrogel results, a modification of the technique should be considered. Although more precise, the UV spectrophotometric method is limited by its inapplicability to test products that contain highly UV-absorbing ingredients.

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