

APR 30 2012

510(k) SUMMARY**1.0 Submitter Information:**

Bausch + Lomb
1400 N. Goodman Street
Rochester, NY 14609
Contact: Tricia Garrett
Senior Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609
(585) 338-6706 (office)
(585) 338-0702 (fax)
Tricia.m.garrett@bausch.com

2.0 Device Name:

Trade Name:	TBD
Common Name:	Soft (hydrophilic) contact lens care products Rigid Gas Permeable contact lens care products
Device Classification:	Class II (21 CFR 886.5918 & 21 CFR 886.5928)
Product Code	LPN, MRC

3.0 Predicate Device:

The predicate device is Ciba, Clear Care Cleaning and Disinfecting Solution cleared in K022687 on November 19, 2002 and K023455 on February 28, 2003.

4.0 Device Description:

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is a sterile, buffered solution containing 3% hydrogen peroxide which

(b)(4)

5.0 Intended Use:

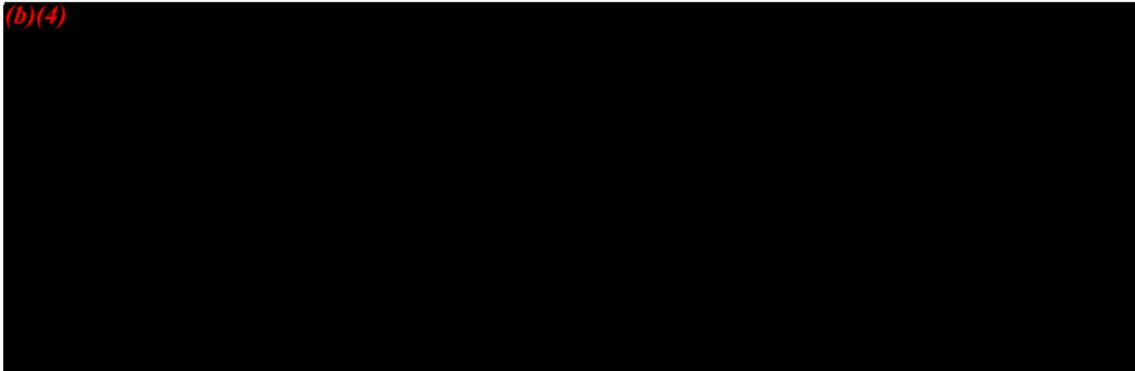
Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.

6.0 Description of Safety and Substantial Equivalence:

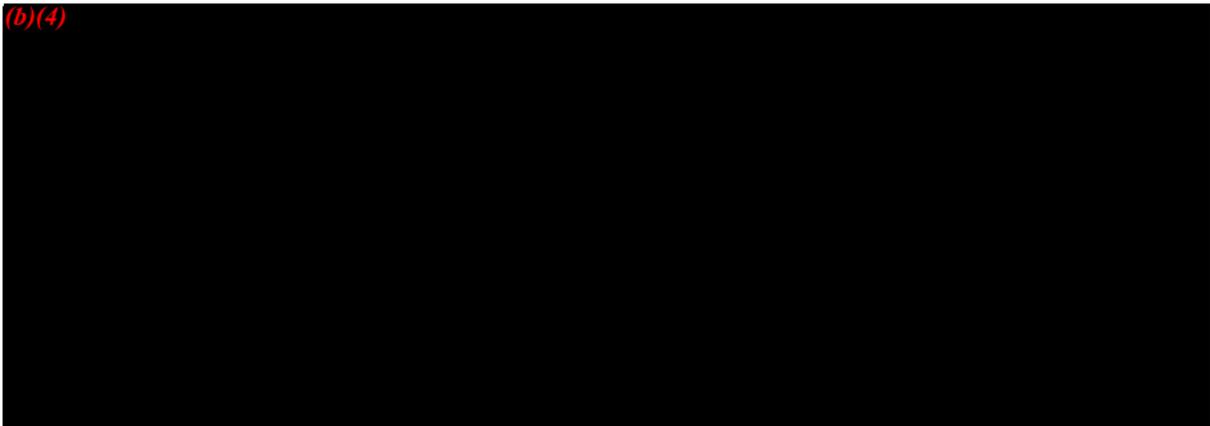
A series of preclinical testing was performed to demonstrate the safety and effectiveness of Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution. A summary of the test results is provided below:

6.6 Biocompatibility

(b)(4)

**6.7 Microbiology**

(b)(4)

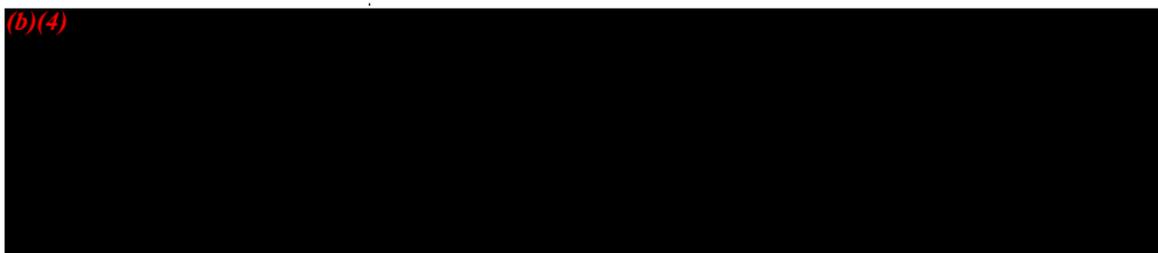


6.8 Lens Compatibility

The results of lens compatibility studies demonstrate Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is compatible with soft contact lenses including, silicone hydrogel contact lenses and rigid gas permeable lenses.

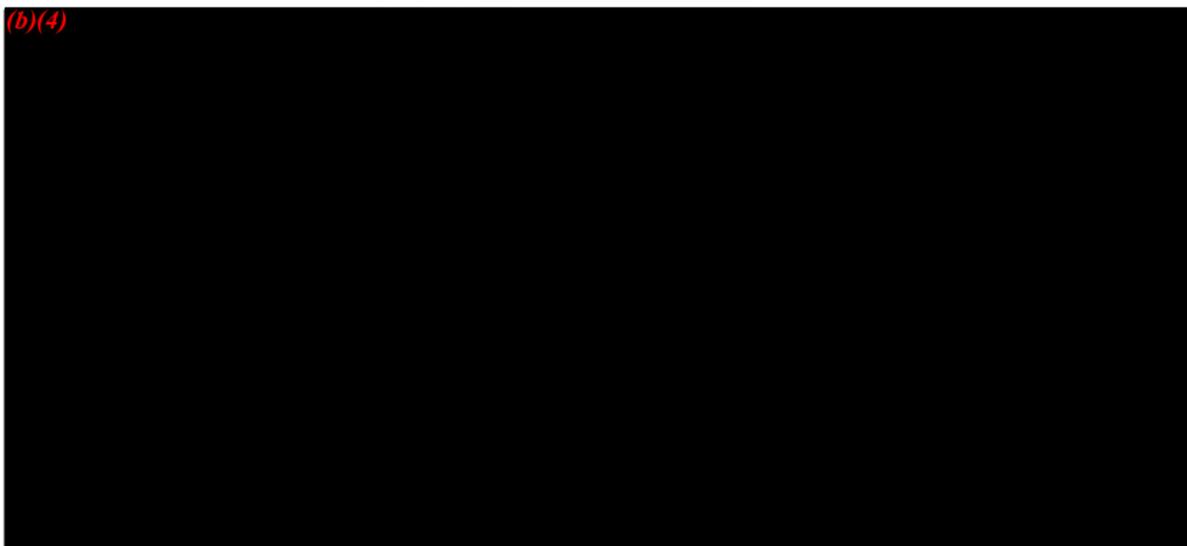
6.9 Residual Peroxide and Area Under Curve

(b)(4)

A large black rectangular redaction box covers the content of section 6.9. The text "(b)(4)" is written in red at the top left corner of the redacted area.

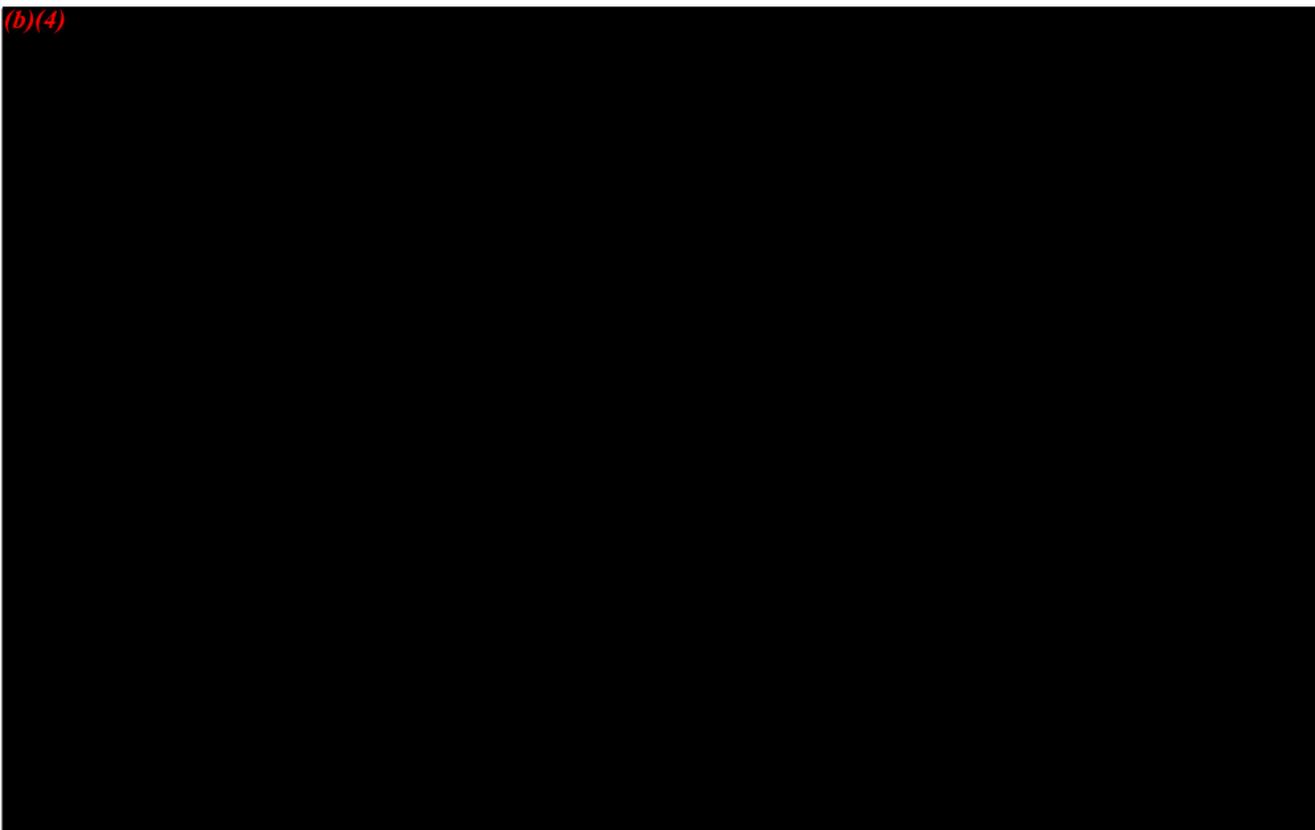
6.10 In-Vitro Protein Removal and Cleaning Efficacy

(b)(4)

A large black rectangular redaction box covers the content of section 6.10. The text "(b)(4)" is written in red at the top left corner of the redacted area.

7.0 Clinical Evaluation Summary:

(b)(4)



8.0 Substantial Equivalence Conclusion:

The cumulative results of laboratory, in vitro and in vivo testing sponsored by Bausch + Lomb demonstrate that the safety, efficacy and performance of Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution are substantially equivalent to Ciba Clear Care Cleaning and Disinfecting Solution for soft contact lenses (including silicone hydrogels) as well as rigid gas permeable lenses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

APR 30 2012

Bausch and Lomb
c/o Ms. Tricia Garrett
Senior Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

Re: K112909

Trade/Device Name: Bausch and Lomb OCD04 3% Hydrogen Peroxide Cleaning and
Disinfecting Solution

Regulation Number: 21 CFR 886.5928

Regulation Name: Soft (hydrophilic) contact lens care products

Regulatory Class: Class II

Product Code: LPN, MRC

Dated: April 25, 2012

Received: April 26, 2012

Dear Ms. Garrett:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

Page 2- Ms. Tricia Garrett

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

APR 30 2012

Bausch and Lomb
c/o Ms. Tricia Garrett
Senior Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

Re: K112909

Trade/Device Name: Bausch and Lomb OCD04 3% Hydrogen Peroxide Cleaning and
Disinfecting Solution

Regulation Number: 21 CFR 886.5928

Regulation Name: Soft (hydrophilic) contact lens care products

Regulatory Class: Class II

Product Code: LPN, MRC

Dated: April 25, 2012

Received: April 26, 2012

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Sincerely yours,



for
Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112909

Device Name: **Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution**

Indications for Use:

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.

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 OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

Page 1 of 1

510(k) Number K112909



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

April 26, 2012

BAUSCH & LOMB, INC.
 1400 NORTH GOODMAN ST.
 ROCHESTER, NEW YORK 14609-3547
 ATTN: TRICIA GARRETT

510k Number: K112909

Product: OCD04 3% HYDROGEN PEROXIDE

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 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 in 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.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Mcdonald, Lisa *

From: Mcdonald, Lisa *
Sent: Thursday, April 26, 2012 2:03 PM
To: 'tricia.m.garrett@bausch.com'
Subject: K112909 AI Letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES**Public Health Service**

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

April 26, 2012

GARRETT

TRICIA

BAUSCH & LOMB, INC.

1400 NORTH GOODMAN ST.

ROCHESTER, NEW YORK 14609-3547

ATTN: TRICIA GARRETT

510k Number: K112909

Product: OCD04 3% HYDROGEN PEROXIDE

CLE

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 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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510(k) Staff



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

February 29, 2012

BAUSCH & LOMB, INC.
 1400 NORTH GOODMAN ST.
 ROCHESTER, NEW YORK 14609-3547
 ATTN: TRICIA GARRETT

510k Number: K112909

Product: OCD04 3% HYDROGEN PEROXIDE CLE
 On Hold As of 2/28/2012

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 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

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), 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 (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. 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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Wednesday, February 29, 2012 10:05 AM
To: 'tricia.m.garrett@bausch.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
 U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center, WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20910-6002

February 29, 2012

GARRETT
 TRICIA

BAUSCH & LOMB, INC.
 1400 NORTH GOODMAN ST.
 ROCHESTER, NEW YORK 14609-3547
 ATTN: TRICIA GARRETT
 510k Number: K112909

Product: OCD04 3% HYDROGEN PEROXIDE CLE

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2/29/2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Product: OCD04 3% HYDROGEN PEROXIDE

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Sincerely,

510(k) Staff

BAUSCH + LOMB

Traditional 510(k): Premarket Notification

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution

September 30, 2011

Sponsor: Bausch & Lomb
1400 North Goodman Street
Rochester, New York 14609
(585) 338-6000
Facility Registration #: 1313525
www.bausch.com

Submitted by: Tricia Garrett
Senior Specialist, Global Regulatory Affairs
Phone (585) 338-6706
Fax (585) 338-0702
Email: tricia.m.garrett@bausch.com

1250

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Form Approved OMB No. 0910-0001 (b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER Write the Payment Identification number on your check.
---	---

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/coversheet.html>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) BAUSCH AND LOMB INC 1400 N GOODMAN STREET ROCHESTER NY 14609 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****5235	2. CONTACT NAME Tricia Garrett 2.1 E-MAIL ADDRESS tricia.m.garrett@bausch.com 2.2 TELEPHONE NUMBER (include Area code) 585-338-6706 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
--	--

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:

<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 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. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/cdrh/mdufma> for additional information)

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

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

7. 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

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

(b)(4) SUBMITTED FOR THIS PREMARKET APPLICATION 12-Sep-2011

"Close Window" Print Cover sheet

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Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 2 FDA FORMS 3514 AND 3654
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Section 2: FDA Forms 3514 and 3654

Section 2.1: FDA Cover Sheet Form 3514

Section 2.2: Standard Data Report for 510(k)s Form 3654

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.		
Date of Submission September 30, 2011	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)		
SECTION A IF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	610(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class II Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name Bausch & Lomb Incorporated		Establishment Registration Number (if known) 1313525		
Division Name (if applicable) NA		Phone Number (including area code) 585-338-6706		
Street Address 1400 North Goodman Street		FAX Number (including area code) 585-338-0702		
City Rochester	State / Province New York	ZIP/Postal Code 14609	Country USA	
Contact Name Tricia Garrett				
Contact Title Senior Specialist, Global Regulatory Affairs		Contact E-mail Address Tricia.M.Garrett@Bausch.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name				
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City	State / Province	ZIP Code	Country	
Contact Name				
Contact Title		Contact E-mail Address		

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager	
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment	
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address	
<input type="checkbox"/> Other Reason (specify):			

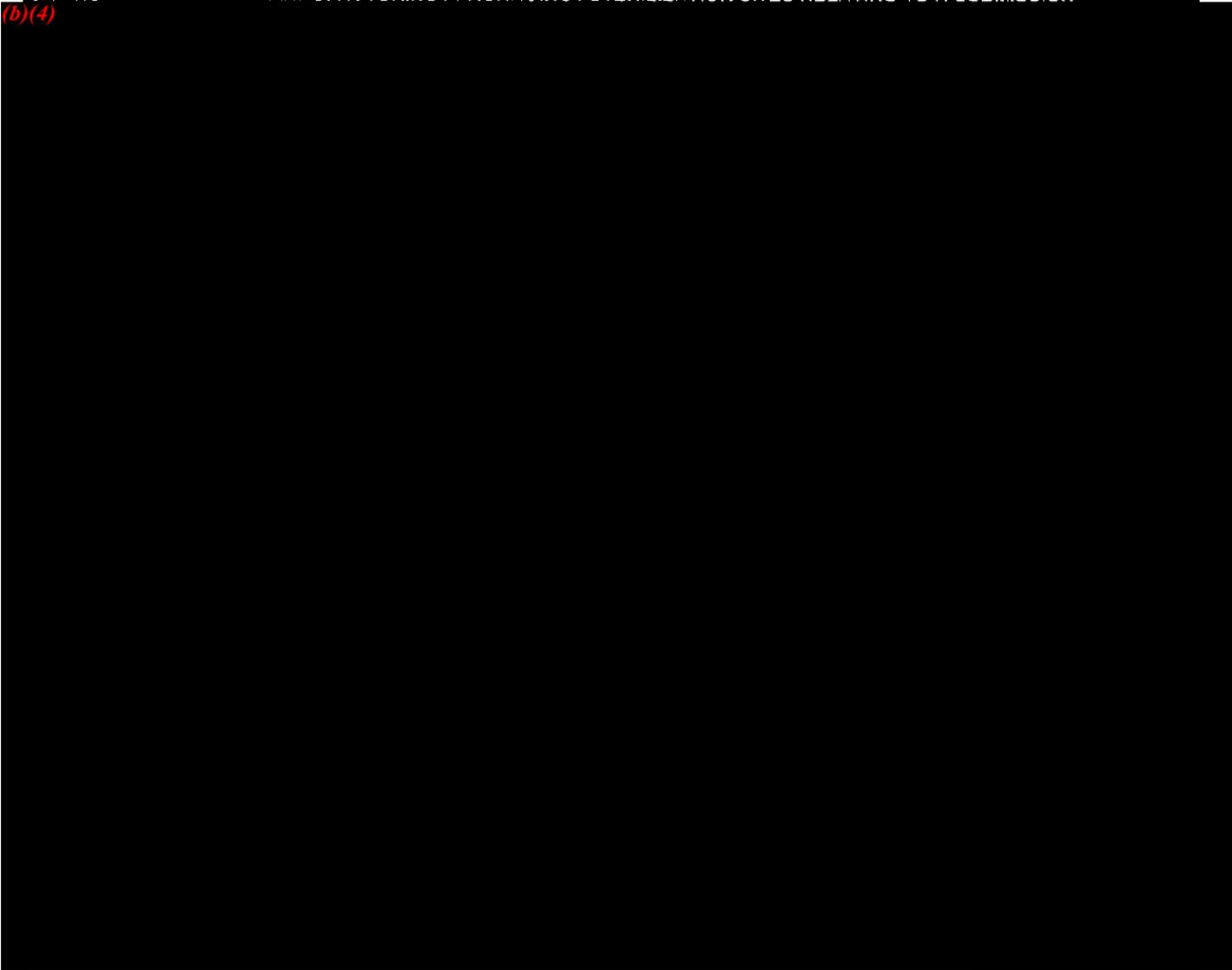
SECTION D2			REASON FOR APPLICATION - IDE
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing	
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Other Reason (specify):		

SECTION D3			REASON FOR SUBMISSION - 510(k)
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology	
<input type="checkbox"/> Other Reason (specify):			

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 information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement							
1	LPN	2		3		4									
5	MRC	6		7		8									
Information on devices to which substantial equivalence is claimed (if known)															
	510(k) Number			Trade or Proprietary or Model Name				Manufacturer							
1	K022687			1 AOSEPT CLEAR CARE CLEANING AND DISINFECTING SOLUTION				1 Ciba							
2	K023455			2 AOSEPT CLEAR CARE CLEANING AND DISINFECTING SOLUTION				2 Ciba							
3				3				3							
4				4				4							
5				5				5							
6				6				6							
SECTION F												PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS			
Common or usual name or classification name															
Soft (hydrophilic) contact lens care products															
Rigid Gas Permeable contact lens care products															
	Trade or Proprietary or Model Name for This Device						Model Number								
1	TBD						1								
2							2								
3							3								
4							4								
5							5								
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															
<input checked="" type="checkbox"/> Laboratory Testing <input checked="" type="checkbox"/> Animal Trials <input checked="" type="checkbox"/> Human Trials															
SECTION G												PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS			
Product Code		C.F.R. Section (if applicable)				Device Class									
LPN, MRC		21 CFR 886.5918 & 21 CFR 886.5928				<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified									
Classification Panel															
Ophthalmic Devices															
Indications (from labeling)															
Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.															

<p>Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.</p>	<p>FOA Document Number (if known)</p>
--	---------------------------------------

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION
(b)(4)



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1			See the following FDA 3654 Forms		
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 1350 Piccard Drive, Room 400
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

K112909

Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 3 COVER LETTER
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September 30, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

OCT 03 2011

Received

Reference: 510(k) Notification: BAUSCH + LOMB OCD04 3% HYDROGEN PEROXIDE Cleaning and Disinfecting Solution

Dear CDRH Staff:

Bausch + Lomb hereby submits this Traditional 510(k) Premarket Notification to demonstrate that Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is substantially equivalent to legally marketed predicate devices. The submitter is Bausch & Lomb Incorporated, 1400 North Goodman Street, Rochester, NY 14609 and Tricia Garrett, Senior Specialist Global Regulatory Affairs is the contact person.

Bausch + Lomb declares that the following are applicable to the subject medical device:

Classification Regulation: 21 CFR 886.5918 and 21 CFR 886.5928
 Device Class: Class II
 Device Regulation Panel: 86
 Product Codes: LPN, MRC

Enclosed is the original copy of this Premarket Notification, one paper copy, and an electronic copy on a compact disc as an Acrobat Portable Document Format file (PDF). Per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

The design and use for this device include:

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	<input type="checkbox"/>	X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	<input type="checkbox"/>
Does the device contain components derived from a tissue or other biologic source?	<input type="checkbox"/>	X
Is the device provided sterile?	X	<input type="checkbox"/>
Is the device intended for single use?	<input type="checkbox"/>	X
Is the device a reprocessed single use device?	<input type="checkbox"/>	X
If yes, does this device type require reprocessed validation data?	<input type="checkbox"/>	N/A
Does the device contain a drug?	<input type="checkbox"/>	X
Does the device contain a biologic?	<input type="checkbox"/>	X

<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 3 COVER LETTER</p>
--	--

Traditional 510(k) Premarket Notification
 Bausch + Lomb
 September 30, 2011
 Page 2 of 2

Question	YES	NO
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?		X

Bausch + Lomb hereby requests that this submission and its contents be held as confidential commercial information, and that the sponsor considers the intent to market the device to be confidential commercial information within the meaning of 21 CFR 807.95 and associated regulations.

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at (585) 338-6706. In my absence, please contact my colleague Jennifer Murray at 585.338.8460, or jennifer.murray@bausch.com.

Sincerely,



Tricia Garrett
 Senior Specialist, Global Regulatory Affairs
 (585) 338-6706 (office)
 (585) 338-0702 (fax)
Tricia.M.Garrett@Bausch.com

Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 4 INDICATIONS FOR USE STATEMENT
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Section 4: Indications for Use Statement

Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 4 INDICATIONS FOR USE STATEMENT
---	--

Indications for Use Statement

510(k) Number (if known): _____

Device Name: **Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution**

Indications for Use:

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement

510(k) Number (if known): _____

Device Name: **Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution**

Indications for Use:

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.

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 OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 5 510(k) SUMMARY
---	---

Section 5: 510(k) Summary

<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 10 EXECUTIVE SUMMARY</p>
--	---

1.0 Applicant's Name and Address

Bausch & Lomb Incorporated
 1400 N. Goodman Street
 Rochester, NY 14609

Contact Person:
 Tricia Garrett
 Senior Specialist, Global Regulatory Affairs
 1400 N. Goodman Street
 Rochester, NY 14609
 (585) 338-6706 (office)
 (585) 338-0702 (fax)
Tricia.M.Garrett@bausch.com

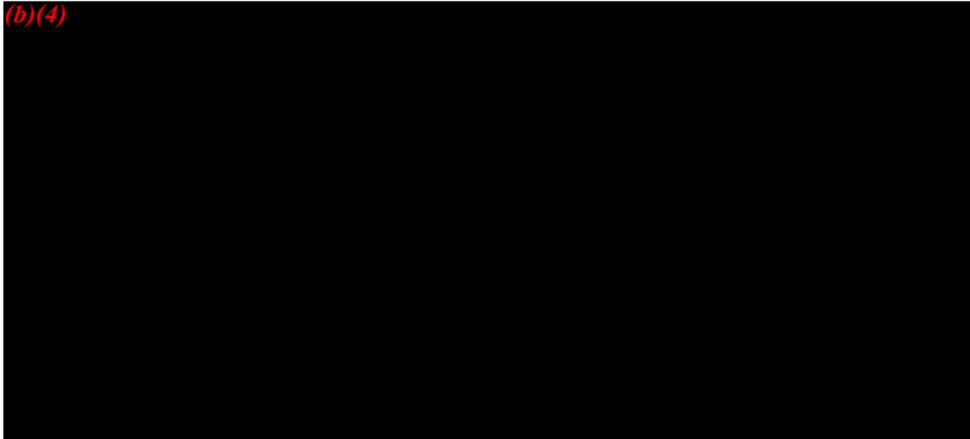
2.0 Device Identification and Classification

Common Name:	Contact Lens Disinfection Solution
Trade Name:	TBD
Classification:	Soft (hydrophilic) contact lens care products Rigid Gas Permeable contact lens care products
Device classification:	Class II (21 CFR 886.5918 & 21 CFR 886.5928)
Product Codes:	LPN, MRC

3.0 Establishment Identification Numbers

The owner operator for Bausch & Lomb facilities is Bausch & Lomb Incorporated. The owner operator number for Bausch & Lomb Incorporated (b)(4) located at One Bausch & Lomb Place, Rochester, New York 14604.

The establishment registration number and address for each manufacturing and sterilization site for Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution:



Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 10 EXECUTIVE SUMMARY
---	---

Owner/Operator Number:
Bausch & Lomb, Incorporated
One Bausch & Lomb Place
Rochester, New York 14604-2701
Owner/Operator Number - 9913003

4.0 Performance Standards

No performance standards for this device have been promulgated under Section 514, Federal Food, Drug and Cosmetics Act.

5.0 Description of Device

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is a sterile, buffered solution containing 3% hydrogen peroxide (b)(4)

[Redacted]

(b)(4)

[Redacted]

Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 10 EXECUTIVE SUMMARY
---	---

6.0 Sterility / Sterilization Rationale

In accordance with 21 CFR 800.10, Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is manufactured and marketed as a sterile solution.

7.0 Indications for Use

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.

8.0 Description of Safety and Effectiveness

Bausch + Lomb has followed the FDA guideline titled *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1997* where applicable to prepare this submission.

Non-Clinical Laboratory Testing

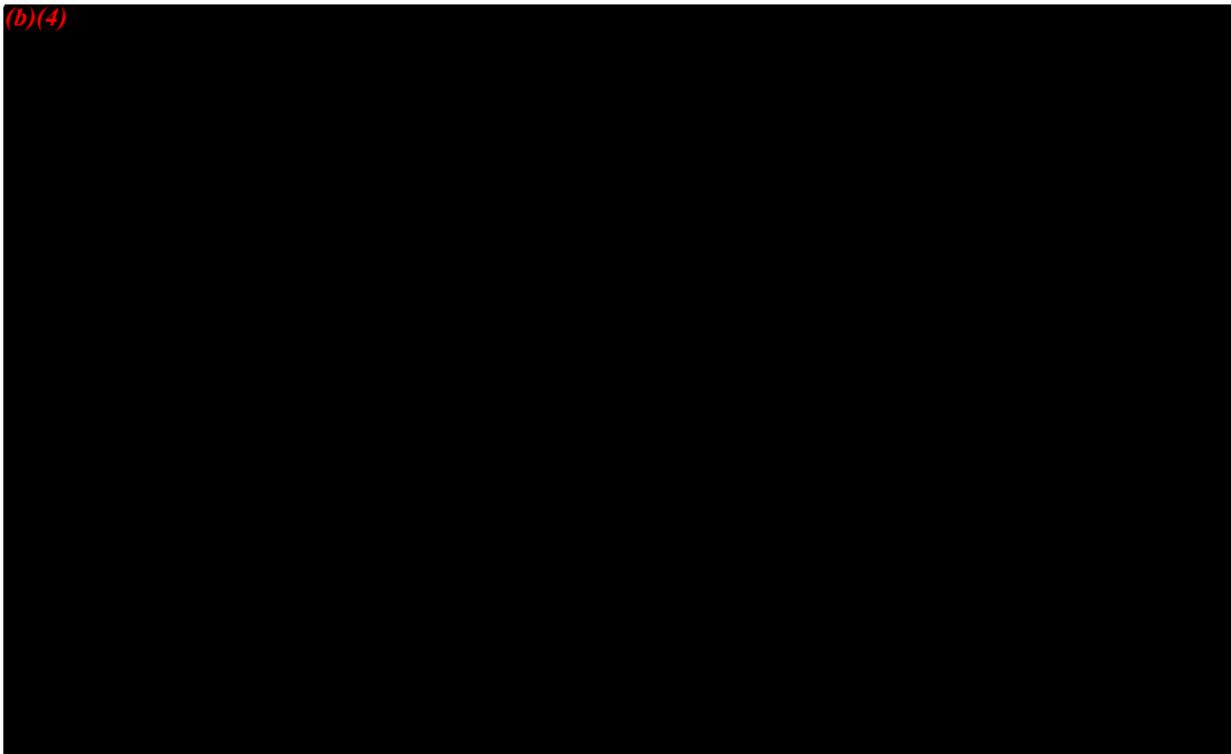
8.1 Biocompatibility Testing



Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 10 EXECUTIVE SUMMARY
---	---

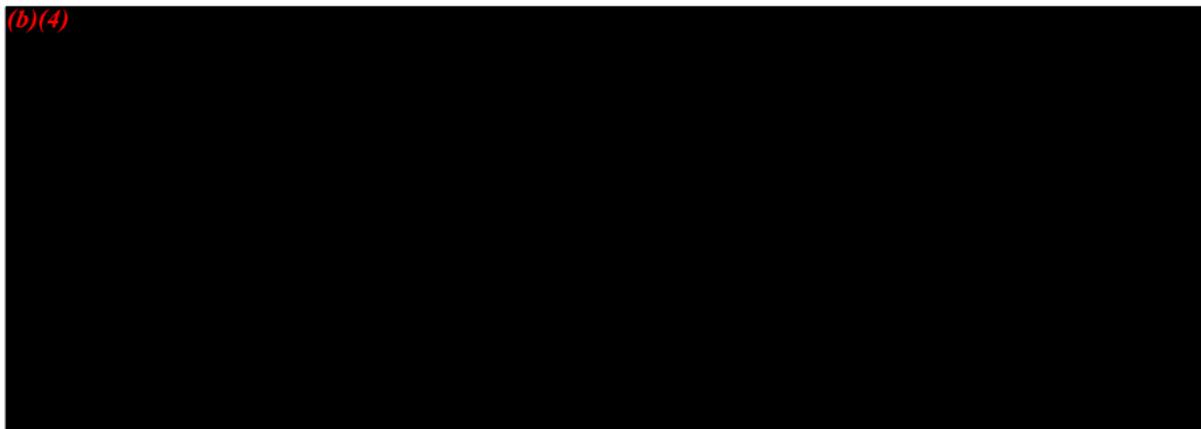
8.2 Microbial Testing

(b)(4)



8.3 Chemical Testing

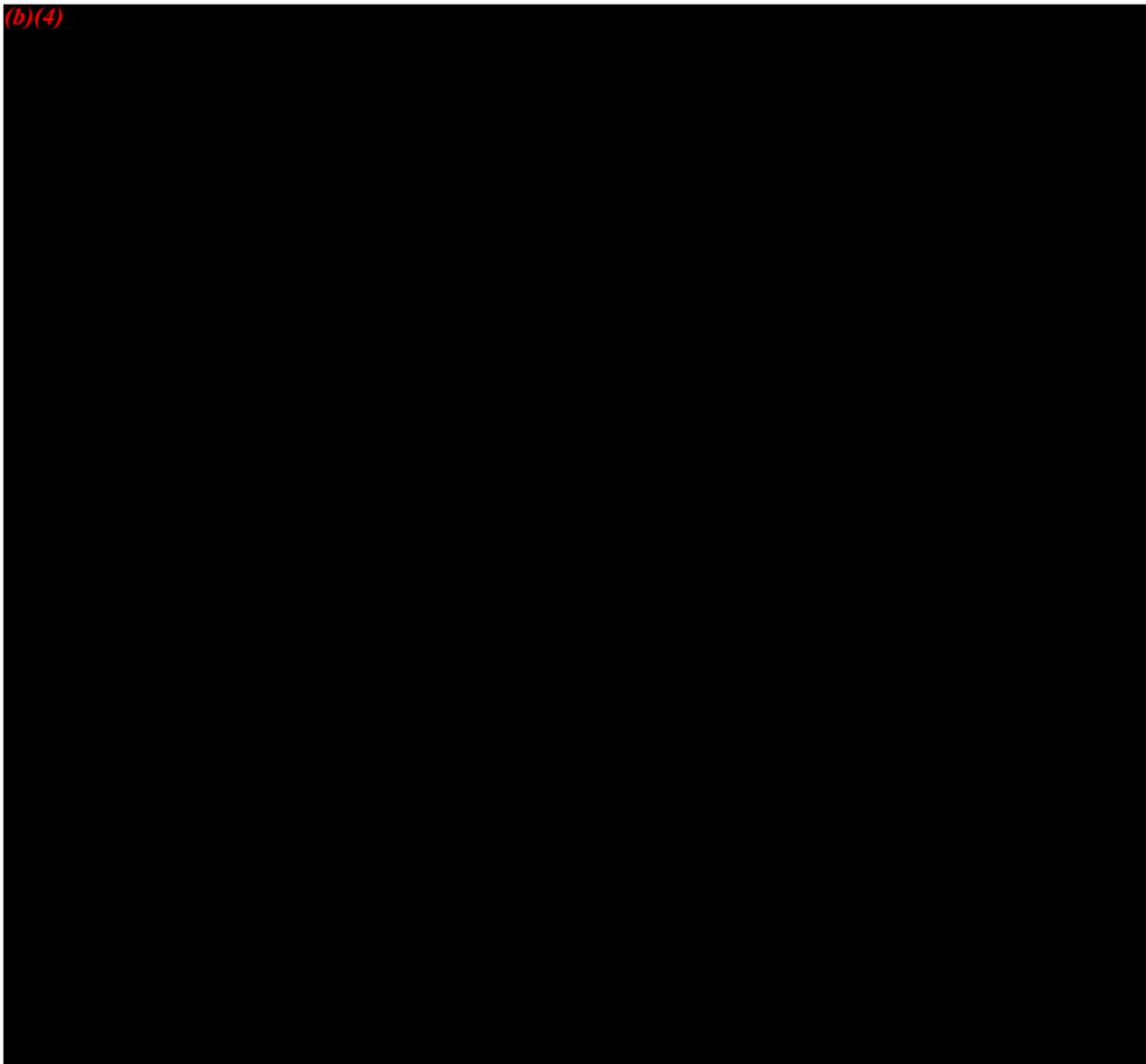
(b)(4)



Bausch & Lomb, Inc.
Traditional 510(k) Premarket Notification
Bausch + Lomb OCD04 Cleaning and
Disinfecting Solution

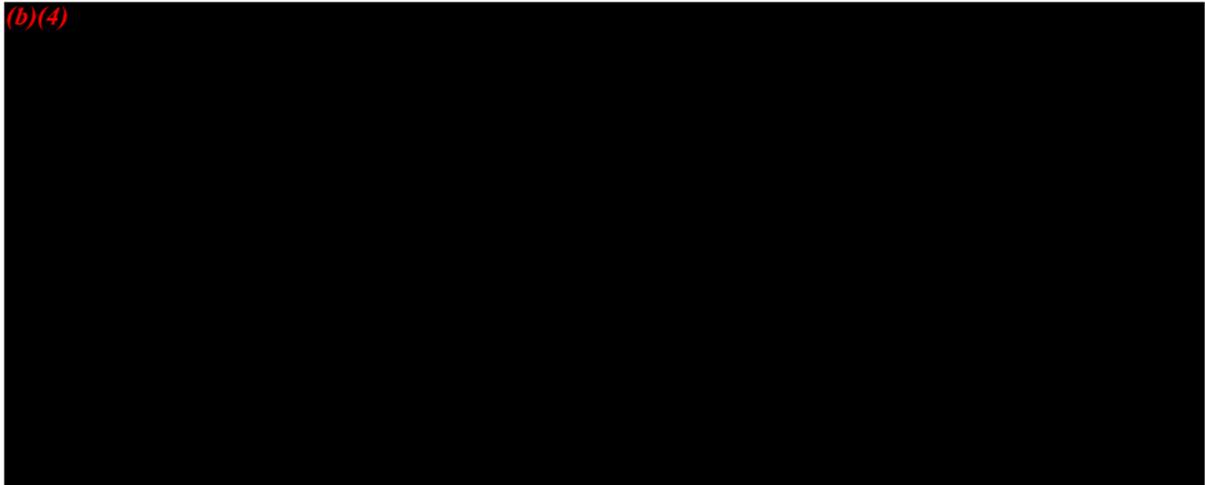
SECTION 10
EXECUTIVE SUMMARY

(b)(4)

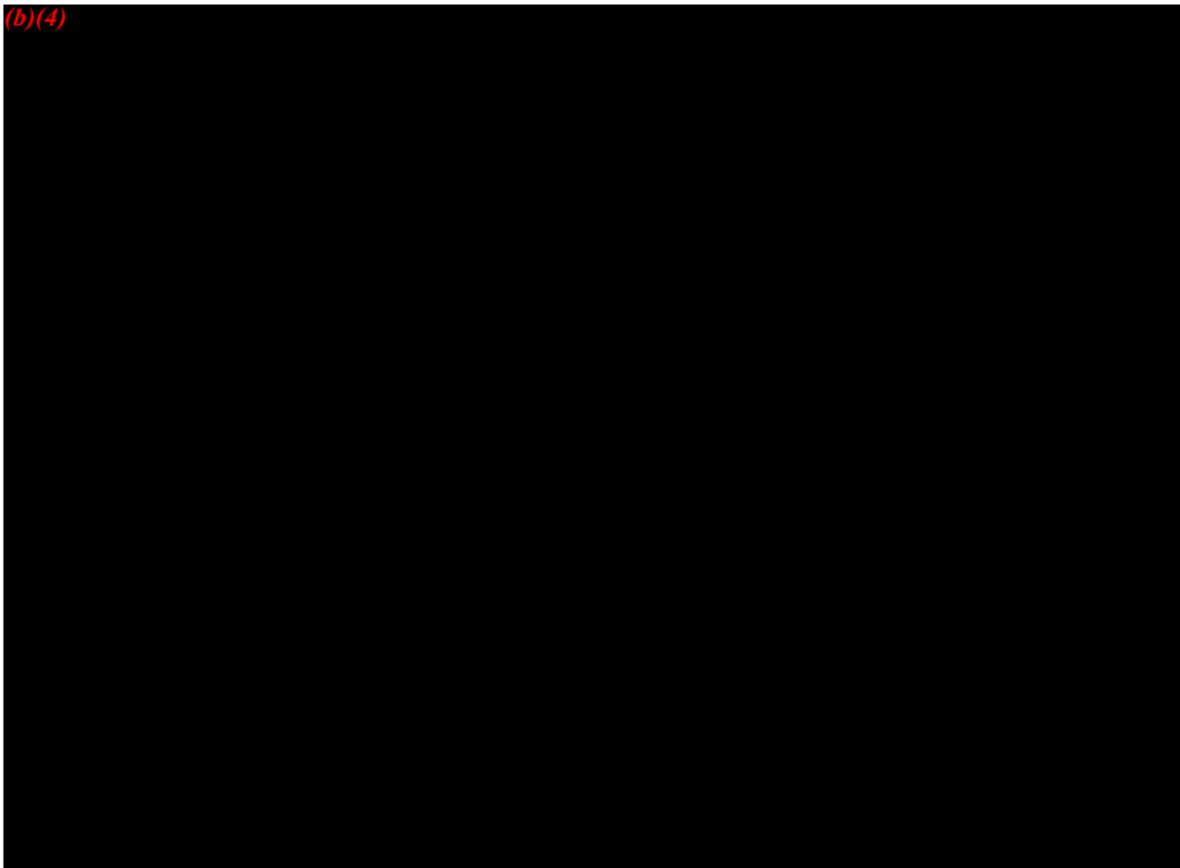


8.4 Clinical Evaluation

(b)(4)



Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 10 EXECUTIVE SUMMARY
---	---



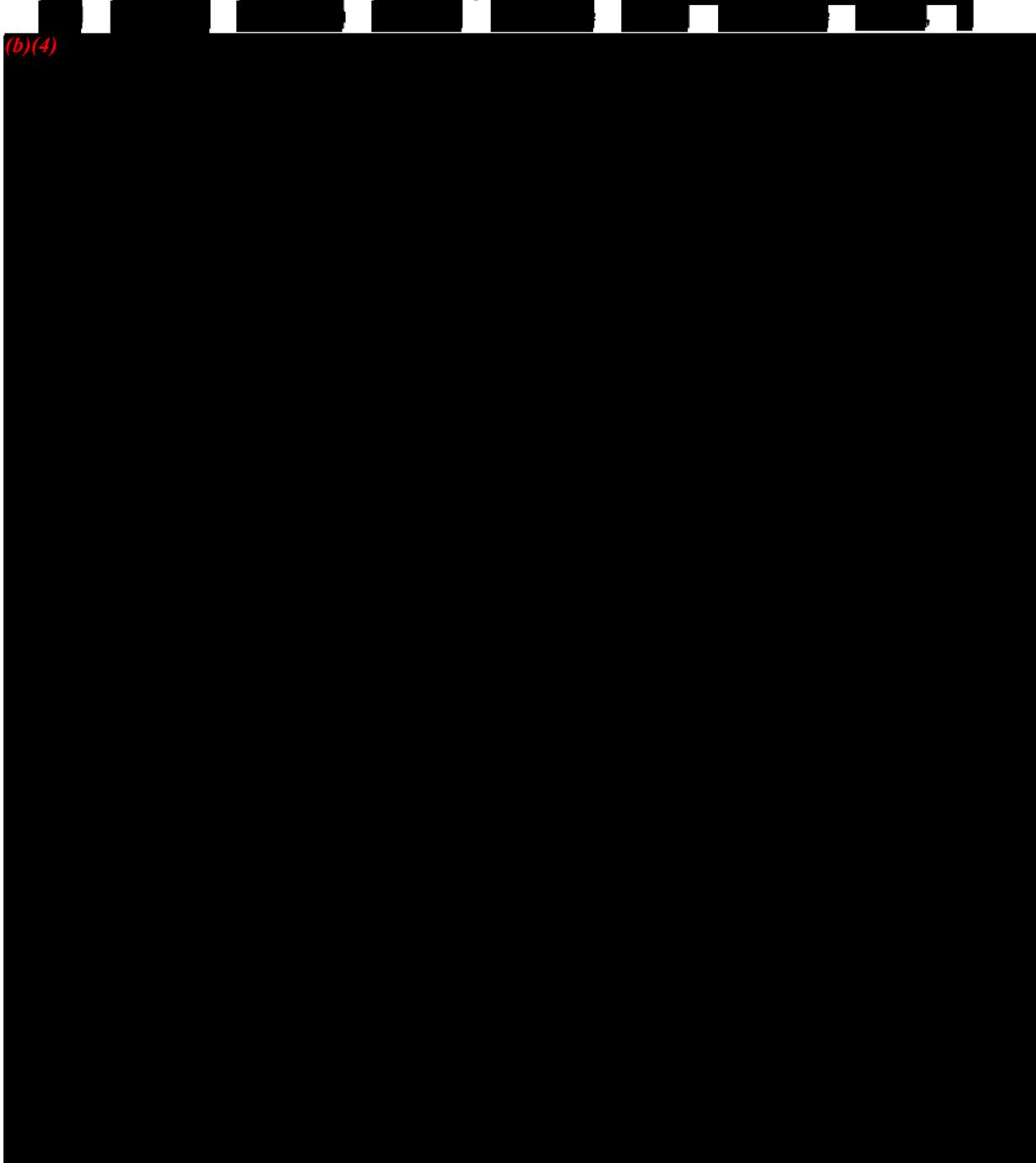
9.0 Purpose of Submission

The sponsor submitted this Traditional 510(k) Premarket Notification for a new medical device, Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution, to demonstrate that it is substantially equivalent to legally marketed devices.

Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 11 DEVICE DESCRIPTION
---	--

Section 11: Device Description

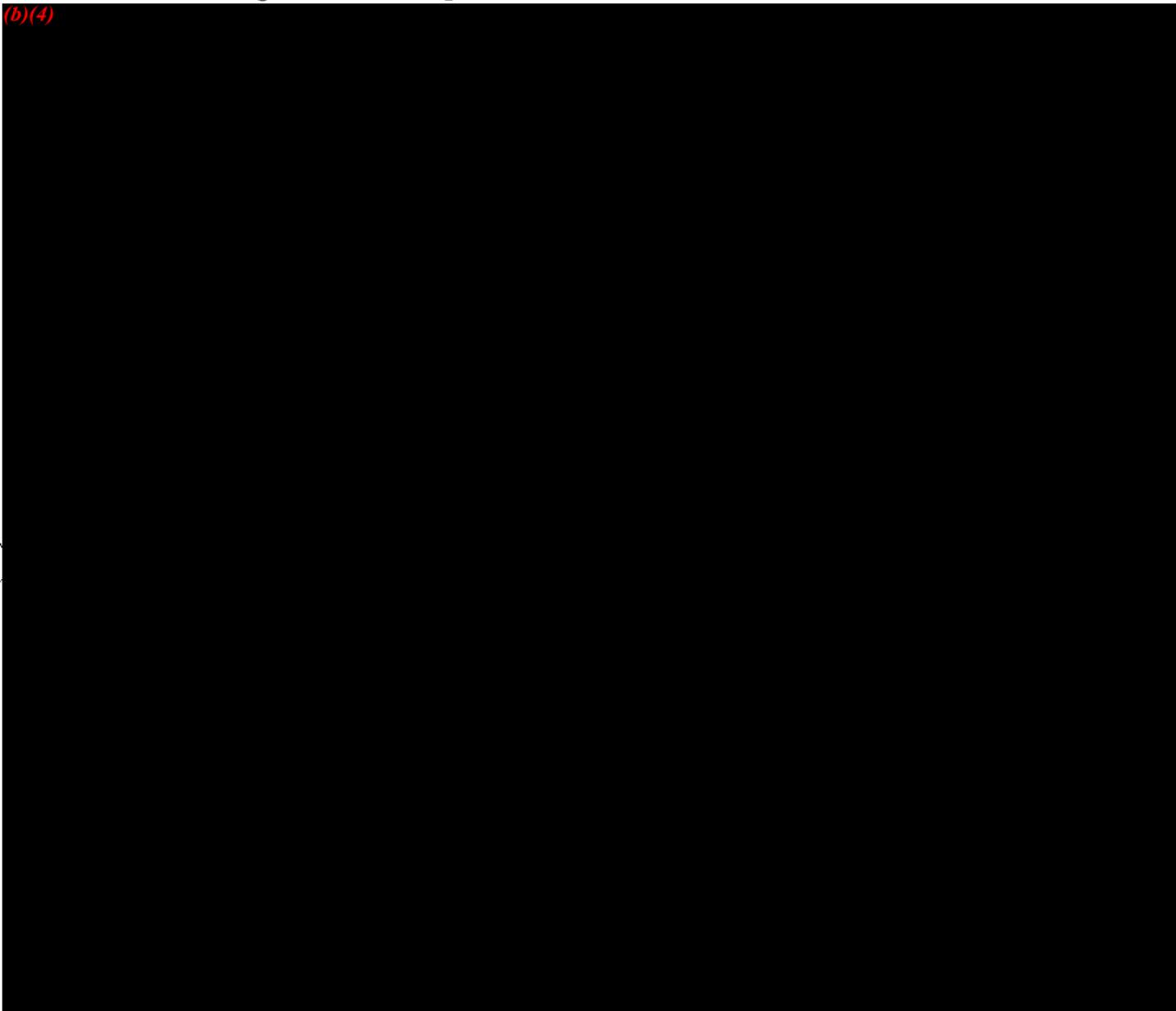
Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is a sterile, buffered solution containing 3% hydrogen peroxide (b)(4)



to be replaced. See picture below.

<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 11 DEVICE DESCRIPTION</p>
--	--

Manufacturing Process Flow For Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution:



<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 11 DEVICE DESCRIPTION</p>
--	--

Picture: Bausch + Lomb 3% Hydrogen Peroxide Cleaning and Disinfecting Solution Lens Case

(b)(4)

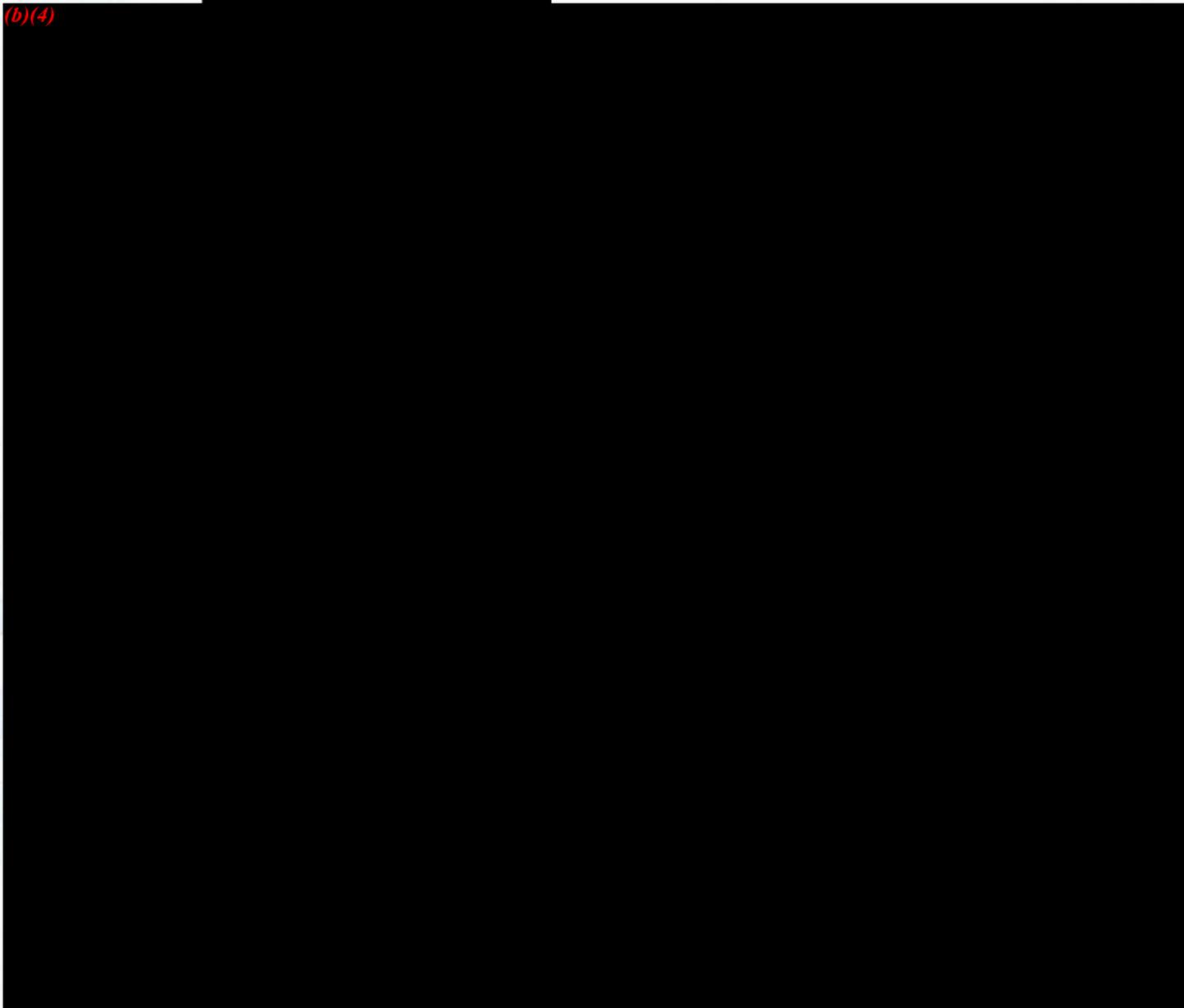


FLOWCHART

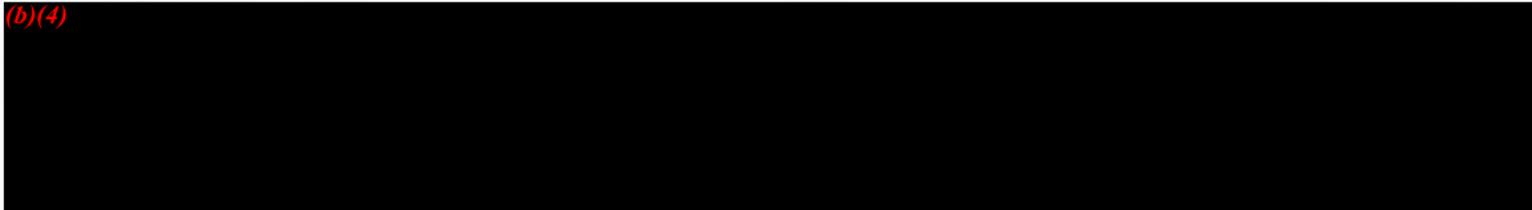
Assembly & Packaging

(b)(4)

(b)(4)



(b)(4)



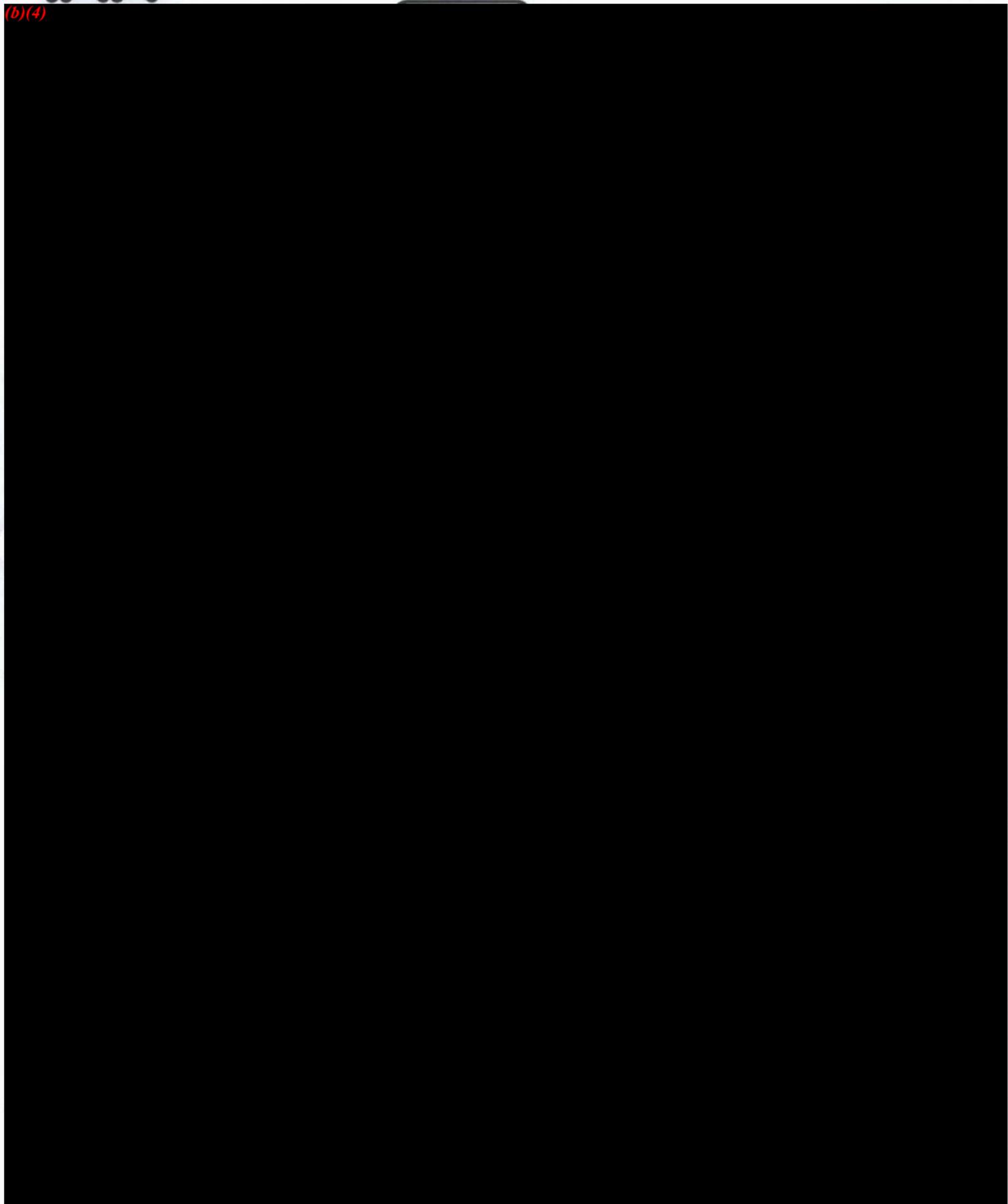
(b)(4)

FLOWCHART

(b)(4)

Advanced – Assembly & Packaging

(b)(4)

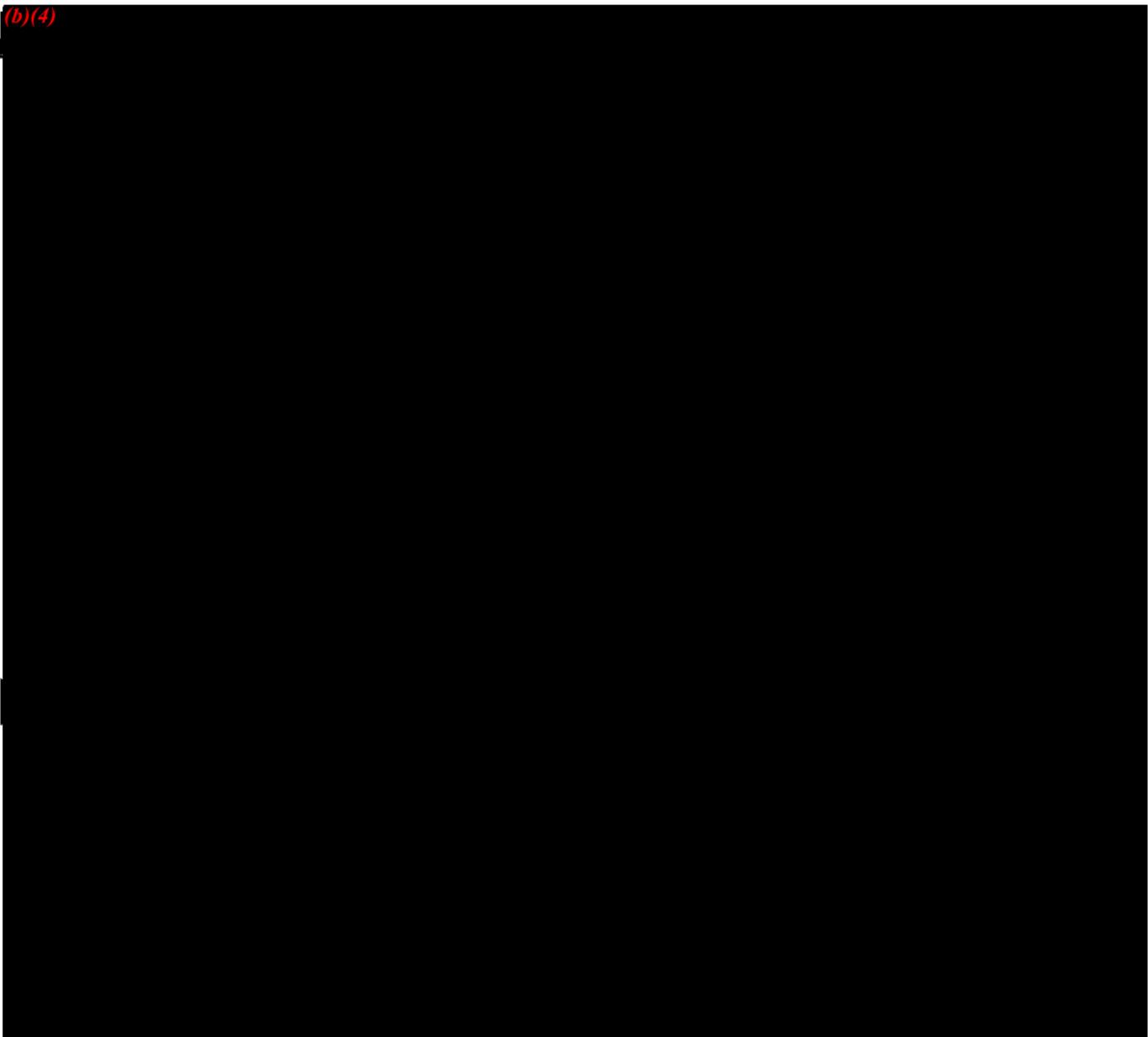


Bausch & Lomb

Certificate of Analysis

Page 1 of 1

(b)(4)



Last Refreshed Page 2/20/08 11:17:28 AM

IMPORTANT: Failure to follow directions for use will result in burning and stinging.

CLEAR CARE

3% HYDROGEN PEROXIDE
Cleaning & Disinfecting Solution
TRIPLE ACTION
CLEANING



#1 IN CLEANING AND COMFORT

- DEEP CLEANS
- LOOSENS DIRT
- ENHANCES PROTEIN REMOVAL

12 FL OZ (355ml) Sterile

CONTRAINDICATIONS: There are no known contraindications for use of Clear Care® solution. However, if you are allergic to any ingredient in this solution, do not use.

CONTENTS: Clear Care® One Bottle Cleaning and Disinfecting Solution is a sterile solution containing micro-fine hydrogen peroxide (3% sodium chloride 0.27%, salicylic acid with potassium acid, a lubricate buffered system, and Puronic™ 1764 (a cleaning agent)). Includes specialized lens case with neoprene gasket. Do not use if safety seal around the bottle cap is broken or missing.

DIRECTIONS FOR USE:

To ensure proper disinfection of your lenses, you must follow the instructions completely. **DISPOSE OF YOUR OLD LENS CASE WITH EACH PURCHASE.** Do not skip any steps. Always wash and rinse your hands before handling your lenses. See package insert for special RGP instructions.



1. Remove and place each lens into the appropriately marked L/R domed lens holder. Rinse with Clear Care® for 5 seconds.
 2. Fill the lens case to fill line with Clear Care® and place the lens holder in the case.
 3. Tighten the cap and store lenses for at least 6 hours or overnight. **DO NOT SHAKE THE CASE.**
- YOUR LENSES ARE READY TO WEAR AFTER SOAKING FOR 6 HOURS.** No final rinse with saline is necessary.

DISCARD DATE:
Should be 3 months after opening

If unneutralized Clear Care® solution comes into contact with the eyes, it will cause burning and stinging and redness. Remove lenses immediately and flush eyes with a large amount of water or sterile saline. If burning or irritation continues, seek professional assistance from an eye care professional. If you have sensitivity or want to use Clear Care® with your eyes, consult your eye care professional for information regarding use of contact lenses. Store at room temperature.

WARNINGS:

- Do not squirt Clear Care® directly into your eyes or burning and stinging will result.
- Do not use flat lens case. Clear Care® only works with the special lens case provided.
- Do not remove lenses from case until at least 6 hours after the solution needs time to neutralize.
- Do not rinse lenses with Clear Care® prior to inserting lenses into your eyes. If you want to rinse lenses, use a sterile saline.

© 2013 Ciba Vision Corporation. All rights reserved. Clear Care® is a registered trademark of Ciba Vision Corporation. Clear Care® is a registered trademark of Ciba Vision Corporation. Clear Care® is a registered trademark of Ciba Vision Corporation. Clear Care® is a registered trademark of Ciba Vision Corporation.

G1418U



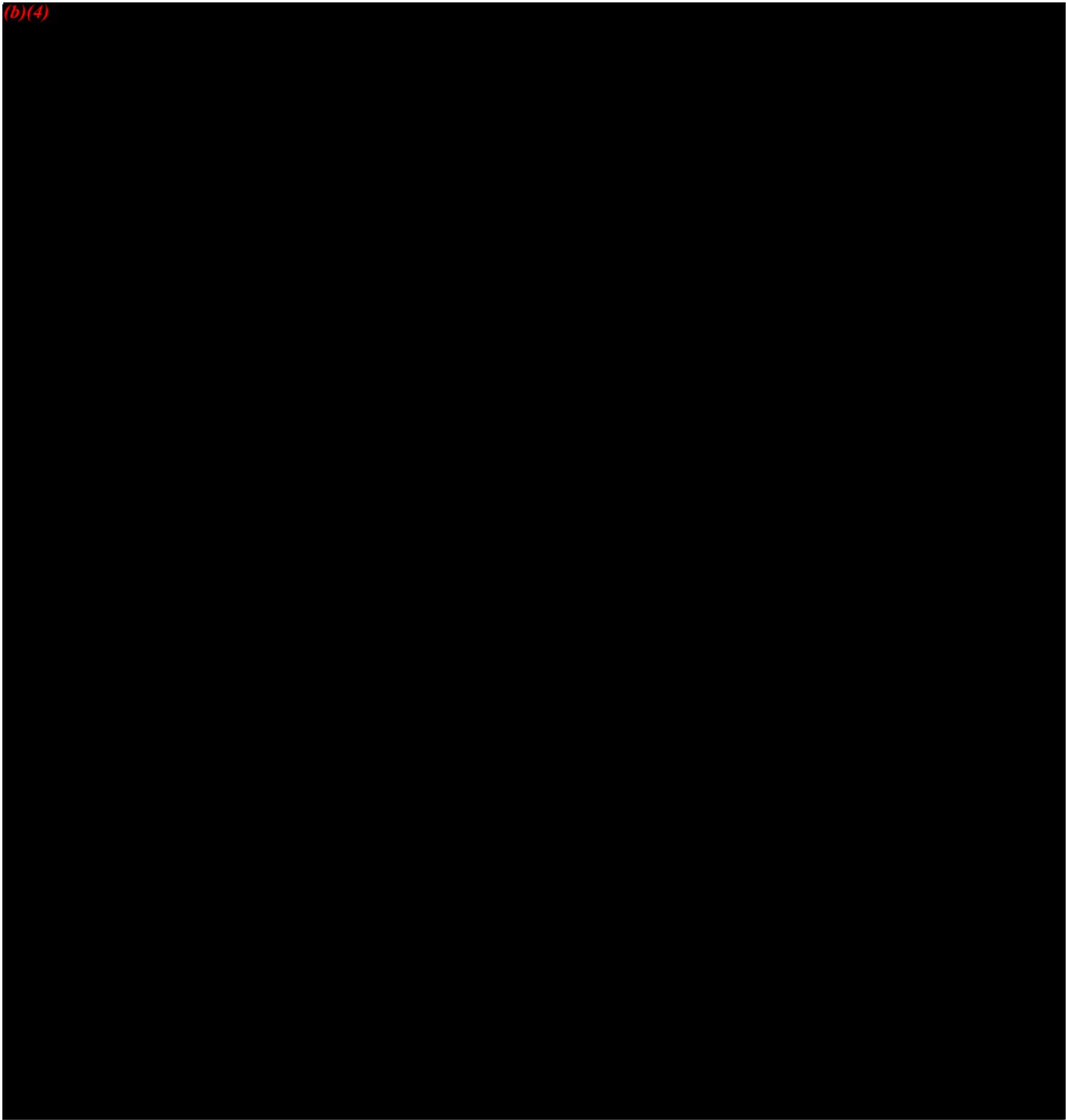
LOT 11118
EXP 2015-04

299

Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 14 STERILIZATION AND SHELF LIFE
---	--

Section 14: Sterilization and Shelf Life

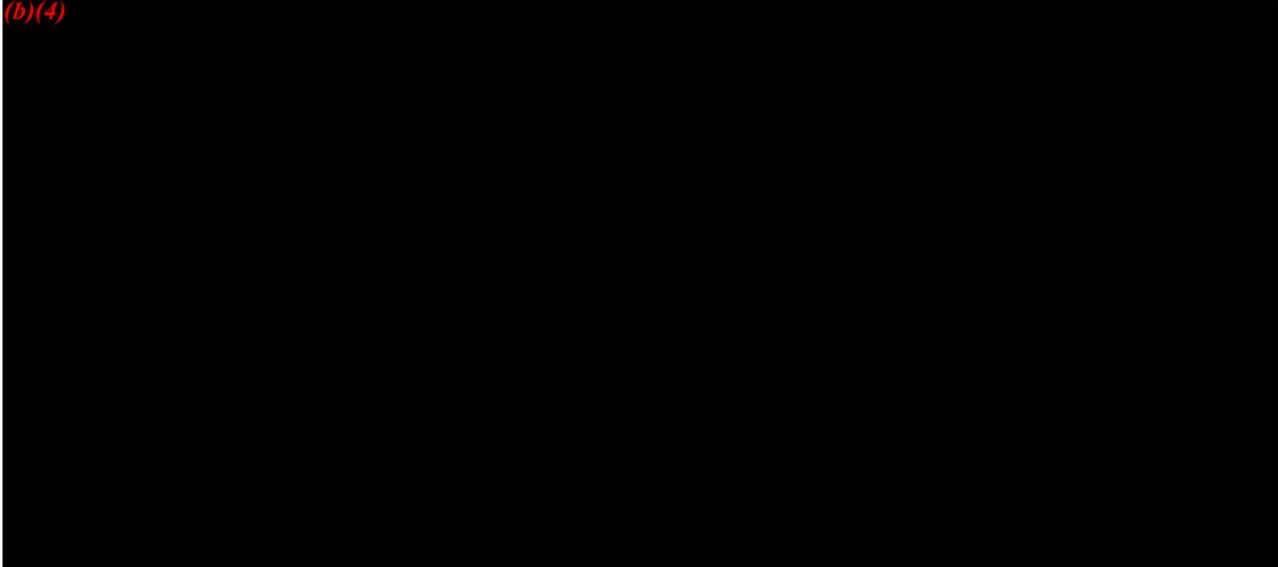
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Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 14 STERILIZATION AND SHELF LIFE
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Section 14.1: Sterility Testing Procedure TP-7810

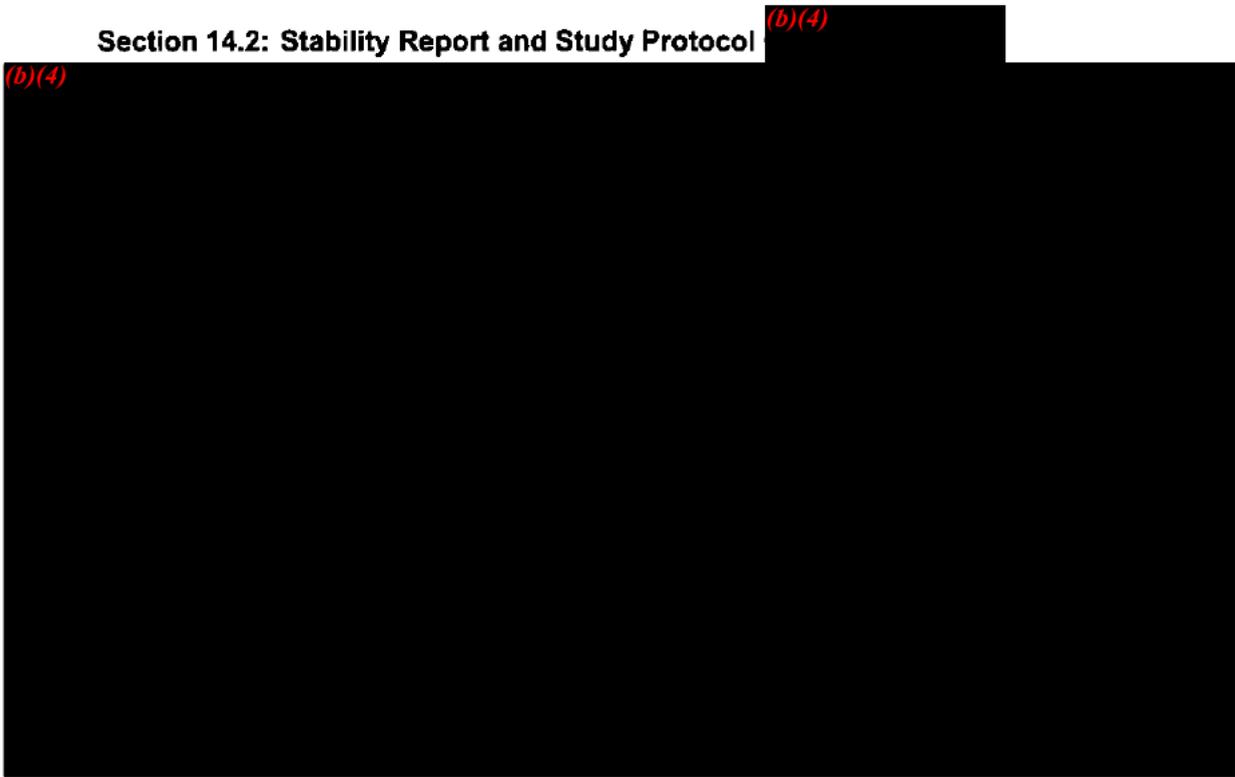
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Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 14 STERILIZATION AND SHELF LIFE
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Section 14.2: Stability Report and Study Protocol

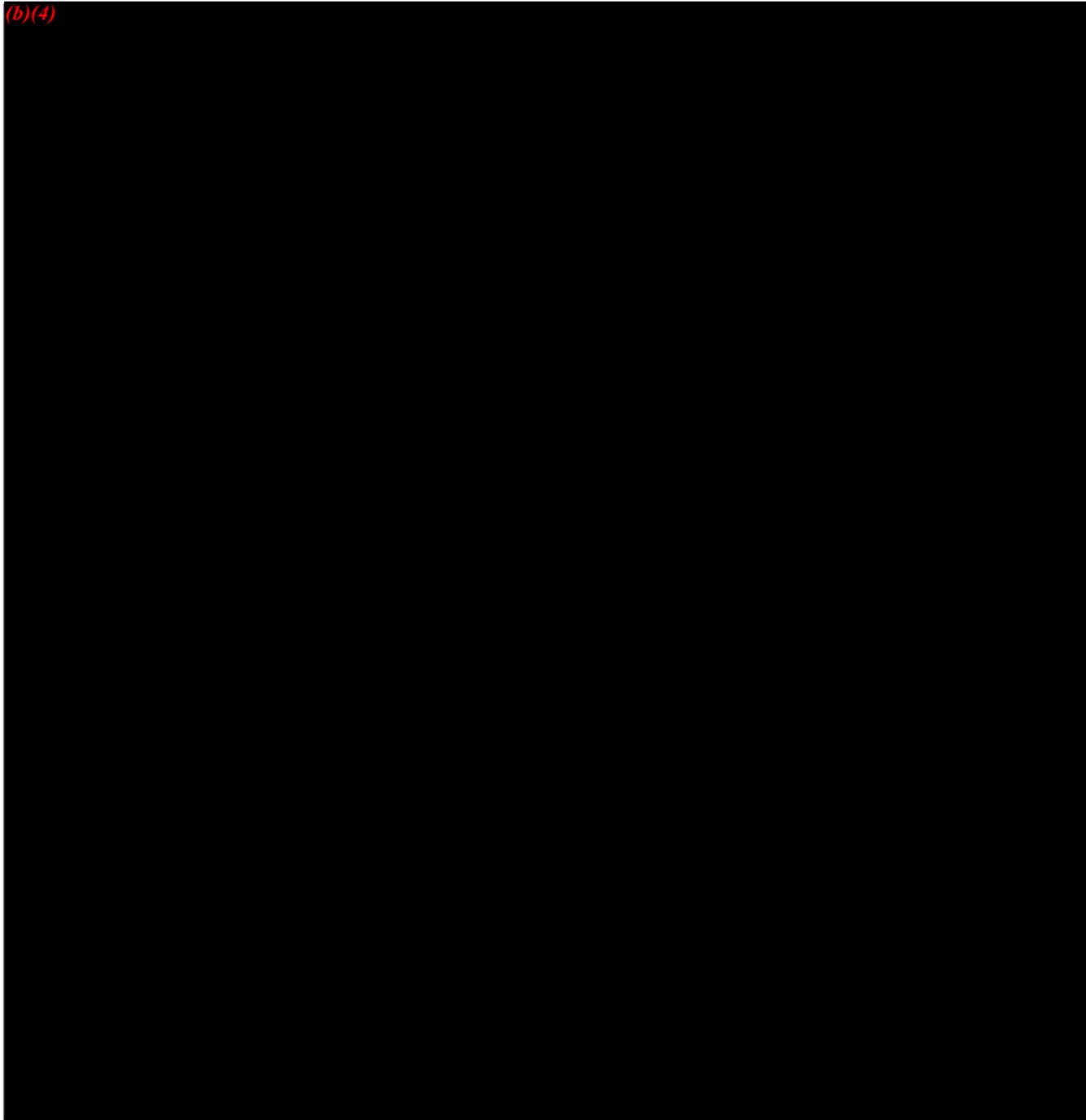
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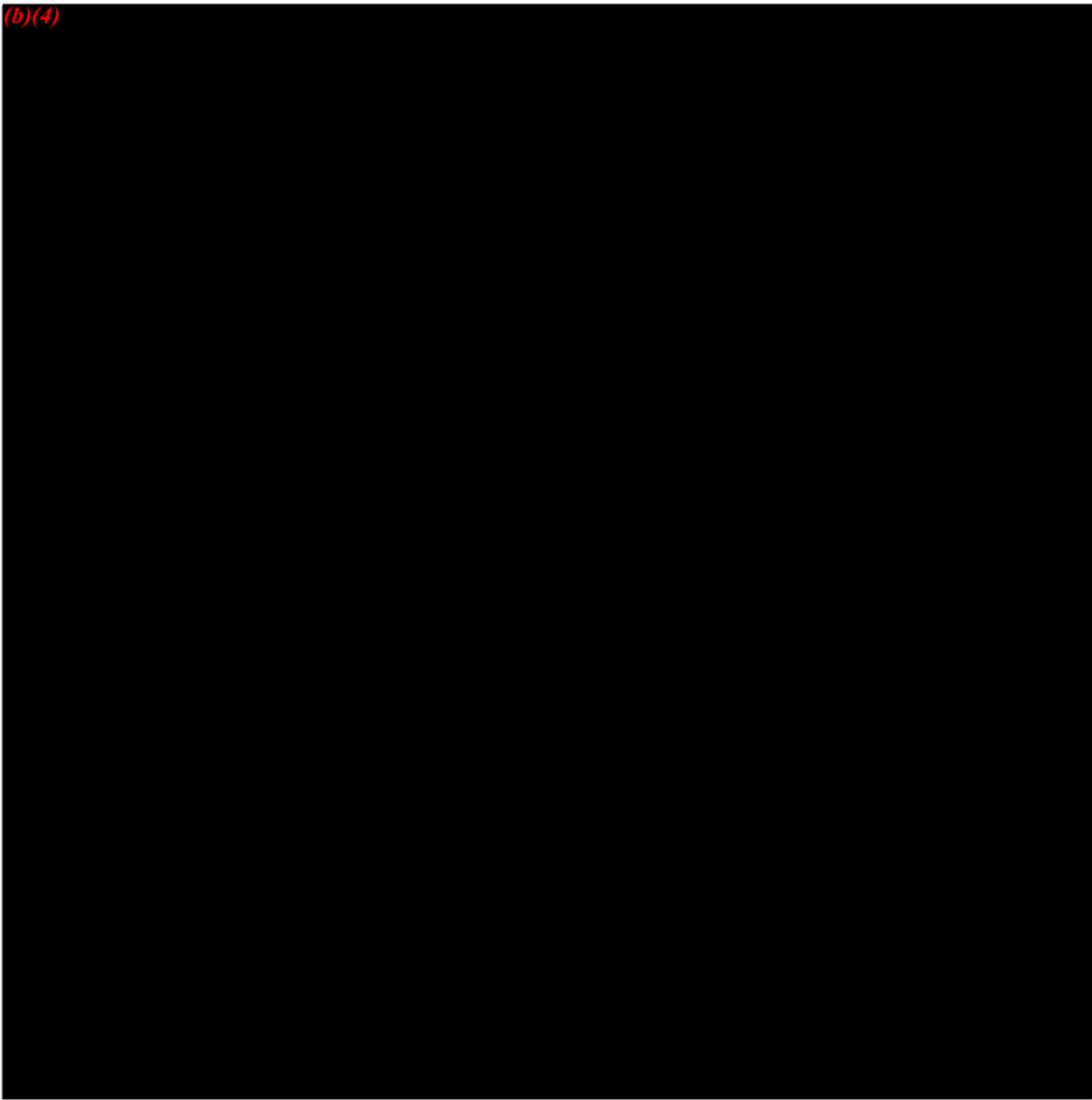
Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 14 STERILIZATION AND SHELF LIFE
---	--

Section 14.3: Microbiological Stability Reports



Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 14 STERILIZATION AND SHELF LIFE
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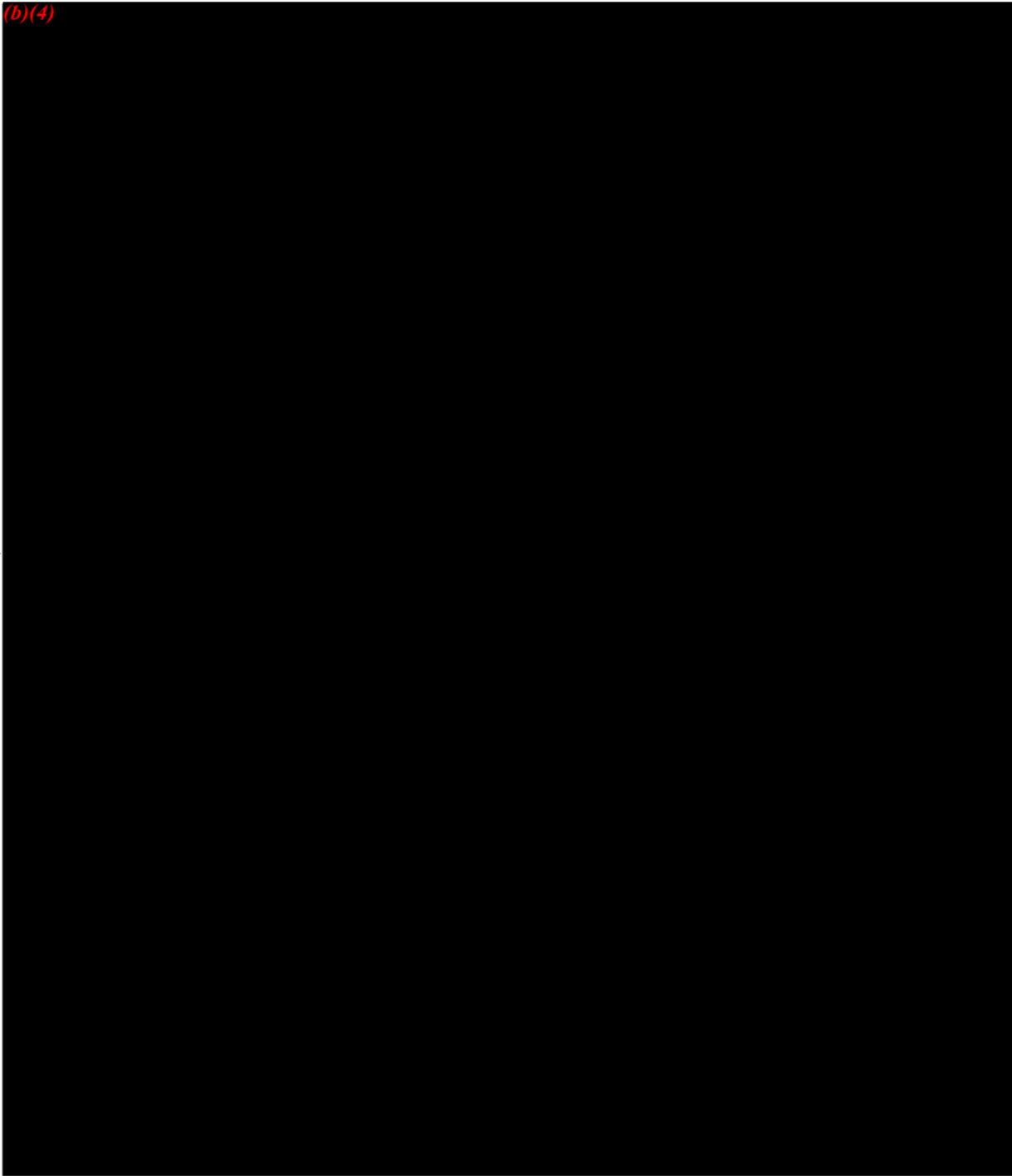
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<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 15 BIOCOMPATIBILITY</p>
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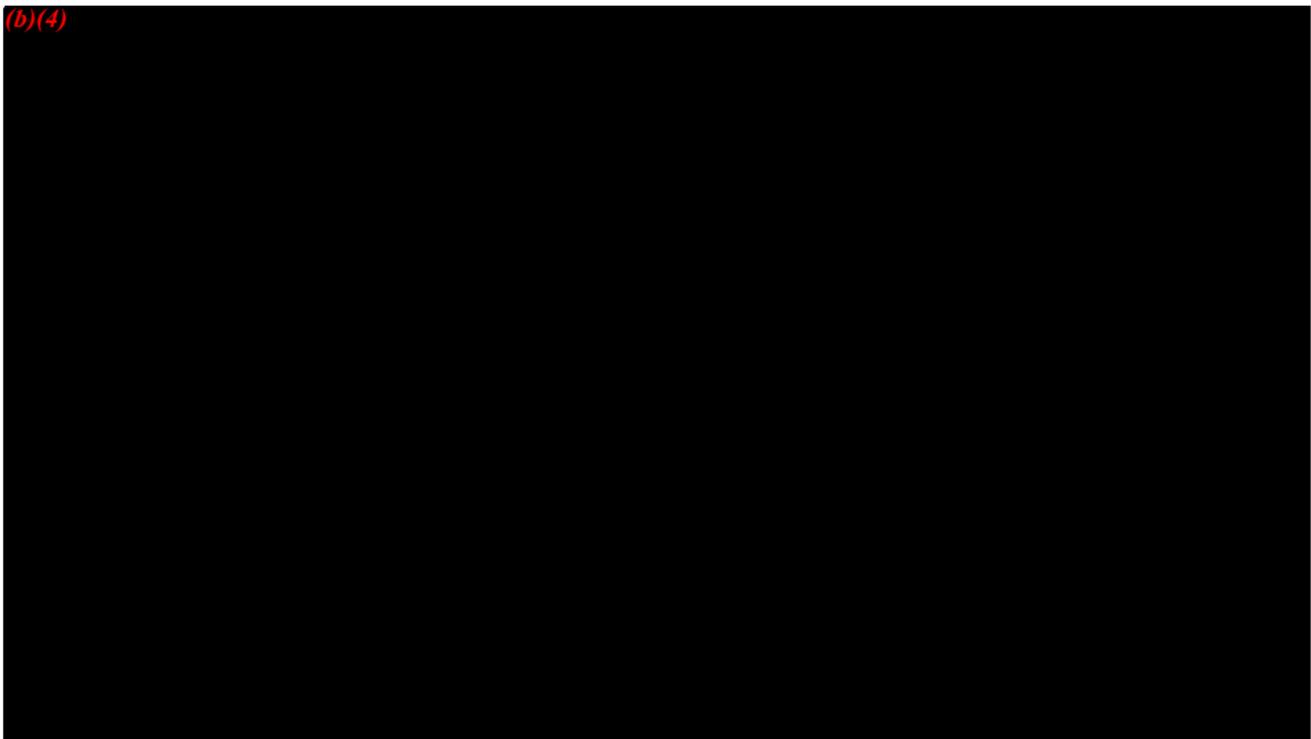
Section 15: Biocompatibility

(b)(4)



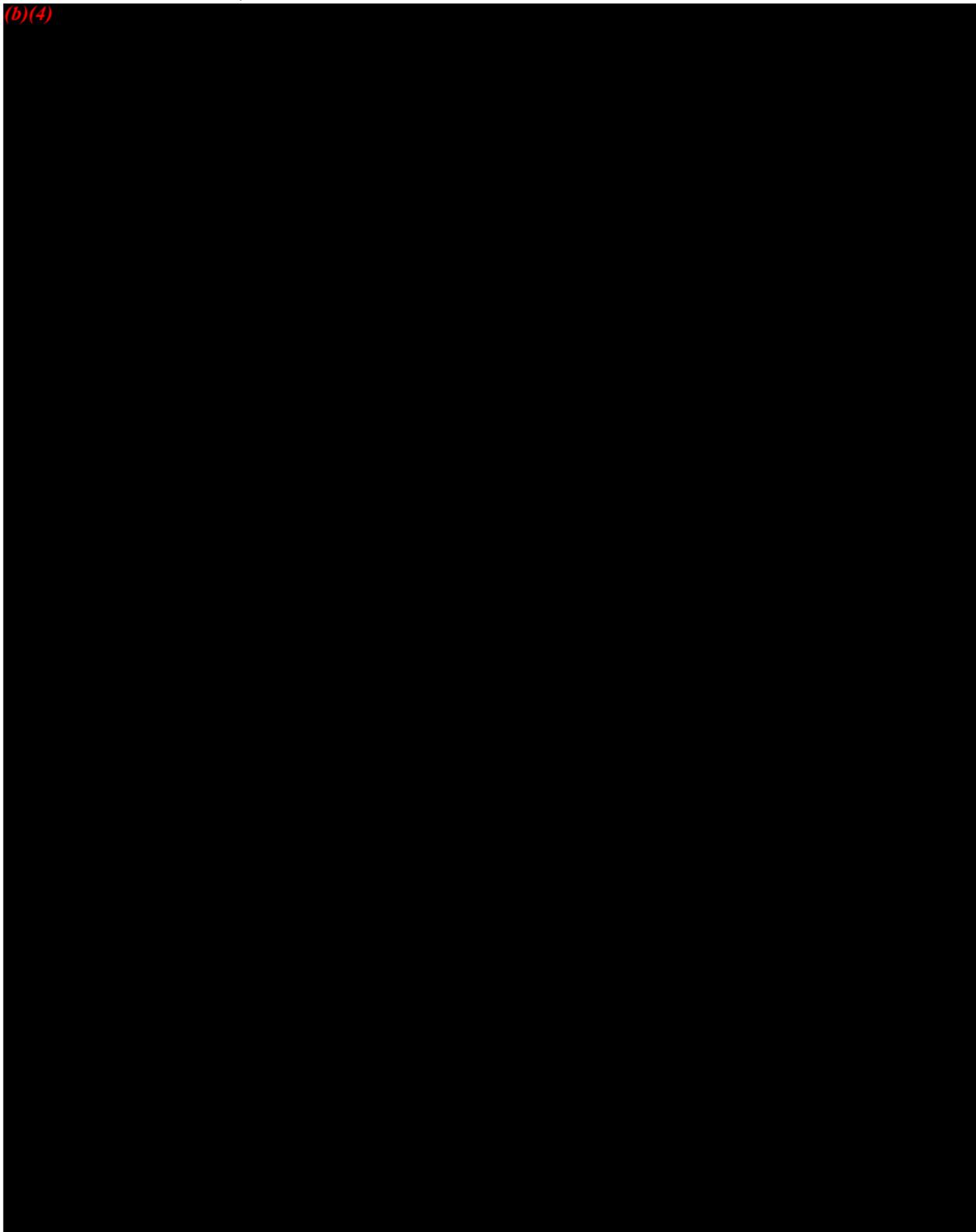
Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 15 BIOCOMPATIBILITY
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(b)(4)



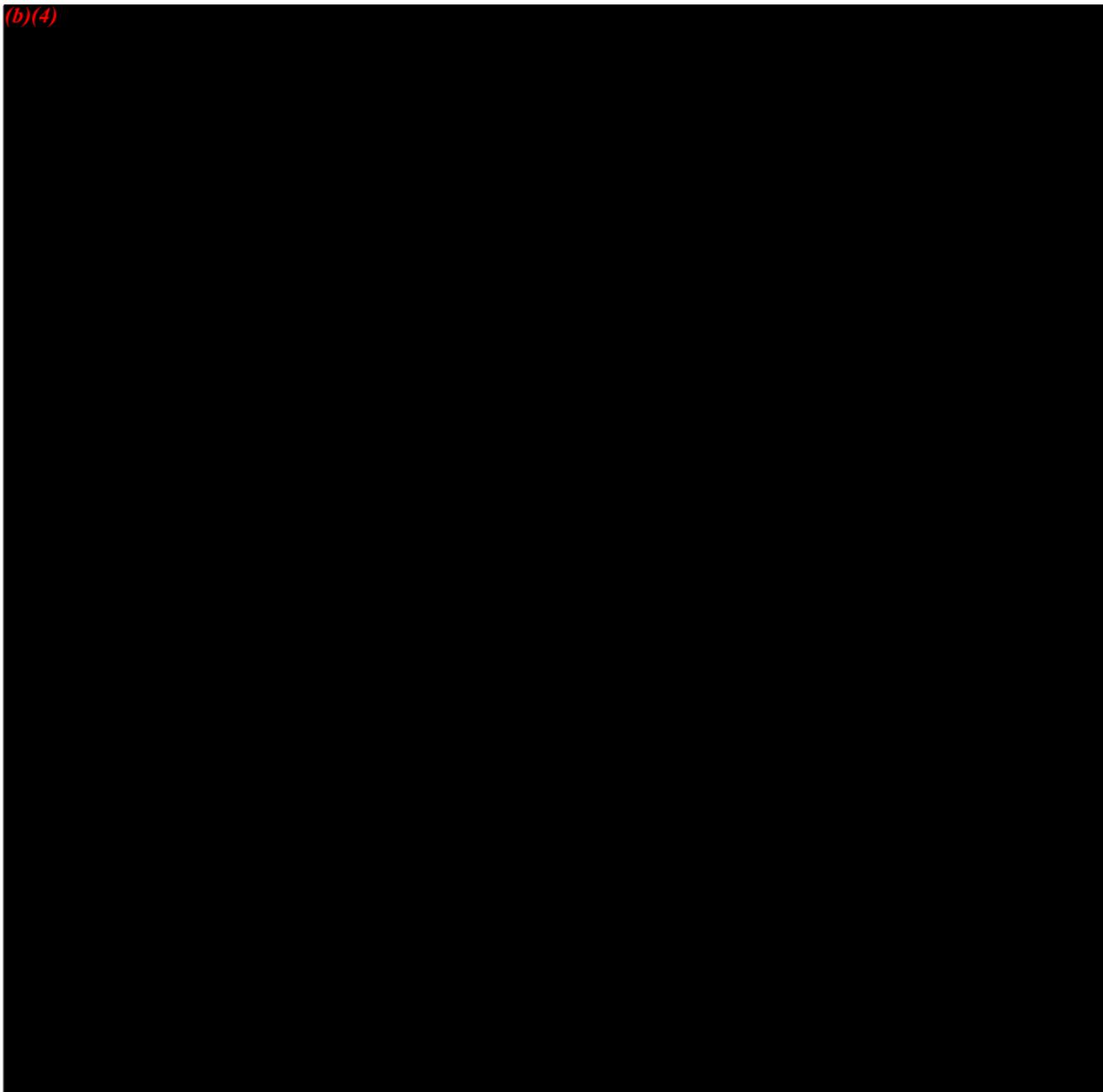
<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 15 BIOCOMPATIBILITY</p>
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(b)(4)



<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 15 BIOCOMPATIBILITY</p>
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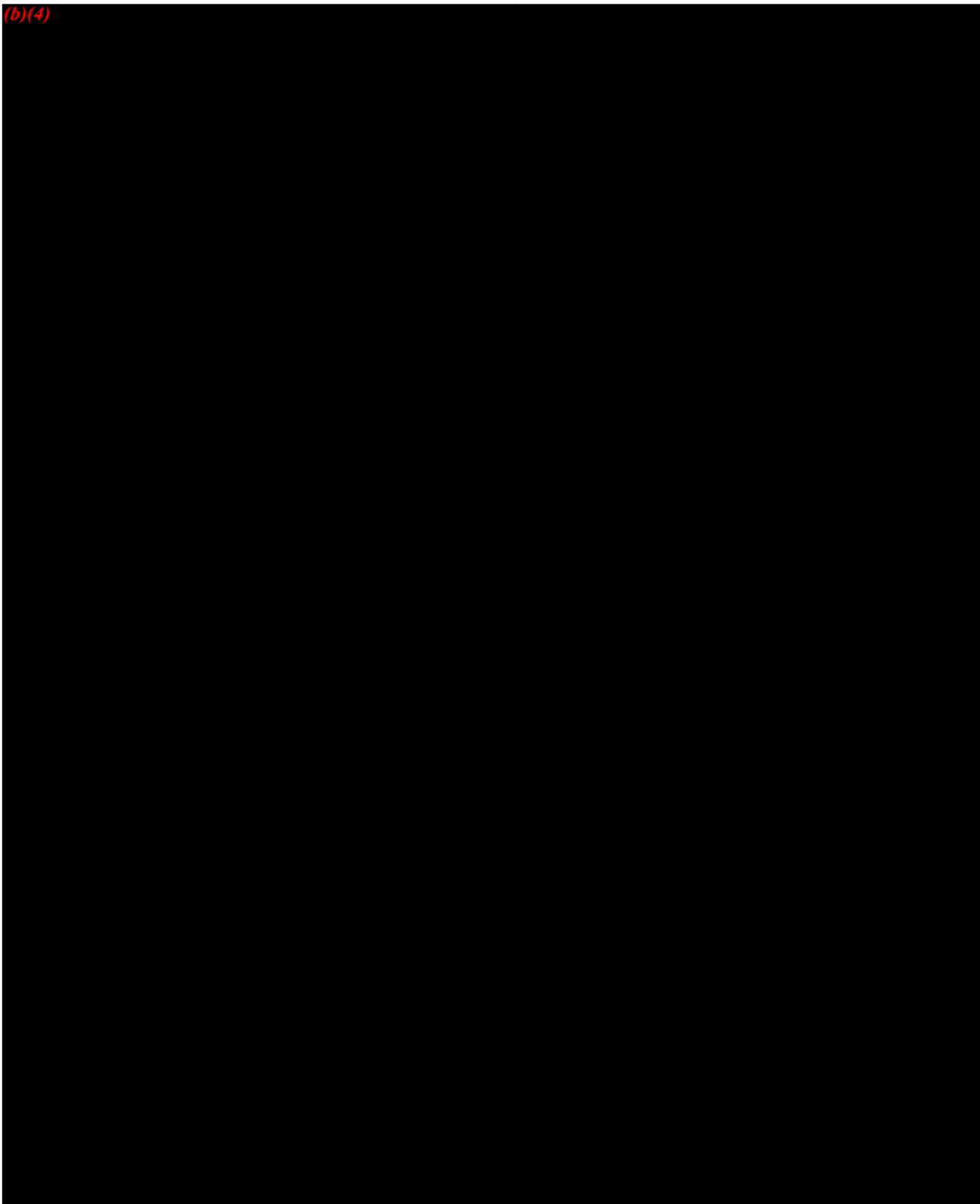
(b)(4)



<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 15 BIOCOMPATIBILITY</p>
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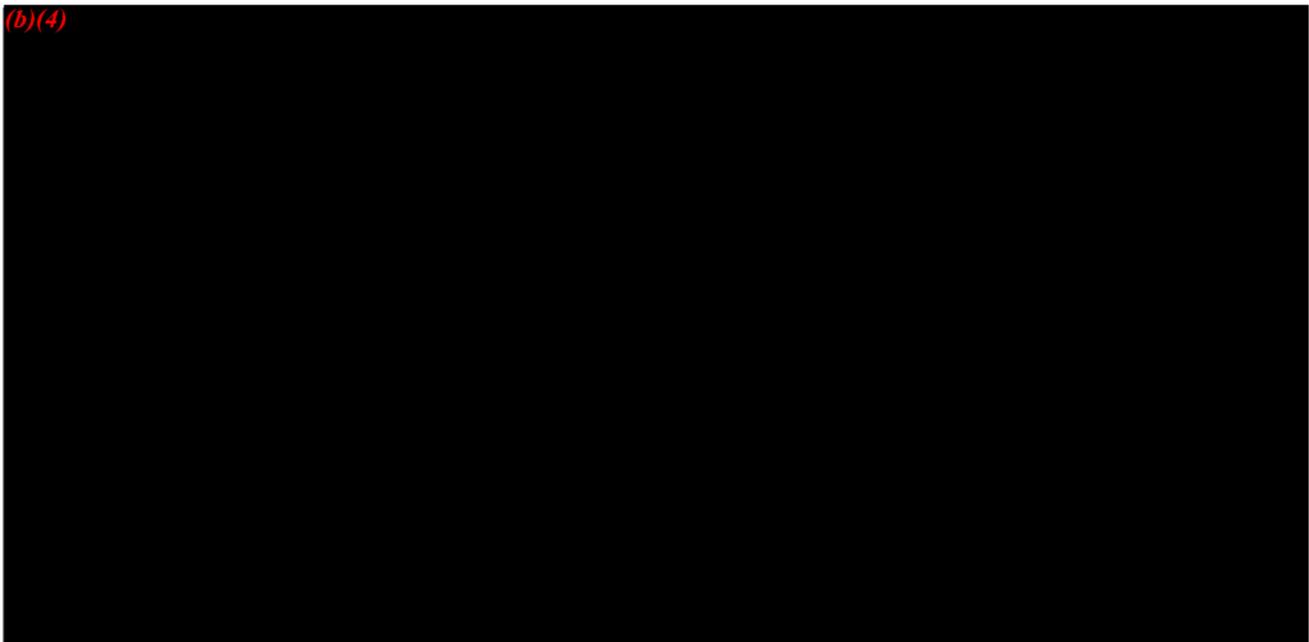
Section 15.2 ISO Elution Method of Packaging Components

(b)(4)



<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 15 BIOCOMPATIBILITY</p>
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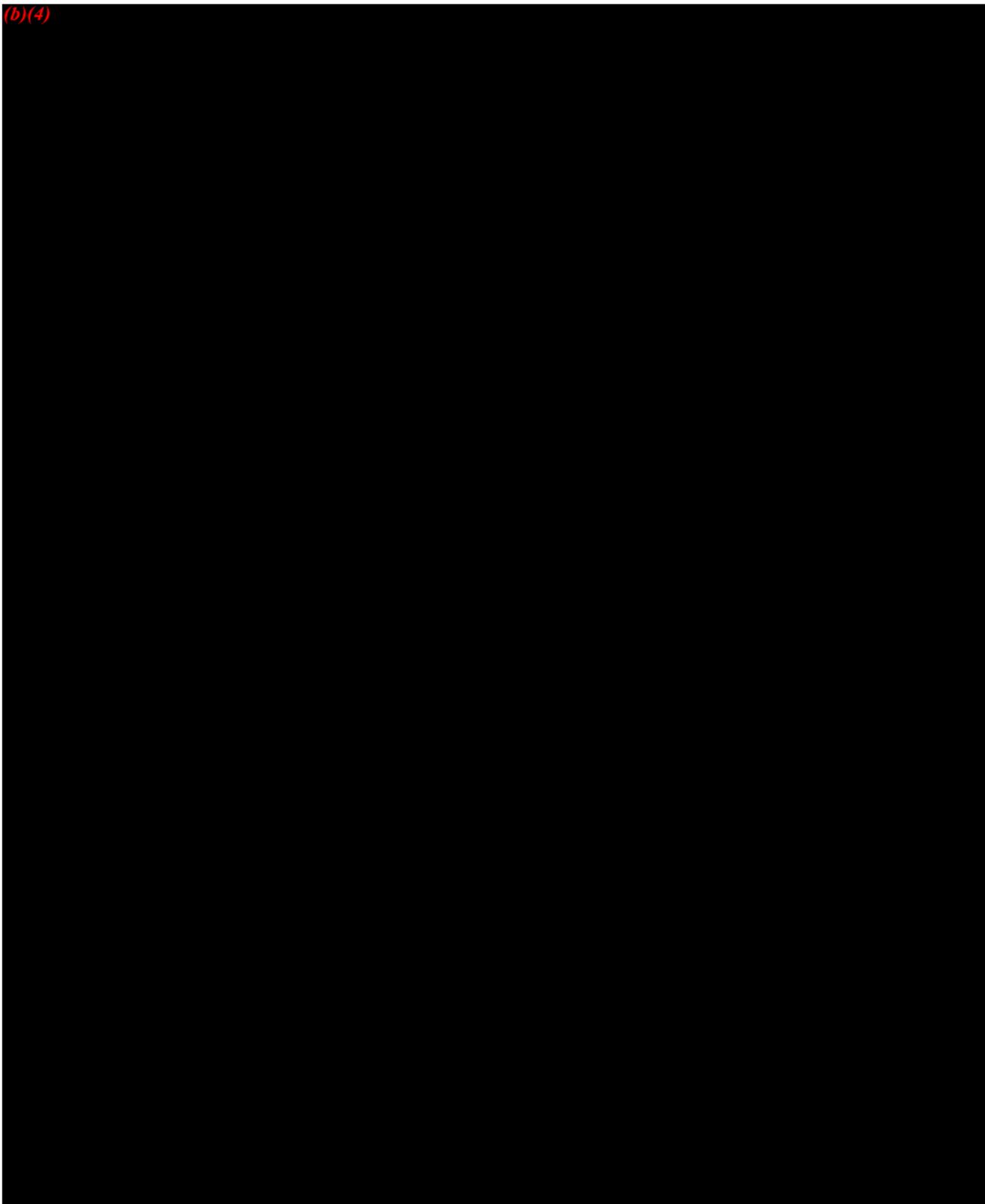
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<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 15 BIOCOMPATIBILITY</p>
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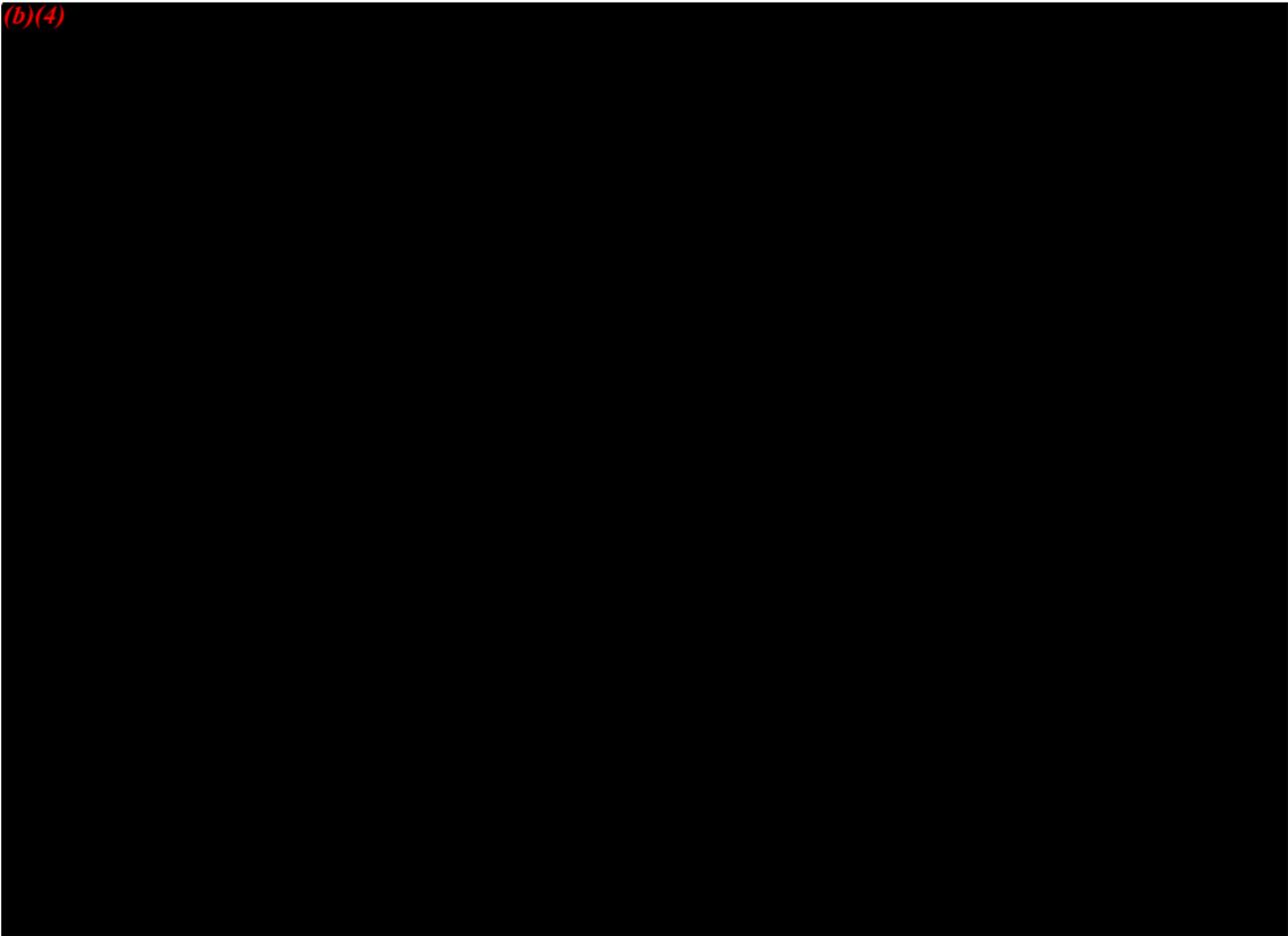
Section 15.3: In-Vivo Biocompatibility

(b)(4)



Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 15 BIOCOMPATIBILITY
---	--

(b)(4)



Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 16 SOFTWARE
---	--

Section 16: Software

This section does not apply to this Tradition 510(k) Premarket Notification. The device, Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution, does not contain any software.

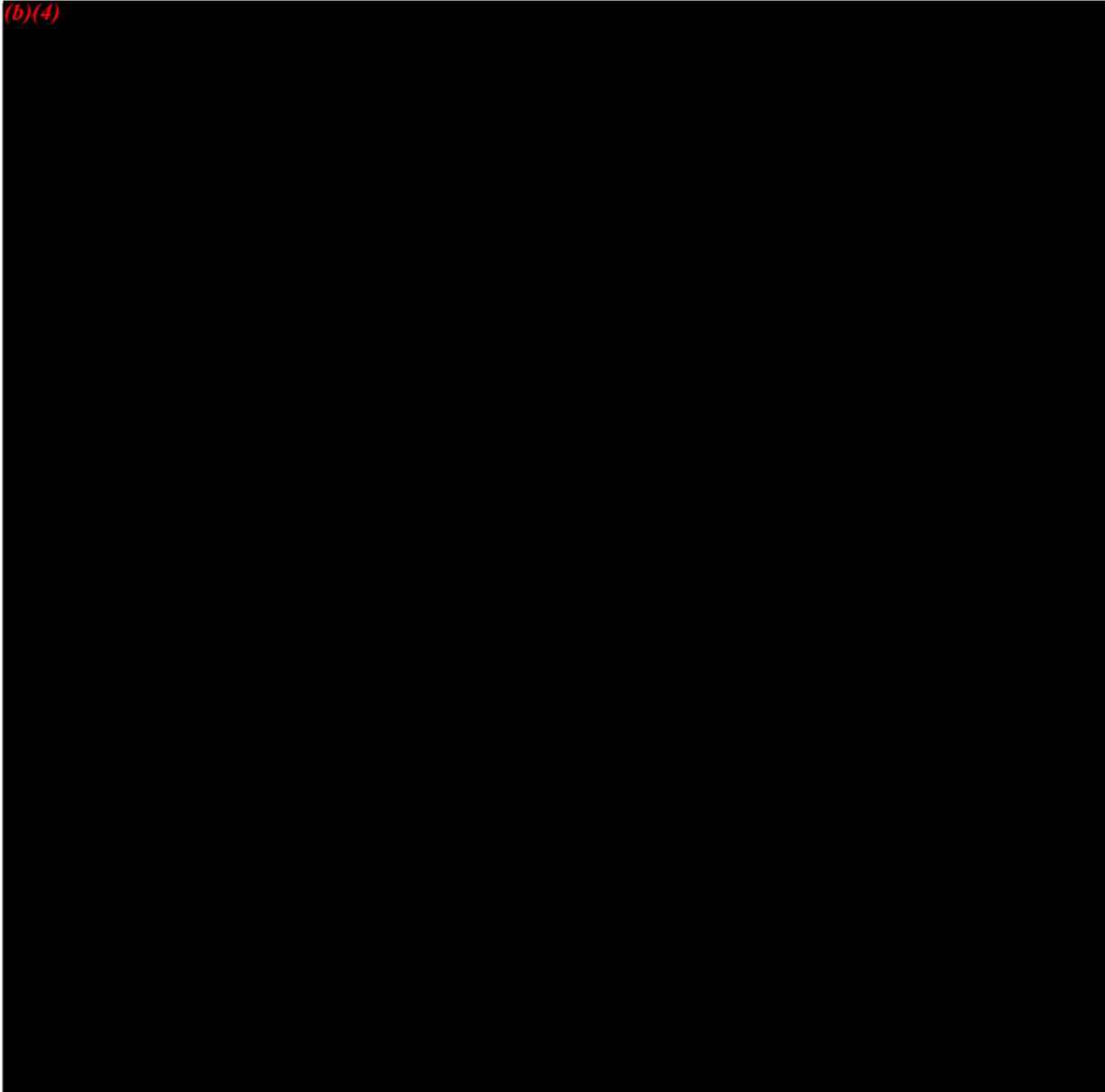
Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 17 ELECTRICAL SAFETY
---	---

Section 17: Electrical Safety

This section does not apply to this Tradition 510(k) Premarket Notification. The device, Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution, does not contain or support electrical equipment.

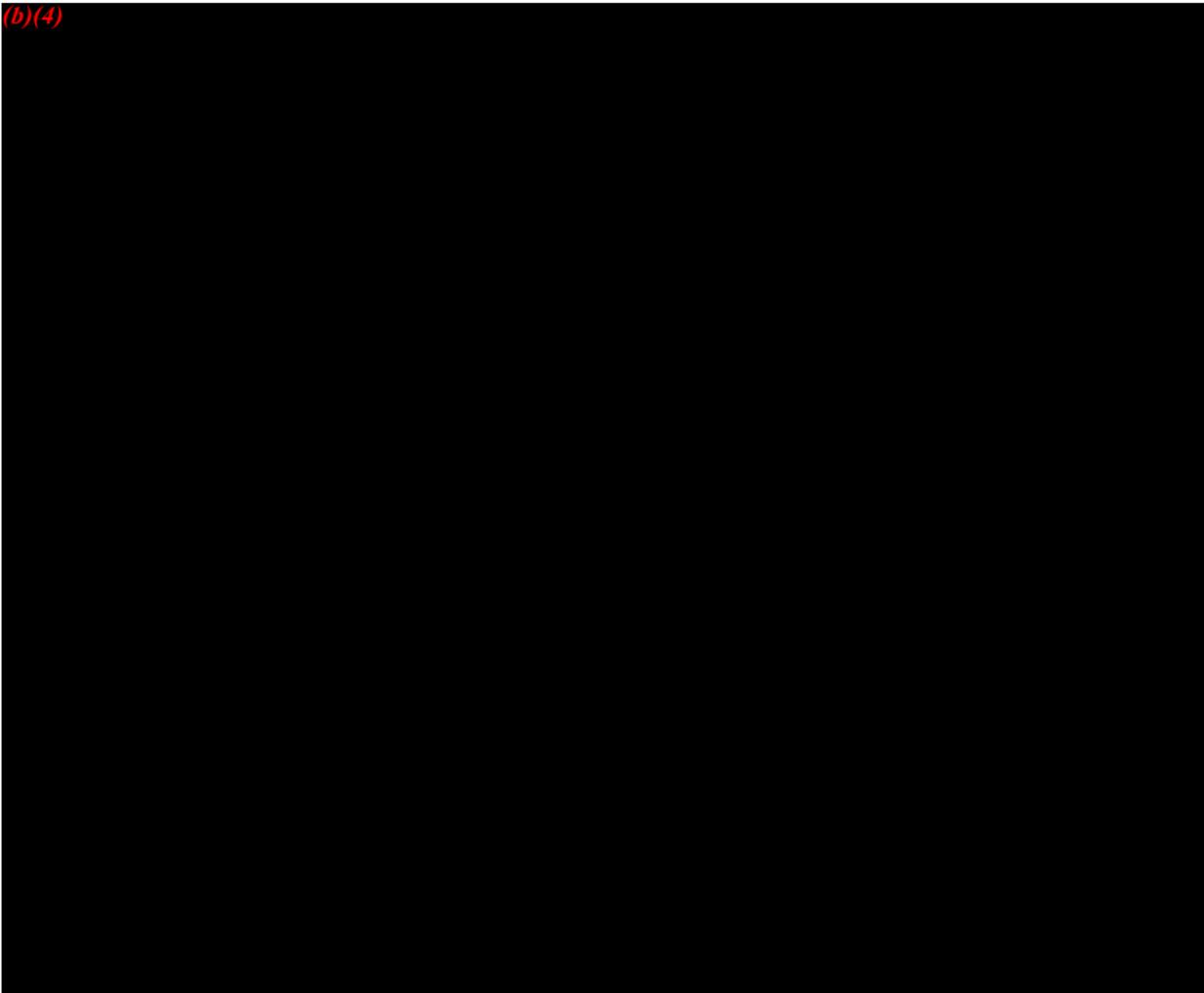
Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 18 PERFORMANCE TESTING – Bench
---	---

Section 18: Performance Testing – Bench



Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution	SECTION 18 PERFORMANCE TESTING – Bench
---	---

(b)(4)

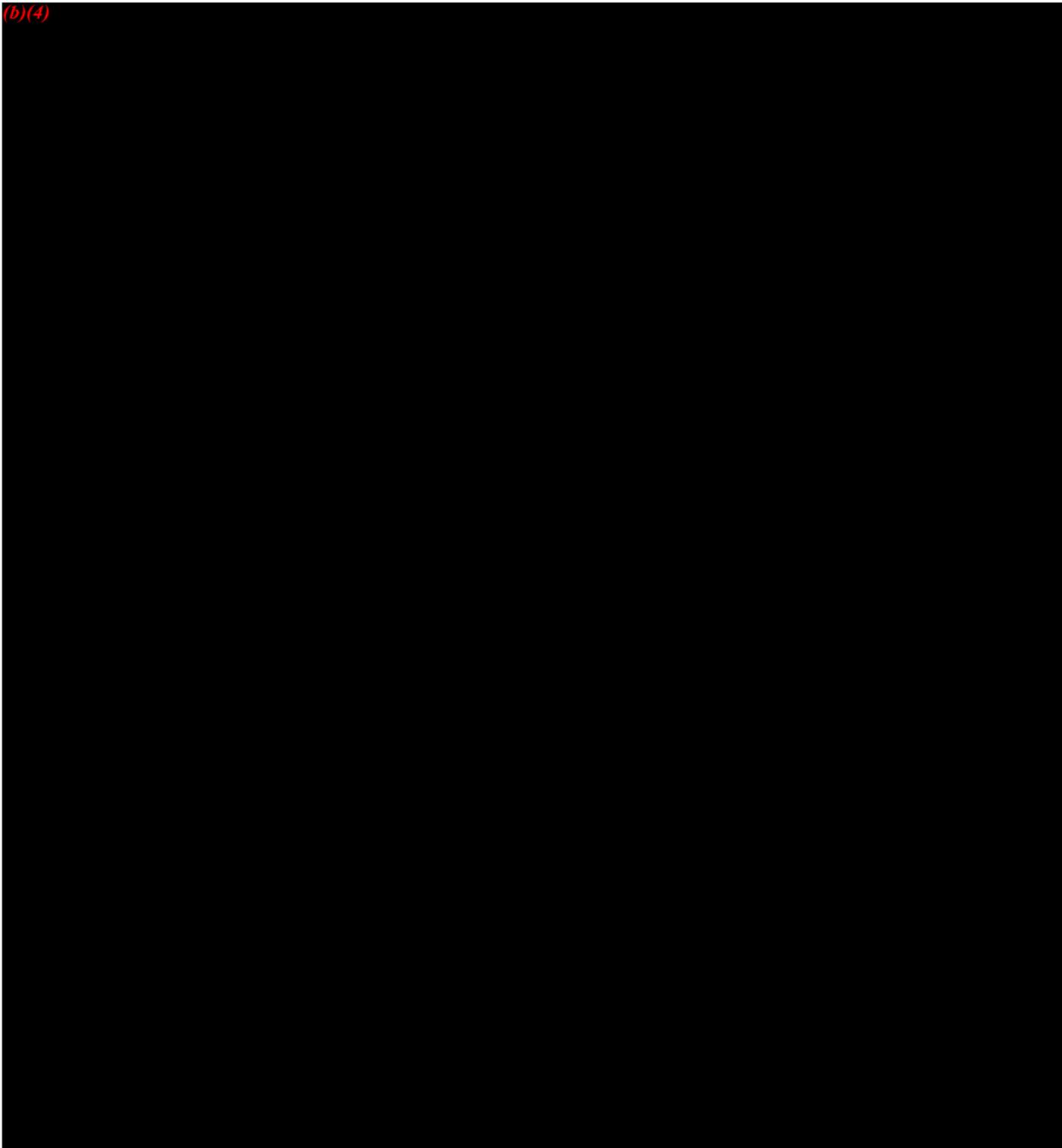


Bausch + Lomb
Test Procedure

TP-7810
Revision P

Sterility Testing

(b)(4)



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(b)(4)

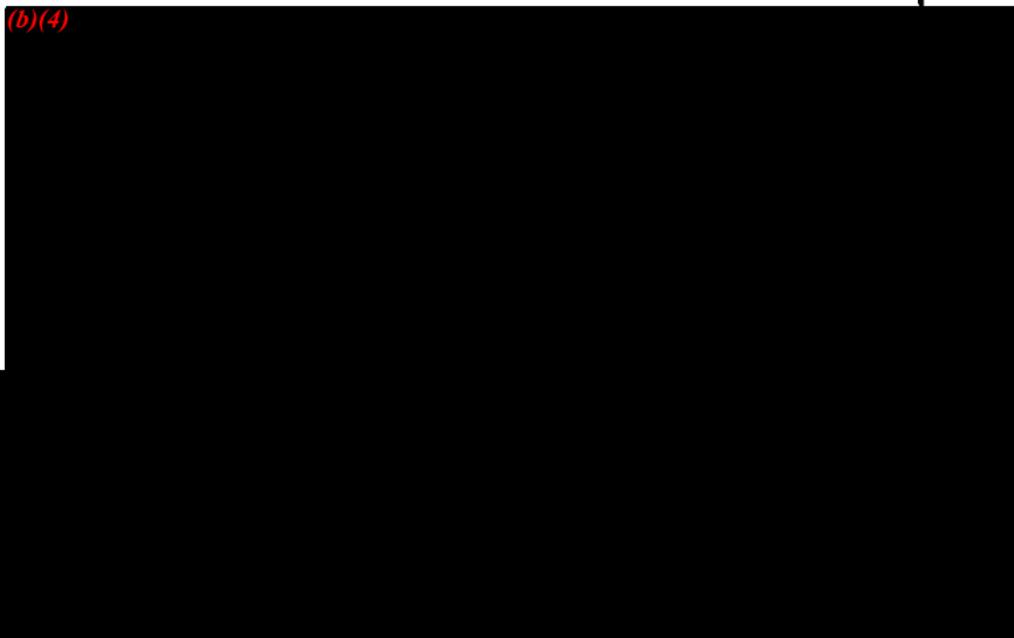
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VALIDATION PROTOCOL:

**VALIDATION OF PALL SUPOR® EKV FILTER MEDIUM FOR THE
STERILIZATION OF BAUSCH & LOMB EASYSEPT HYDROGEN
PEROXIDE SOLUTION FOR BAUSCH & LOMB, ROCHESTER, NY
Revision 2**

(b)(4)



(b)(4)



BAUSCH + LOMB R&D

Ninety Day Discard Date Evaluation of FCP-4289-VAL (BL-400-OCD04.1, Oxidative Chemical Disinfectant 3% Hydrogen Peroxide Multipurpose Solution) In White High Density Polyethylene Containers

(b)(4)

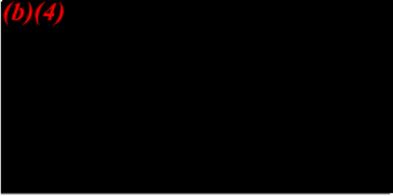
Page 1 of 15

(b)(4)

GLP REPORT

TEST FACILITY

(b)(4)



SPONSOR

Dan O'Mara
Bausch & Lomb
1400 North Goodman Street, R&D S2
Rochester, NY 14609

CONFIDENTIAL

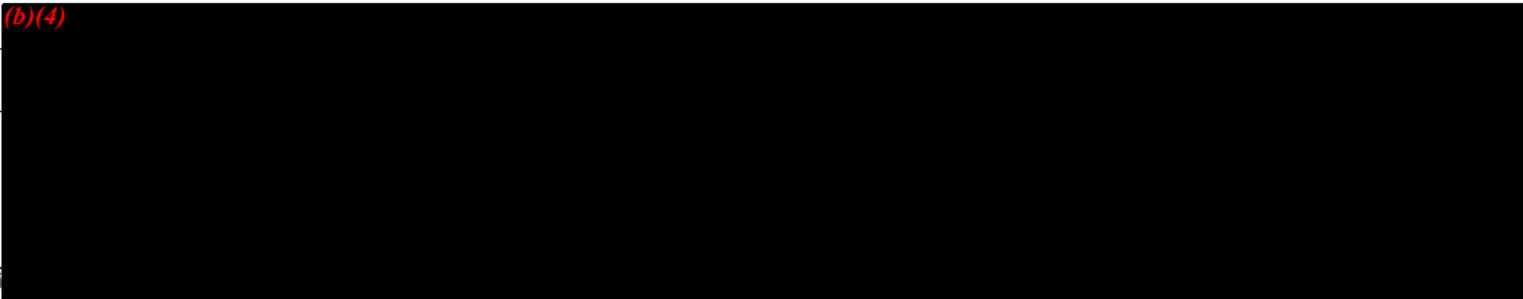
STUDY TITLE

Cytotoxicity Study Using the ISO Agarose Overlay
Method

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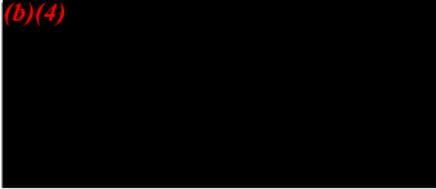


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TEST FACILITY:

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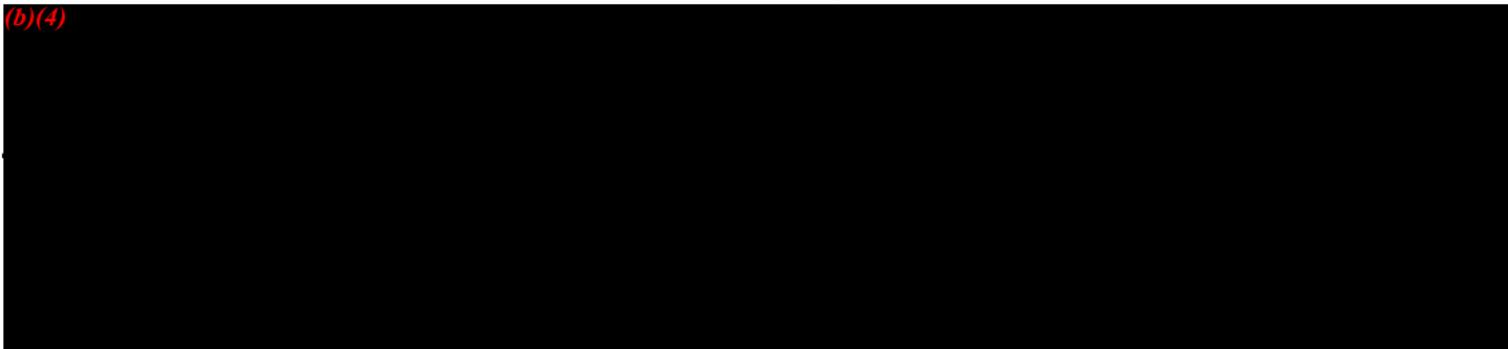
SPONSOR:

Dan O'Mara
Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

STUDY TITLE:

22 Day ISO Ocular Irritation Study in the Rabbit of
Contact Lens Hydrogen Peroxide Solution and
Contact Lenses - with Digital Photography

(b)(4)

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GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

Dan O'Mara
Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

STUDY TITLE

22 Day ISO Ocular Irritation Study in the Rabbit of
Contact Lens Hydrogen Peroxide Solution and
Contact Lenses - with Digital Photography

TEST ARTICLE NAME AND IDENTIFICATION

Peroxide formulation

(b)(4)

(b)(4)

CLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

Dan O'Mara
Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

STUDY TITLE

ISO Ocular Irritation Study in Rabbits - Chemical

TEST ARTICLE NAME

Neutralized peroxide formulation

(b)(4)

TEST ARTICLE IDENTIFICATION

(b)(4)

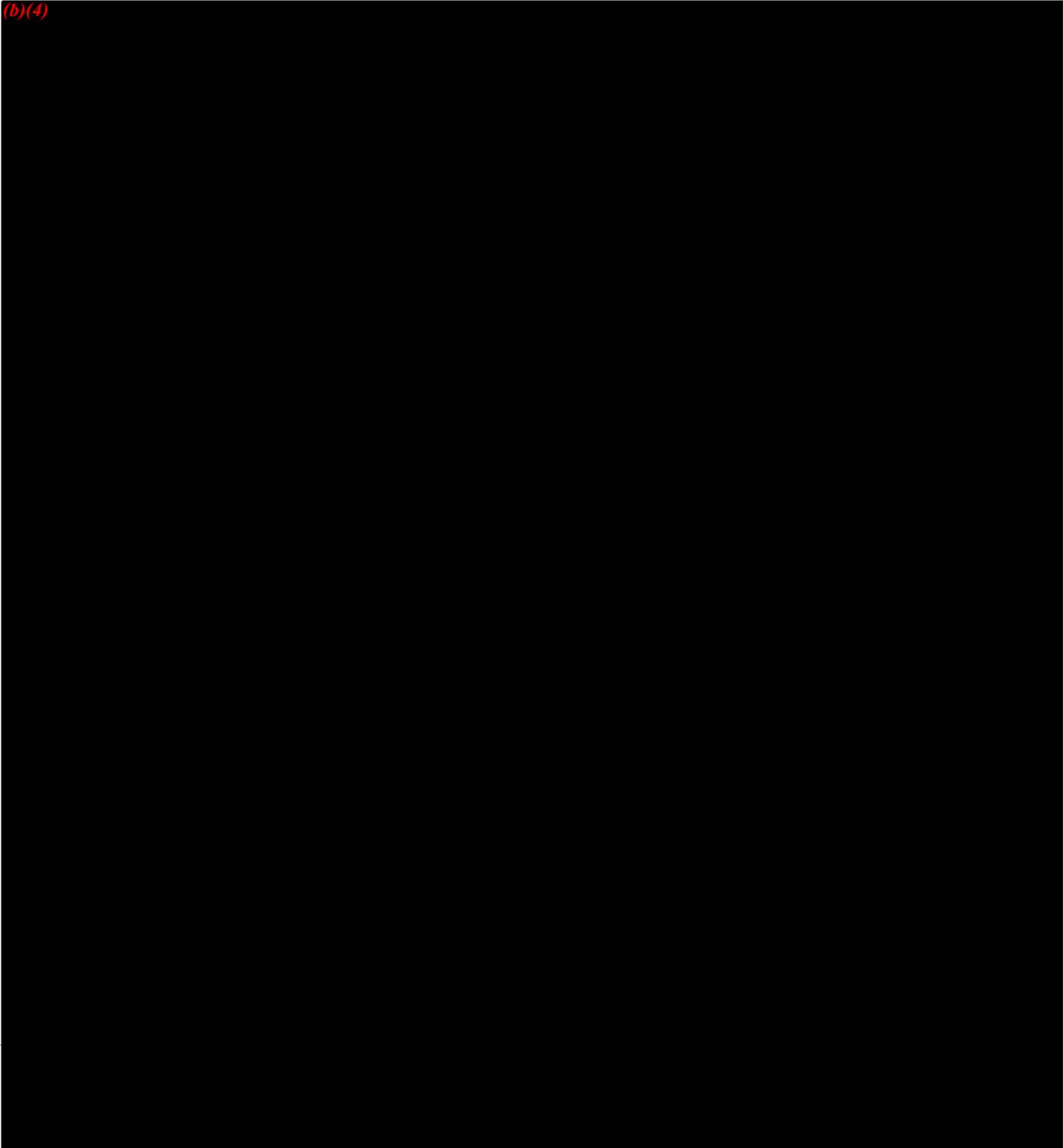
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BAUSCH + LOMB

A Safety and Efficacy Study of a New Contact Lens Cleaning and Disinfecting Solution

PROTOCOL

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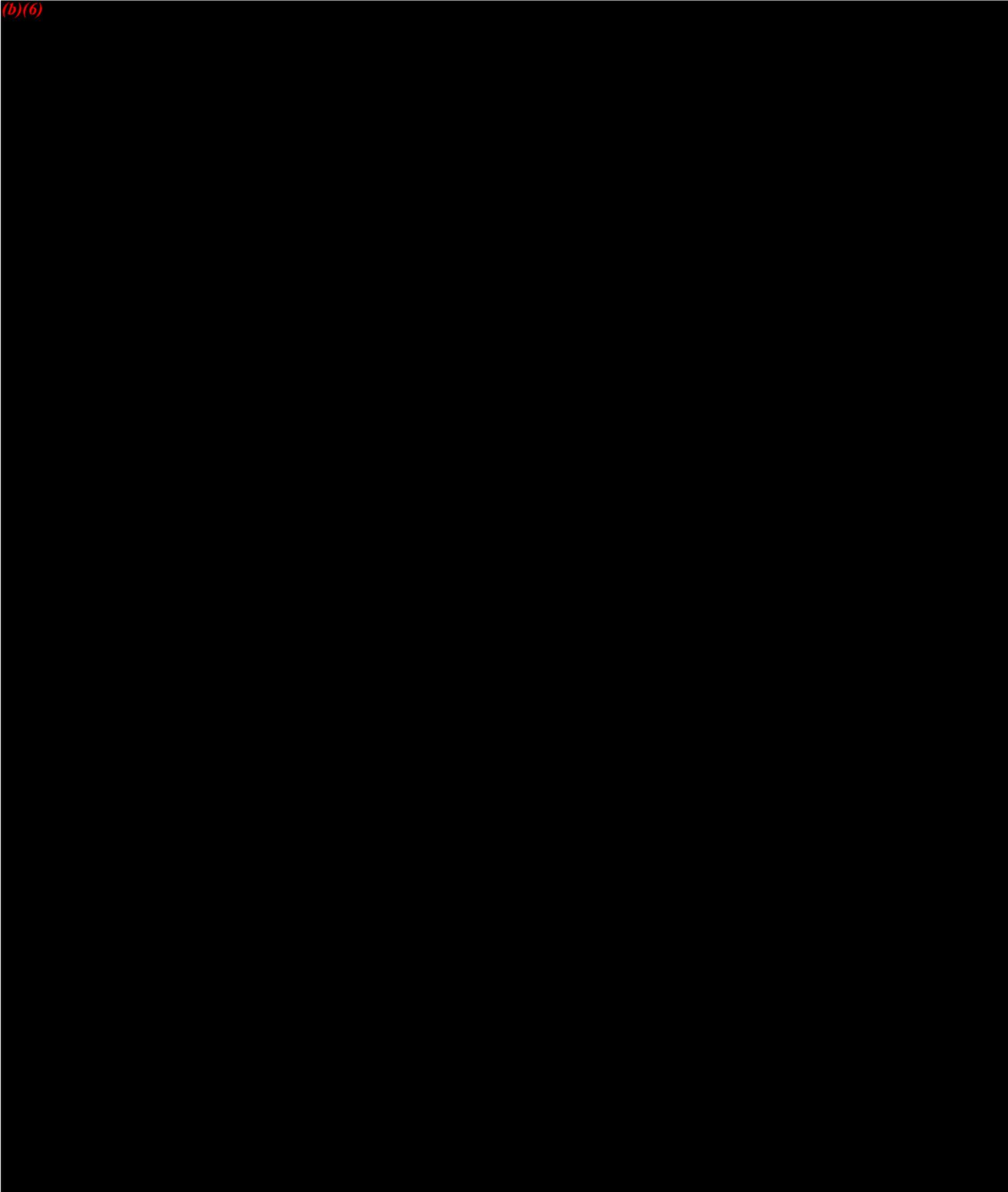


(b)(6)



PERSONNEL AND FACILITIES

(b)(6)



(b)(6)

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APPENDIX E: SUBJECT INSTRUCTIONS FOR CONTROL SOLUTION: FOR ALL SOFT CONTACT LENS WEARERS E-1

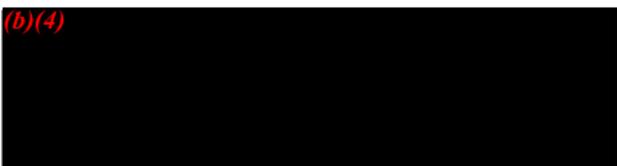
APPENDIX F: SUBJECT INSTRUCTIONS FOR CONTROL SOLUTION: FOR RGP LENS WEARERS F-1

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(b)(4)



4462



Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Denise Hampton, Ph.D.
Subject: 510(k) Number K112909/S002
To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	<i>Attach IFU</i>	✓	
510(k) Summary /510(k) Statement	<i>Attach Summary</i>	✓	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/CO_MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies only : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was			✓



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K112909/S002

Date: April 30, 2012
To: The Record
From: Denise Hampton, Ph.D.

Office: ODE
Division: DONED

510(k) Holder: Bausch & Lomb
Device Name: Bausch & Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution
Contact: Ms. Tricia Garrett
Phone: (585) 338-6706
Fax: (585) 338-0702
Email: tricia.m.garrett@bausch.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Bausch & Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution into interstate commerce. After our review of the original submission, there were clinical/labeling, chemistry, and sterility concerns. Therefore, a **Telephone Hold (TH)** email relaying these concerns (dated 9/30/11) was sent to the sponsor. The sponsor responded to our concerns in S001. However, after our review of this supplement, clinical and sterility concerns remained. Therefore, another TH memo was sent to the sponsor dated 2/27/12. The sponsor responds to those remaining concerns in the current supplement.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	✓		
Truthful and Accuracy Statement	✓		
510(k) Summary or 510(k) Statement	✓		
Standards Form	✓		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?		✓	
Does the device design use software?		✓	
Is the device sterile?	✓		

K112909/S002
510(k) Clinical Review

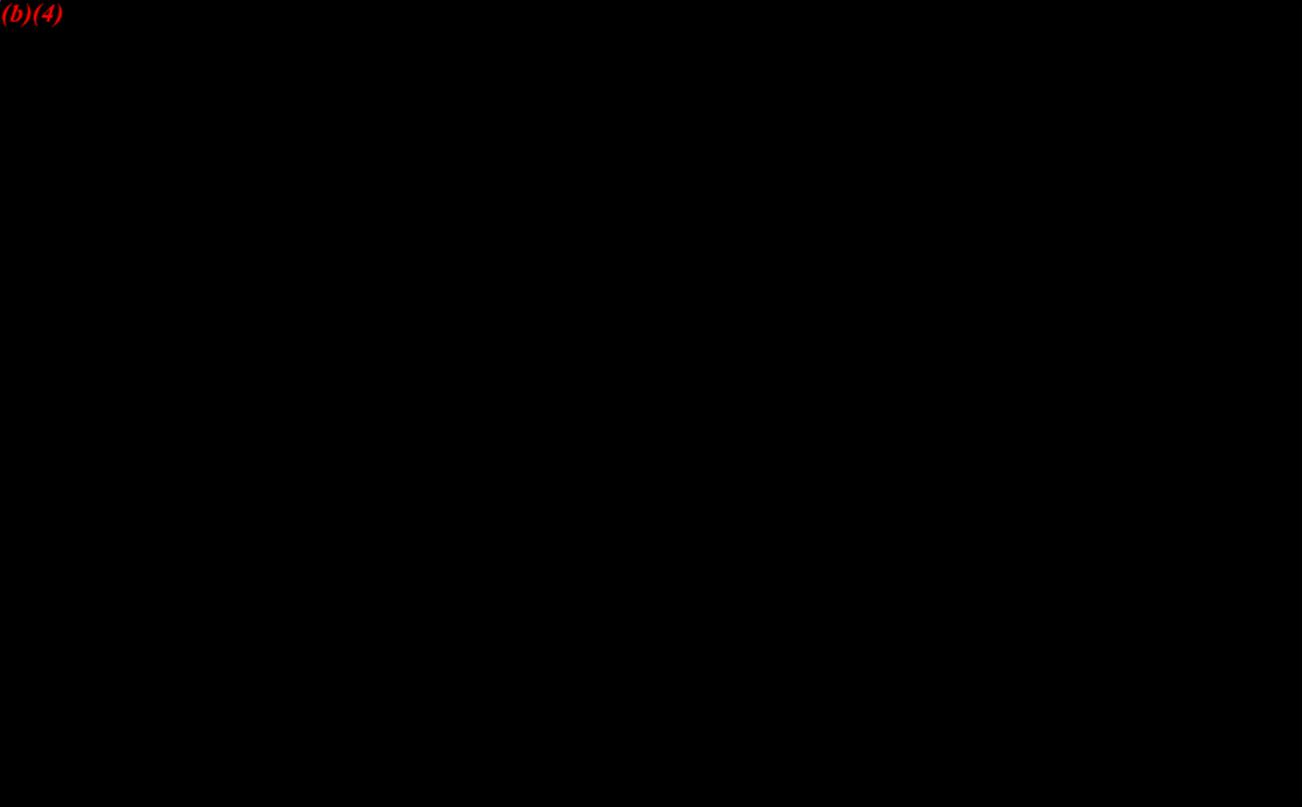
Date: April 30, 2012
From: Marc Robboy *Marc Robboy*
To: Denise Hampton, Ph.D., Team Leader
Subject: K112909/S002 Clinical Review
Device: OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution
Received April 26, 2012
Sponsor: Bausch + Lomb
1400 North Goodman Street
Rochester, NY 14609
Tel: +1 585 338 6399

Indications

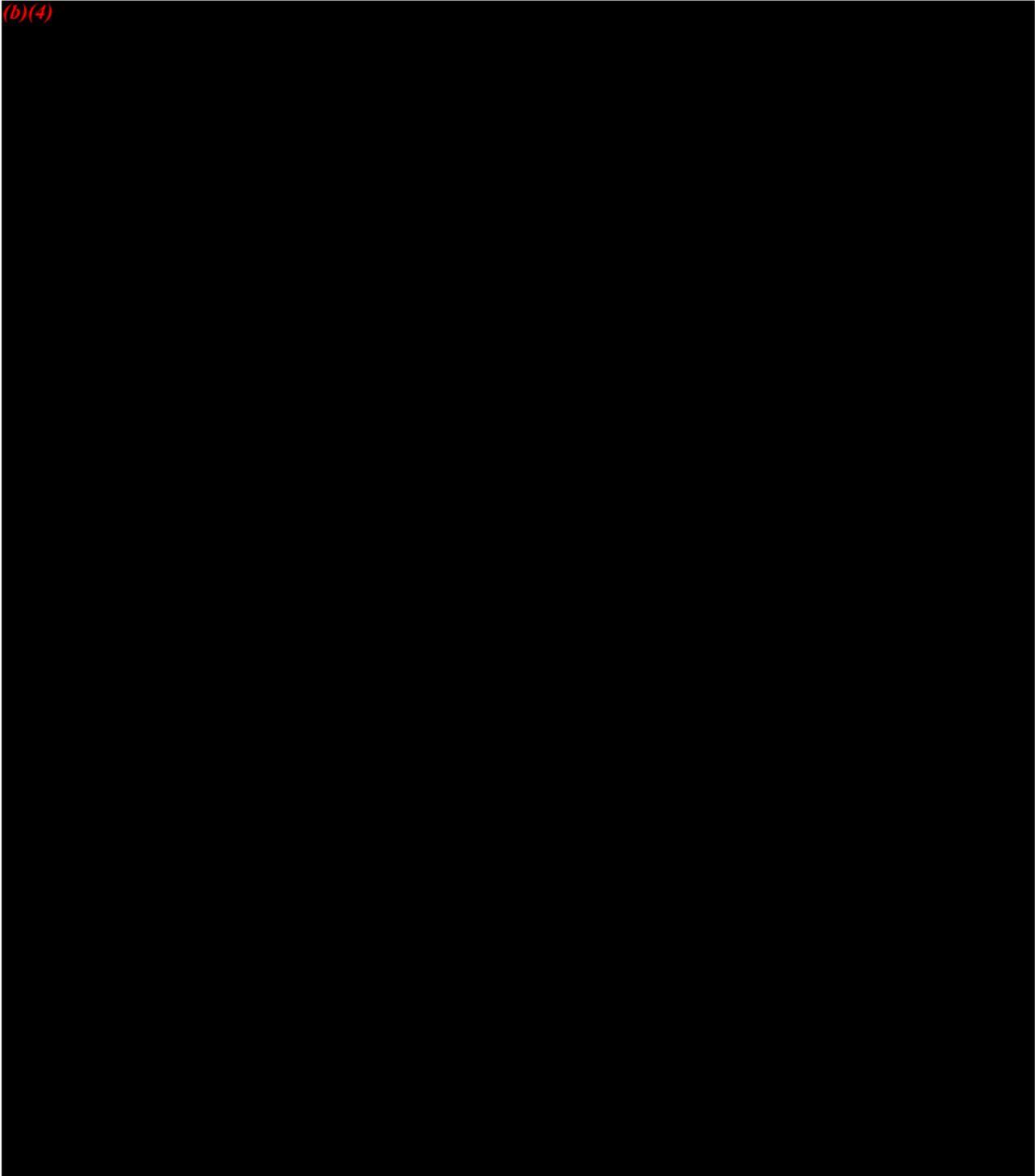
Bausch+ Lomb 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.

Clinical

(b)(4)



(b)(4)



Conclusion/Recommendation

I recommend a determination of Substantial Equivalence.



COVER SHEET MEMORANDUM

From: Reviewer Name Denise Hampton
 Subject: 510(k) Number K112909/S1
 To: The Record

Please list CTS decision code TH
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%20202%2007.doc)
 Hold (Additional Information or Telephone Hold)
 Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <= 21			

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>)

Contact OC.

Regulation Number Class* Product Code

21 CFR 886.5928

II

LPN

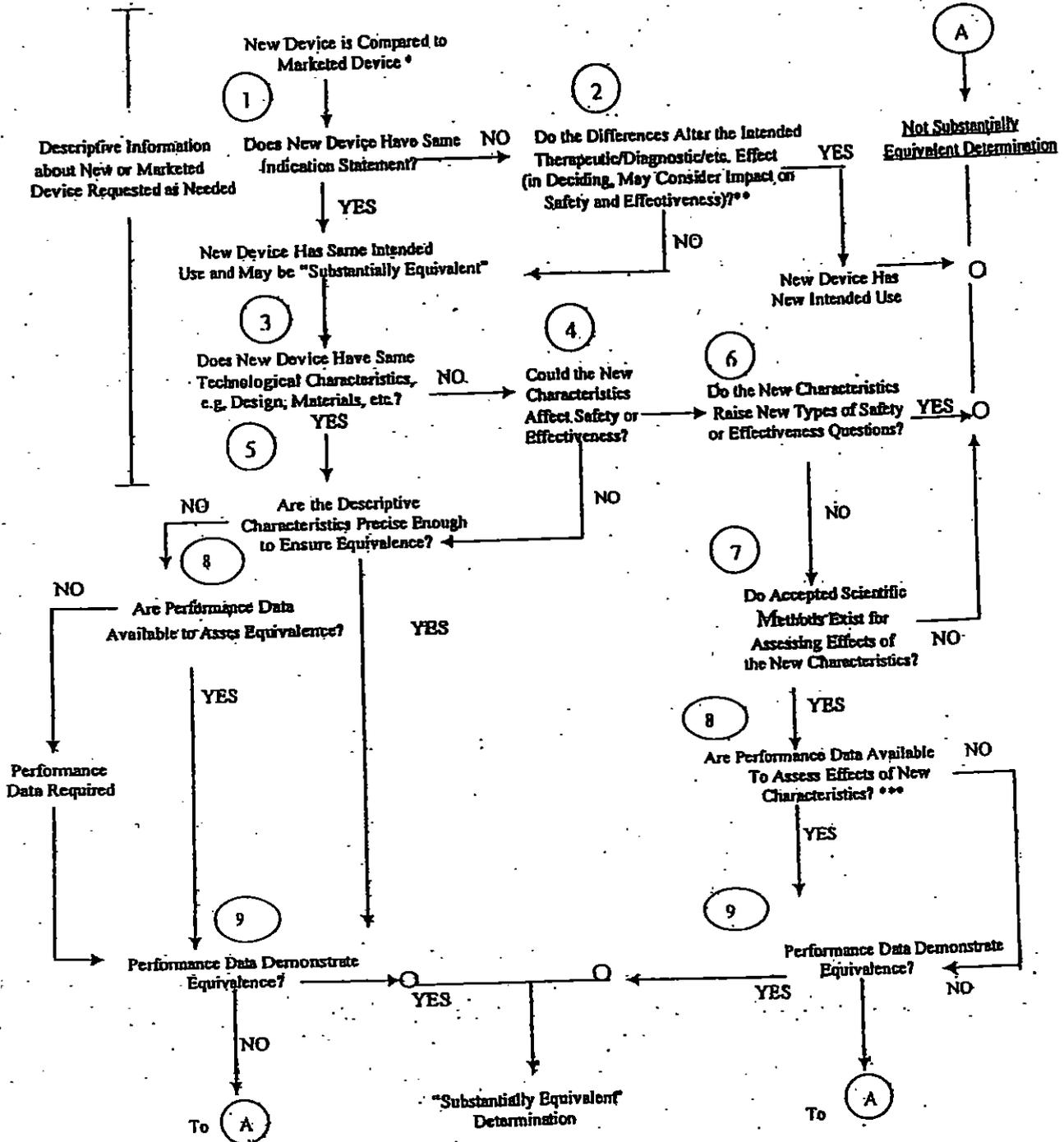
(*if unclassified, see 510(k) Staff)

Additional Product Codes: MRC

Review: _____ (Branch Chief) (Branch Code) (Date)

Final Review: *Kesia Alexander* (Branch Chief) (Branch Code) 2/28/12 (Date)
JW (Division Director)

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.

*** Questions on 510(k) submissions, the Center's classification files, or the literature. Contact: CDRH-FOI@FDA.CDRH.FOIA@FDA or CDRH-FOI@FDA at CDRH-FOI@FDA or fda.hhs.gov or 301-796-8118



Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Denise Hampton
Subject: 510(k) Number K112909
To: The Record

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		YES	NO
1.	Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)		✓
2.	Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?		✓
3.	Does this device type require a PMA by regulation? (Please see management.)		✓
Questions 4-8 are intended to help you start your review:		YES	NO
4.	Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%20%202007.doc)		✓
5.	a. Did the firm request expedited review? (See management.) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)		✓
6.	To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	✓
7.	To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	✓
8.	Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)		✓

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff

Format for Traditional and Abbreviated 510(k)s

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet <u>http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm</u>	✓		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet <u>http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf</u>	✓		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 <u>http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</u>	✓		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D <u>http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm</u>	✓		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E <u>http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm</u>	✓		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G <u>http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm</u>	✓		
Class III Summary and Certification	Class III Summary and Certification Form <u>http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm</u>			✓
Financial Certification or Disclosure Statement	FORM FDA 3454 , Certification: Financial Interests and Arrangements of Clinical Investigators <u>http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf</u> FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators <u>http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf</u> Financial Disclosure by Clinical Investigators <u>http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm</u>	✓		

Title	Related Information	Present	Inadequate	N/A
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	<p>Use of Standards in Substantial Equivalence Determinations http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm</p> <p>FDA Standards program http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9</p> <p>Required Elements for Declaration of Conformity to Recognized Standard http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm</p>			✓
Executive Summary	<p>See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</p>	✓		
Device Description	<p>See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</p>	✓		
Substantial Equivalence Discussion	<p>Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm</p>	✓		
Proposed Labeling	<p>Device Advice " Content of a 510(k)" Section H http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm</p>		✓	
Sterilization/Shelf Life	<p>Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm</p> <p>For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm</p>		✓	
Biocompatibility	<p>FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm</p>	✓		
Software	<p>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm</p>			✓

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	<p>CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm</p> <p>See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)</p>			✓
Performance Testing – Bench	<p>See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</p>		✓	
Performance Testing – Animal	<p>See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</p>			✓
Performance Testing – Clinical	<p>See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf</p>		✓	
FORM FDA 3654, Standards Data Report for 510(k)s - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf	<p>Standards Data Report Form – Form 3654</p> <p>1: No standard used - No Standards Form Required</p> <p>2: Declaration of Conformity – Yes Standards Form Required</p> <p>3: Standard but no declaration – Yes Standards Form Required</p>	✓		
Kit Certification	<p>Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm</p>			✓



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K112909

Date: December 2, 2011
To: The Record
From: Denise Hampton, Ph.D.

Office: ODE
Division: DONED

510(k) Holder: Bausch & Lomb
Device Name: Bausch & Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution
Contact: Ms. Tricia Garrett
Phone: (585) 338-6706
Fax: (585) 338-0702
Email: tricia.m.garrett@bausch.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Bausch & Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution into interstate commerce. After our review of the original submission, there are clinical/labeling, chemistry, and sterility concerns. Therefore, a **Telephone Hold (TH)** email relaying these concerns will be sent to the sponsor.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	✓		
Truthful and Accuracy Statement	✓		
510(k) Summary or 510(k) Statement	✓		
Standards Form	✓		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?		✓	
Does the device design use software?		✓	
Is the device sterile?	✓		
Is the device reusable (not reprocessed single use)?		✓	
Are "cleaning" instructions included for the end user?		✓	



Traditional 510(k): Premarket Notification
Response for additional information dated 12/6/11

**Bausch + Lomb OCD04 3% Hydrogen
Peroxide Cleaning and Disinfecting Solution**

February 3, 2012

Sponsor: Bausch & Lomb
1400 North Goodman Street
Rochester, New York 14609
(585) 338-6000
Facility Registration #: 1313525
www.bausch.com

Submitted by: Tricia Garrett
Senior Specialist, Global Regulatory Affairs
Phone (585) 338-6706
Fax (585) 338-0702
Email: tricia.m.garrett@bausch.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET				
Date of Submission February 3, 2012	User Fee Payment ID Number MD6057622-956733	FDA Submission Document Number (if known) K112909		
SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name Bausch & Lomb Incorporated		Establishment Registration Number (if known) 1313525		
Division Name (if applicable) NA		Phone Number (including area code) (585) 338-6706		
Street Address 1400 North Goodman Street		FAX Number (including area code) (585) 338-0702		
City Rochester	State / Province New York	ZIP/Postal Code 14609	Country USA	
Contact Name Tricia Garrett				
Contact Title Senior Specialist, Global Regulatory Affairs		Contact E-mail Address Tricia.M.Garrett@Bausch.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name				
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City	State / Province	ZIP Code	Country	
Contact Name				
Contact Title		Contact E-mail Address		

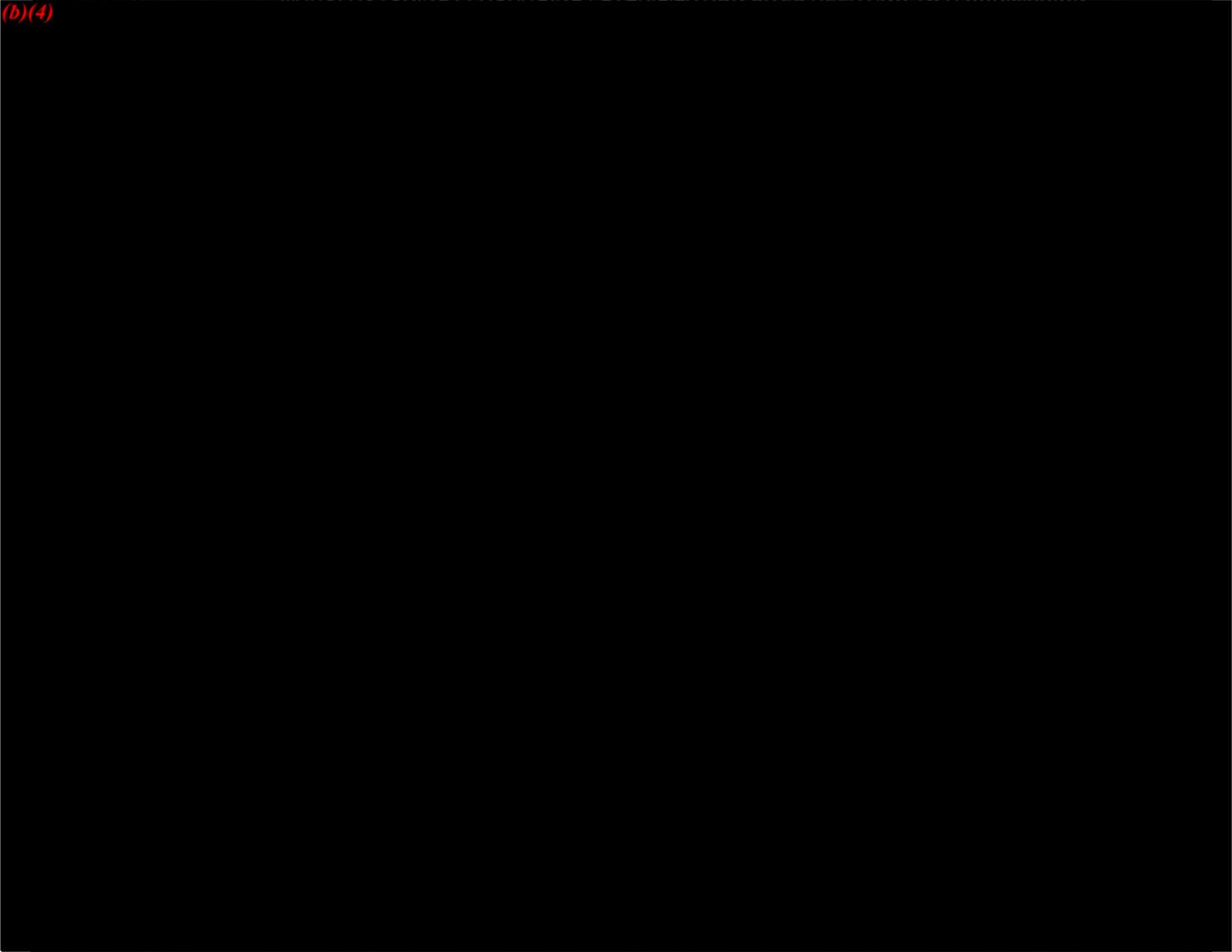
SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software /Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (<i>specify</i>):					
SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent /Applicant <input type="checkbox"/> Design /Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason (<i>specify</i>):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Response for additional information					

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 information <input type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement							
1	LPN	2	MRC	3		4		5		6		7		8	
Information on devices to which substantial equivalence is claimed <i>(if known)</i>															
	<i>510(k) Number</i>		<i>Trade or Proprietary or Model Name</i>		<i>Manufacturer</i>										
1	K022687	1	AOSEPT Clear Care Cleaning and Disinfecting Solution	1	Ciba										
2	K023455	2	AOSEPT Clear Care Cleaning and Disinfecting Solution	2	Ciba										
3		3		3											
4		4		4											
5		5		5											
6		6		6											
SECTION F															
PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS															
Common or usual name or classification name															
Soft (hydrophilic) contact lens care products Rigid Gas Permeable contact lens care products															
	<i>Trade or Proprietary or Model Name for This Device</i>										<i>Model Number</i>				
1	TBD										1				
2											2				
3											3				
4											4				
5											5				
FDA document numbers of all prior related submissions <i>(regardless of outcome)</i>															
1	2	3	4	5	6	7	8	9	10	11	12				
Data Included in Submission															
<input checked="" type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials															
SECTION G															
PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS															
Product Code		C.F.R. Section <i>(if applicable)</i>								Device Class					
LPN, MRC		21 CFR 886.5918 & 21 CFR 886.5928								<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified					
Classification Panel															
Ophthalmic Devices															
Indications <i>(from labeling)</i>															
Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.															

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code)		
Street Address			FAX Number (including area code)		
City		State / Province	ZIP Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 1350 Piccard Drive, Room 400
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.



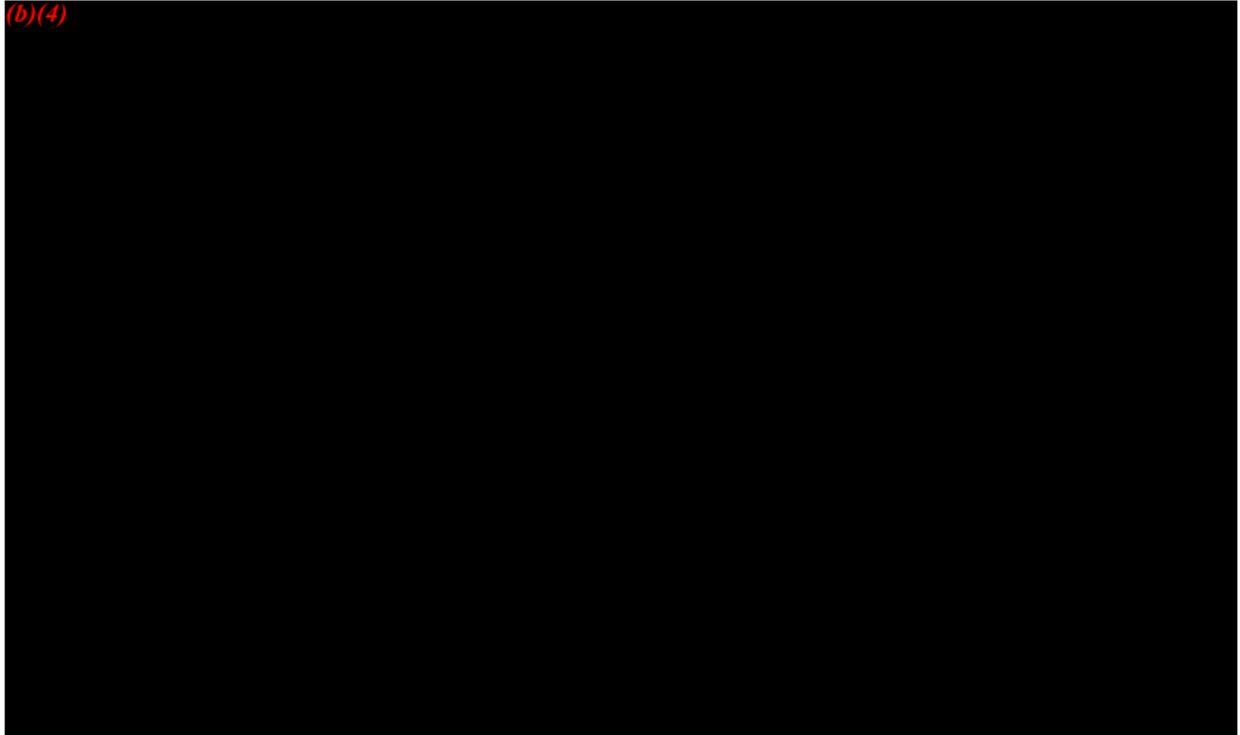
February 3, 2012

RESPONSE TO INQUIRIES

Re: K112909

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution

(b)(4)



Should you have any questions or require further information regarding this response please do not hesitate to contact me. I can be reached at 585-338-6706 or Tricia.M.Garrett@bausch.com. As an alternative, please feel free to contact Jennifer Murray at 585-338-8460 or Jennifer.B.Murray@Bausch.com to ensure we work expeditiously throughout this review period. Thank you.



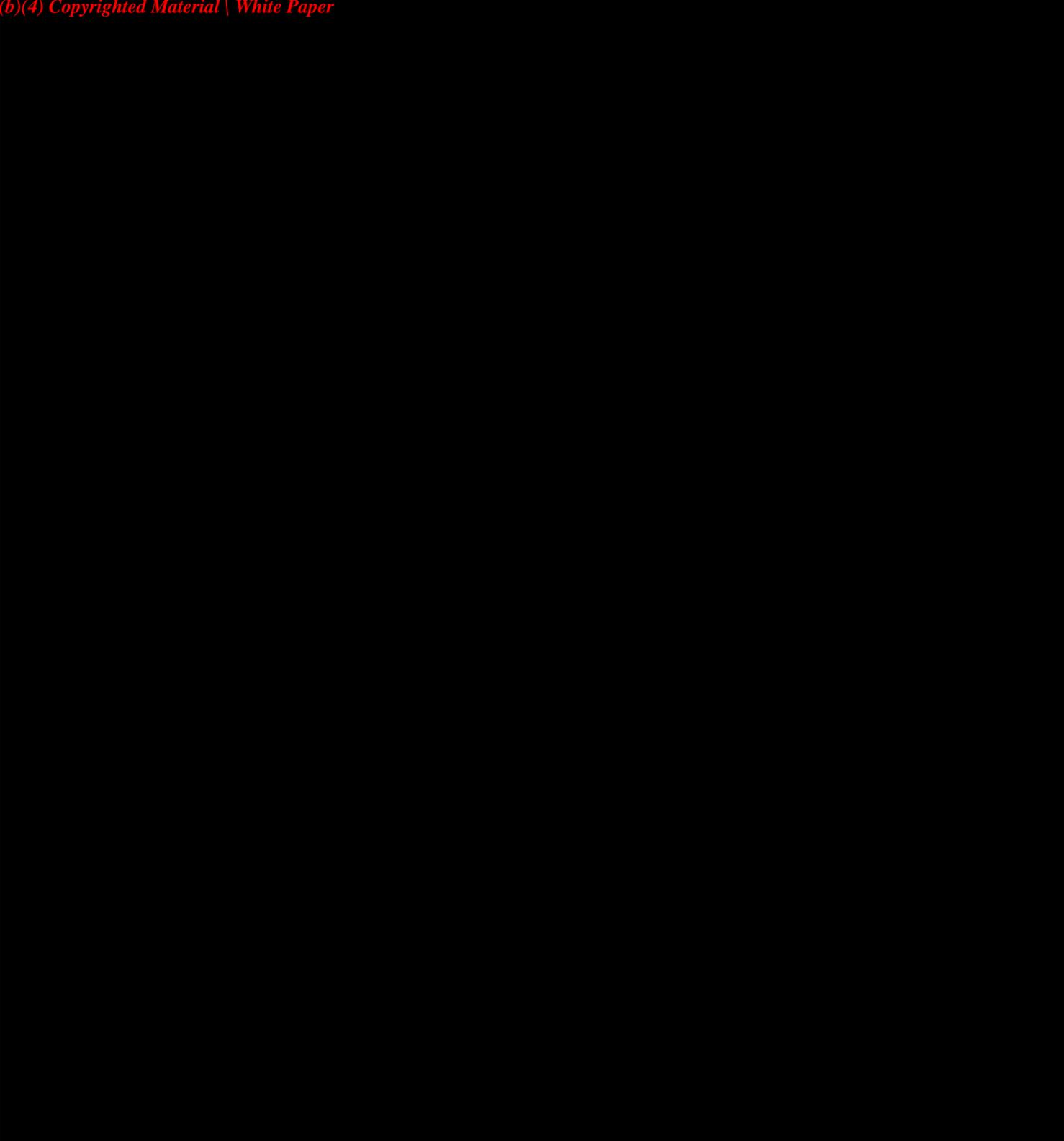
Tricia Garrett
Senior Specialist, Global Regulatory Affairs
(585) 338-6706
(585) 338-0702
Tricia.M.Garrett@Bausch.com

(b)(4) Copyrighted Material \ White Paper

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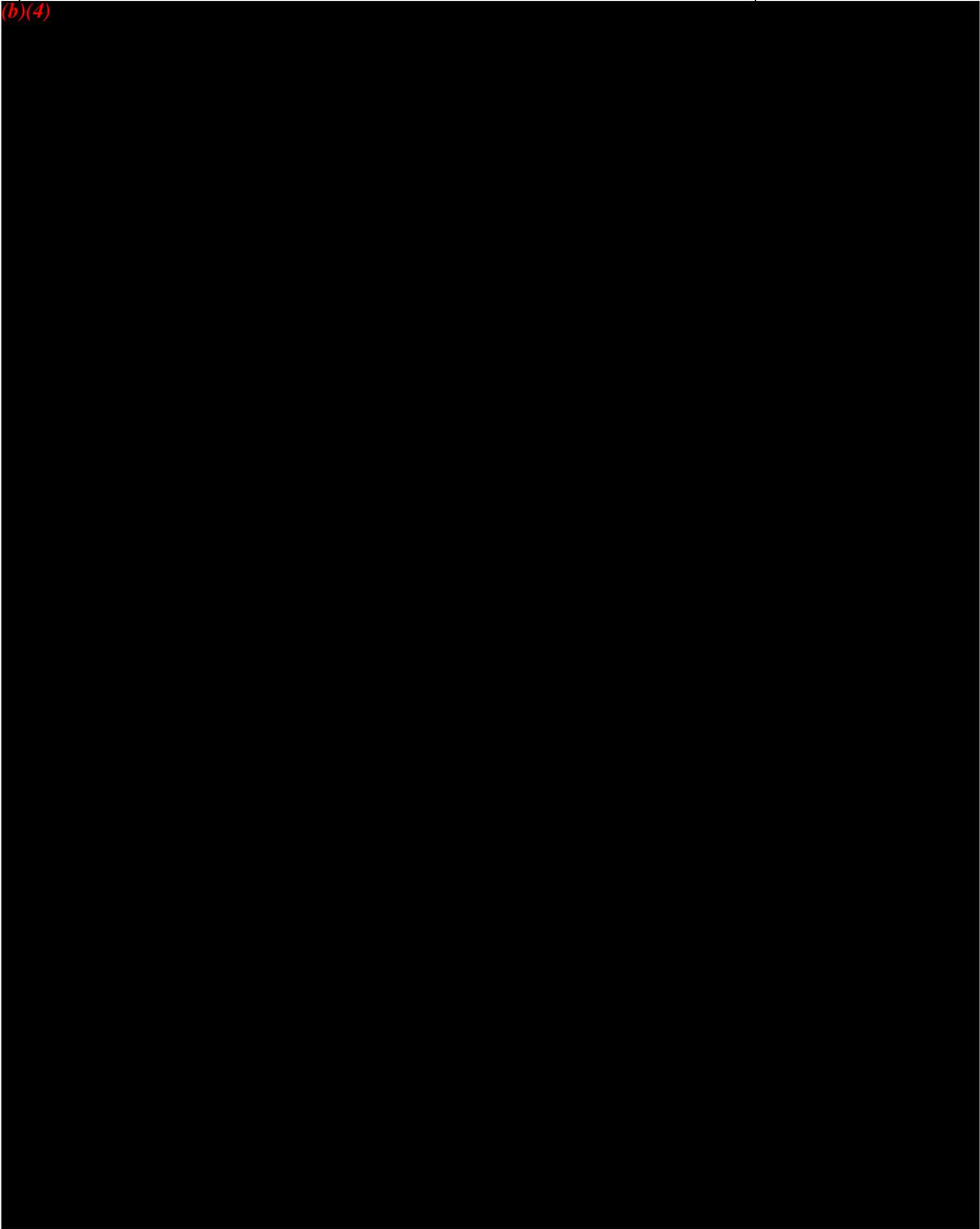
Lysozyme and Lipid Deposition on Silicone Hydrogel Contact Lens Materials

(b)(4) Copyrighted Material \ White Paper

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Labelling / Packaging English Master

(b)(4)



Labelling / Packaging English Master

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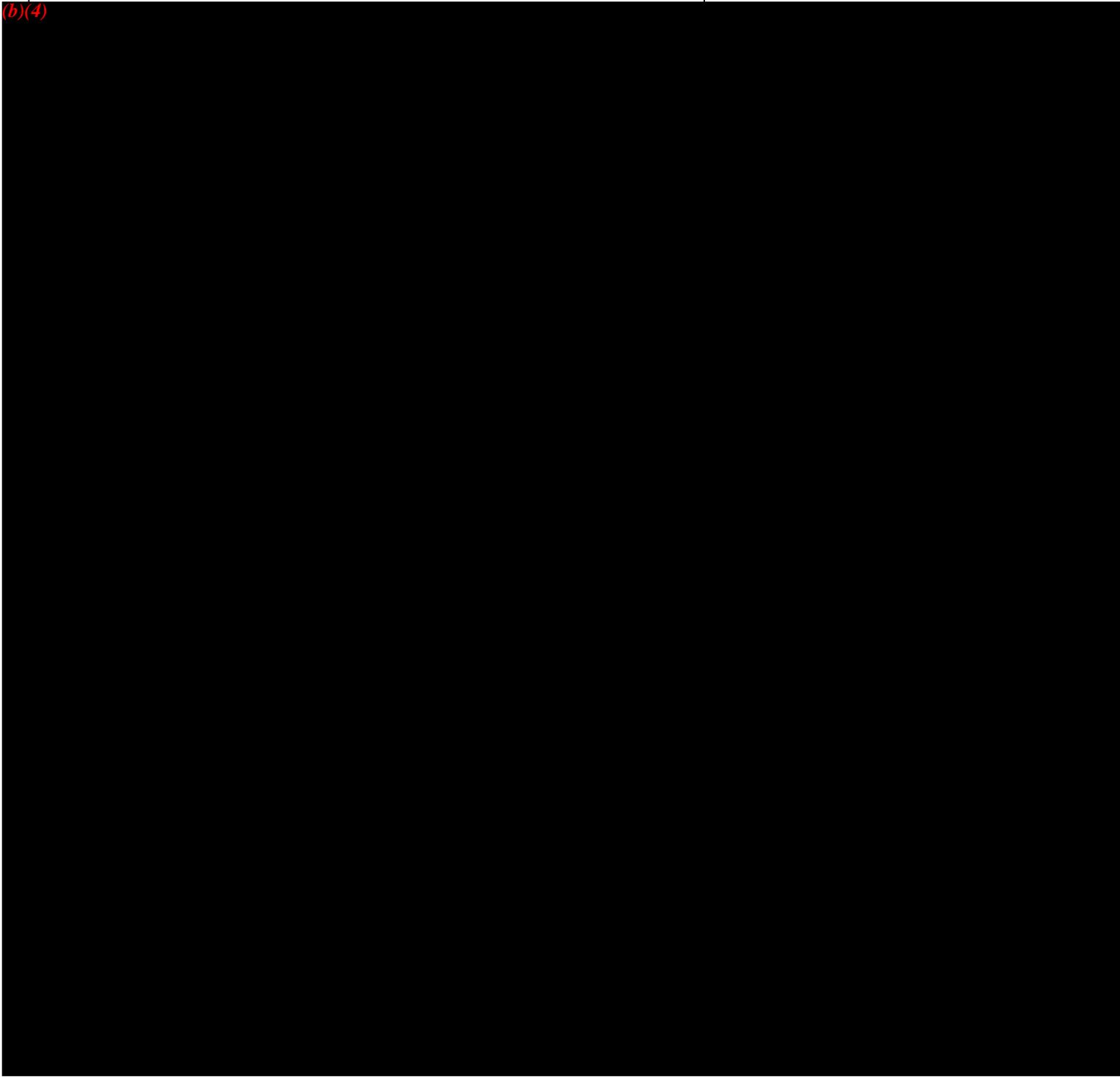
Labelling / Packaging English Master

(b)(4)



Labelling / Packaging English Master

(b)(4)



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Bausch & Lomb, Inc.
c/o Ms. Heather Michaels
Specialist Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

JAN 24 2012

Re: K111877
Trade/Device Name: Bausch & Lomb EZS05 Disinfecting Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: January 17, 2012
Received: January 18, 2012

Dear Ms. Michaels:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

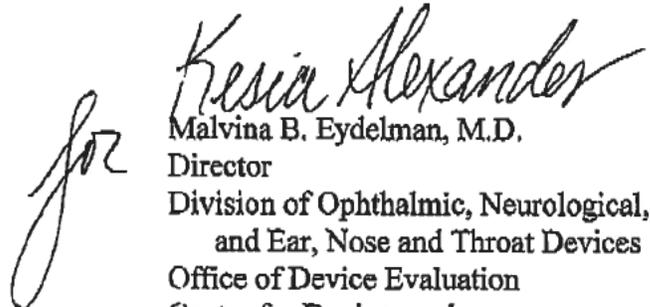
Page 2 - Ms. Heather Michaels

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
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): K111877

Device Name: BAUSCH + LOMB EZS05 Disinfecting Solution

Indications for Use:

BAUSCH + LOMB EZS05 Disinfecting Solution is indicated for disinfecting, protein removal, and storage of soft (hydrophilic) contact lenses, as recommended by your eye care practitioner.

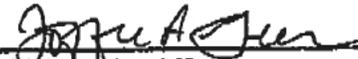
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter-Use X
(Part 21 CFR 807 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, Neurological and Ear,
Nose and Throat Devices

510(k) Number K111877



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Tricia Garret	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES September 30, 2011
3. ADDRESS (Number, Street, State, and ZIP Code) Bausch & Lomb Incorporated 1400 North Goodman Street Rochester, New York 14609	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 585-338-6706 (Fax) 585-338-0702

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)
Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
 IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)
K112909

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)
NCT Number(s): NCT01318577

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Tricia Garret (Title) Senior Specialist, Global Regulatory Affairs
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) Bausch & Lomb Incorporated 1400 North Goodman Street Rochester, New York 14609	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 585-338-6706 (Fax) 585-338-0702
15. DATE OF CERTIFICATION 12/8/11	

<p>Bausch & Lomb, Inc. Traditional 510(k) Premarket Notification Bausch + Lomb OCD04 Cleaning and Disinfecting Solution</p>	<p>SECTION 14 STERILIZATION AND SHELF LIFE</p>
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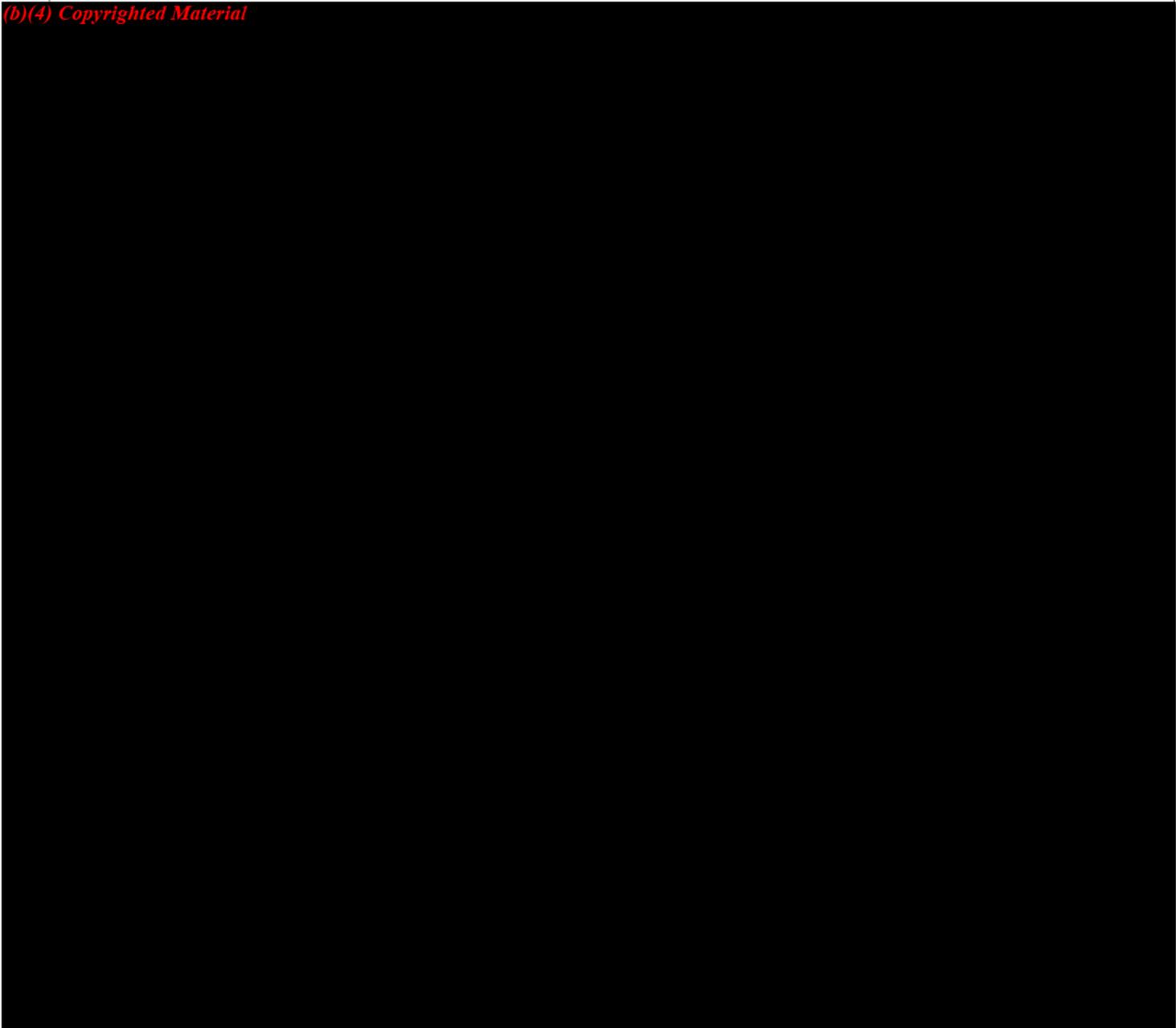
Section 14.1: Sterility Testing Procedure (b)(4)



Artfile #91

Ocular Detection Threshold For Hydrogen Peroxide: Drops vs. Lenses

(b)(4) Copyrighted Material



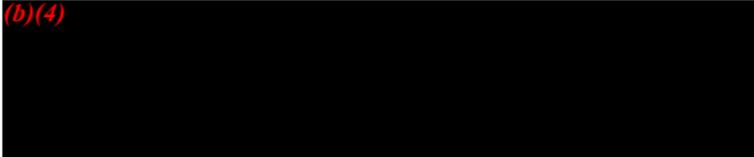
(b)(4)



LABORATORY REPORT

**BAUSCH
+ LOMB**

(b)(4)



TITLE: Effect of Multiple Uses of the Bausch + Lomb Global Peroxide Neutralizing Lens Case on the Osmolality and pH of Neutralized Peroxide Cleaning and Disinfecting Solution. (b)(4)

To: (b)(4)

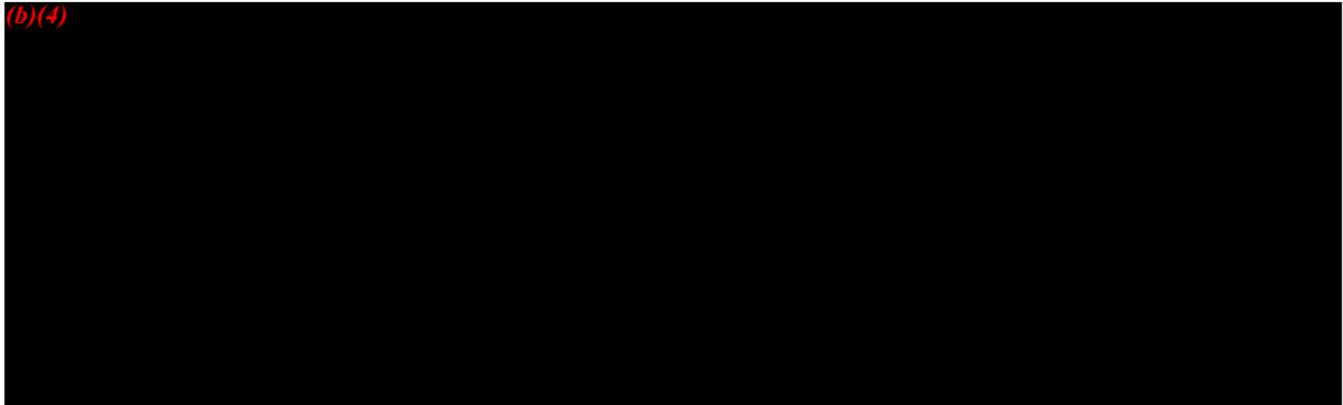
FROM: Kimberly Millard

REFERENCE: B+L (b)(4)

(b)(4)

CONTRIBUTORS:

(b)(4)



(b)(4)



.....
Global R&D – Process Development
.....

Memo

Date:
Author:
Reference:

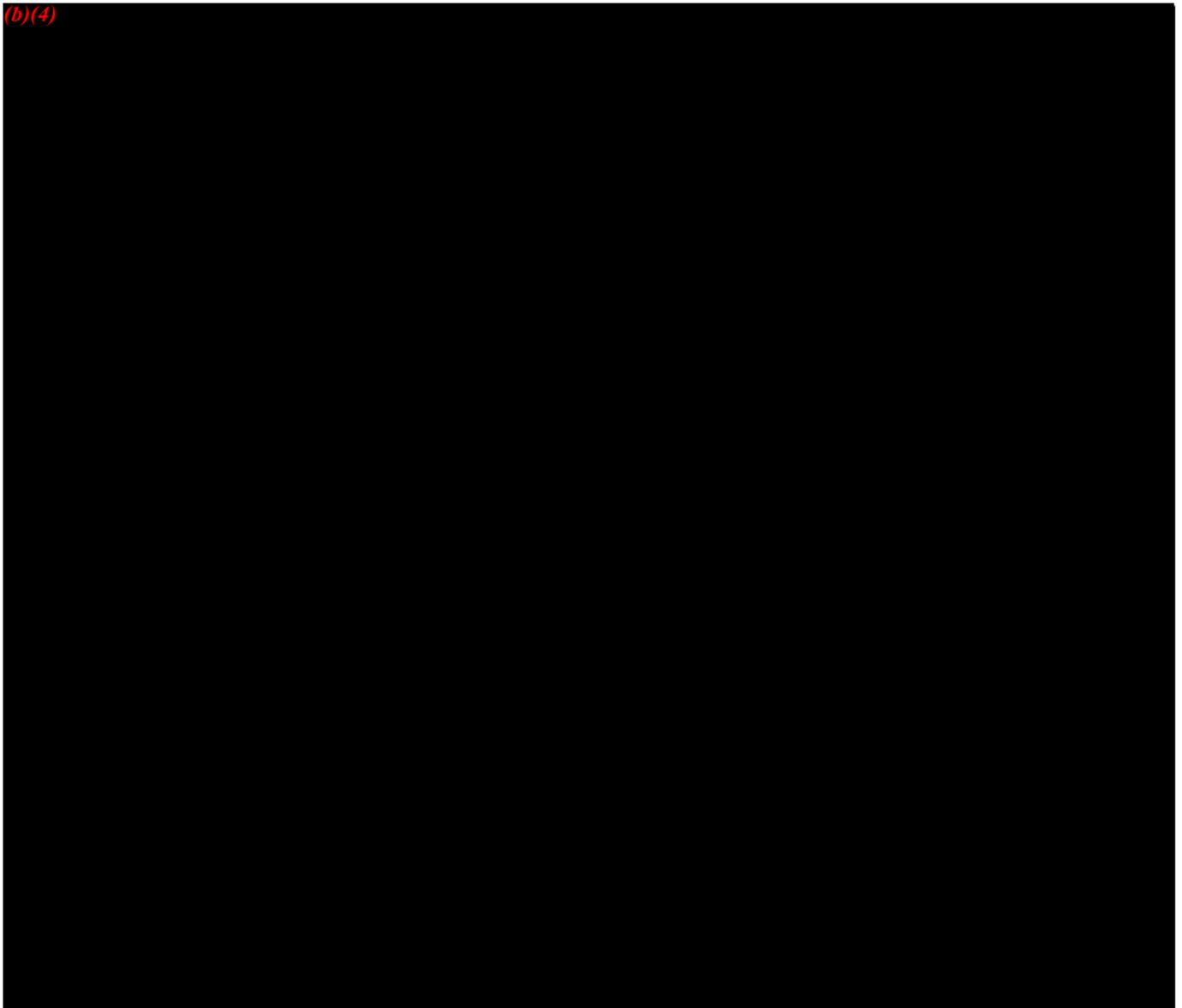
(b)(4)

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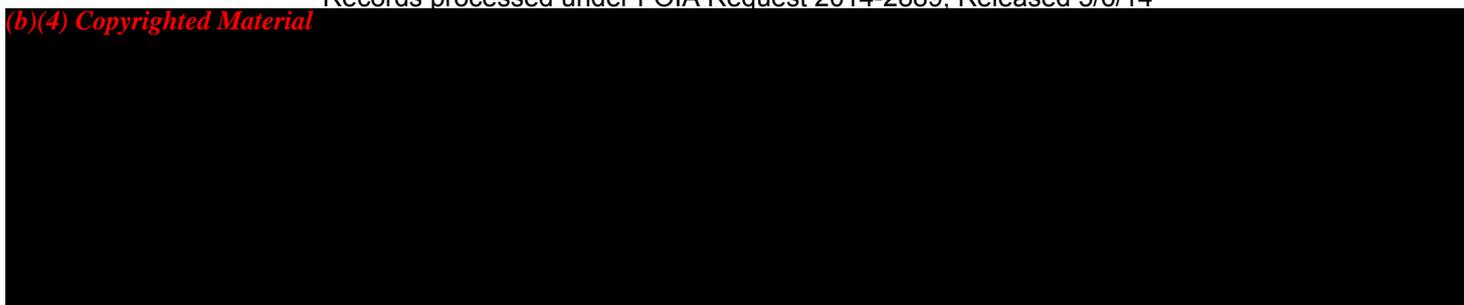
Objective

The purpose of this study is to evaluate the osmolality of un-neutralized One-Step 3% Hydrogen Peroxide Cleaning and Disinfecting Solution (b)(4) at initial time of manufacture and over the shelf-life of the product.

(b)(4)

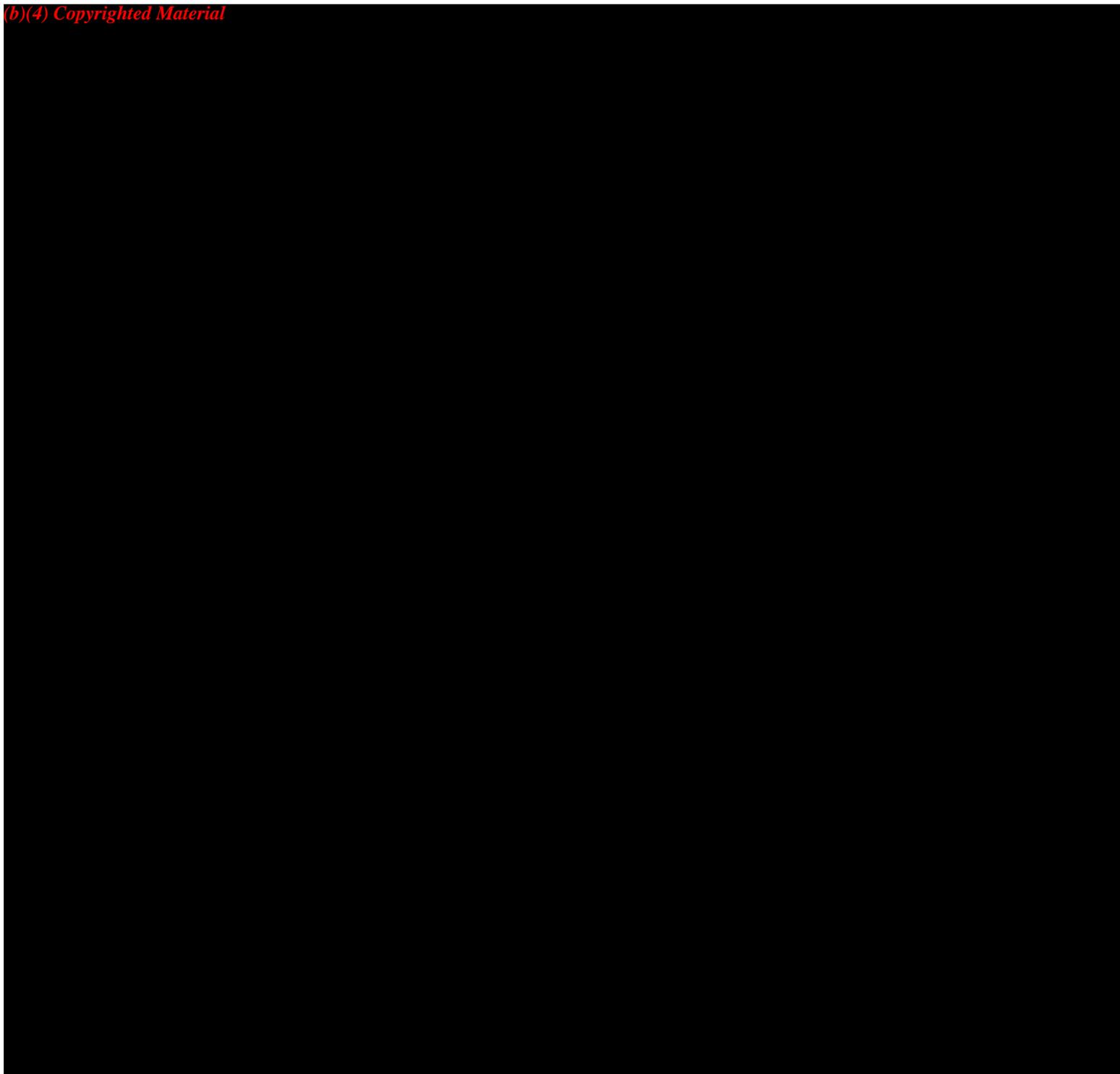
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(b)(4) Copyrighted Material



The effect of lens wear on refractive index of conventional hydrogel
and silicone-hydrogel contact lenses: A comparative study

(b)(4) Copyrighted Material



(b)(4)

BAUSCH+LOMB

Date: Thursday, January 19, 2012

From: (b)(4)

Project: Oxidative Chemical Disinfectant – (OCD)

Subject: Contact angle analysis of contact lenses exposed to (b)(4) and Clear Care

(b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.		
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET				
Date of Submission April 25, 2012		User Fee Payment ID Number (b)(4)		
		FDA Submission Document Number (if known) K112909 / S001		
SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name Bausch & Lomb Incorporated		Establishment Registration Number (if known) 1313525		
Division Name (if applicable) NA		Phone Number (including area code) 585-338-6706		
Street Address 14000 North Goodman Street		FAX Number (including area code) 585-338-0702		
City Rochester	State / Province New York	ZIP/Postal Code 14609	Country USA	
Contact Name Tricia Garrett				
Contact Title Senior Specialist, Global Regulatory Affairs		Contact E-mail Address Tricia.M.Garrett@Bausch.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name				
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City	State / Province	ZIP Code	Country	
Contact Name				
Contact Title		Contact E-mail Address		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (*specify*):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (*specify*):

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
-------------------------------------	---	---

Other Reason (*specify*):
 Response for additional information

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 information <input type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1 LPN	2 MRC	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K022687	1		1	
2	K023455	2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device		Model Number
1	TBD	1	
2		2	
3		3	
4		4	
5		5	

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 - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section (if applicable)	Device Class
LPN, MRC	21 CFR 886.5918 & 21 CFR 886.5928	<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel		
Ophthalmic Devices		

Indications (from labeling)
 Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner

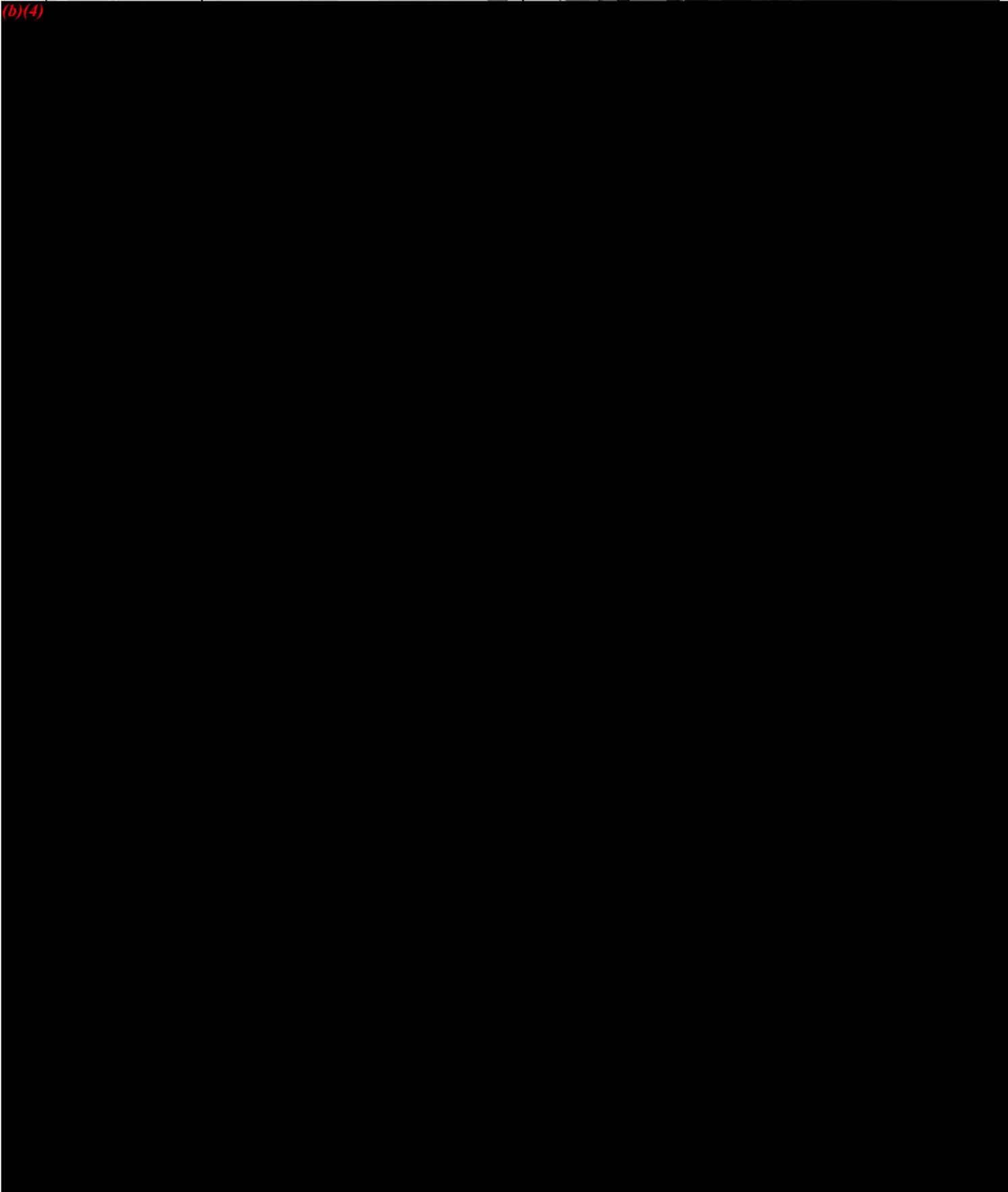
Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*

SECTION H

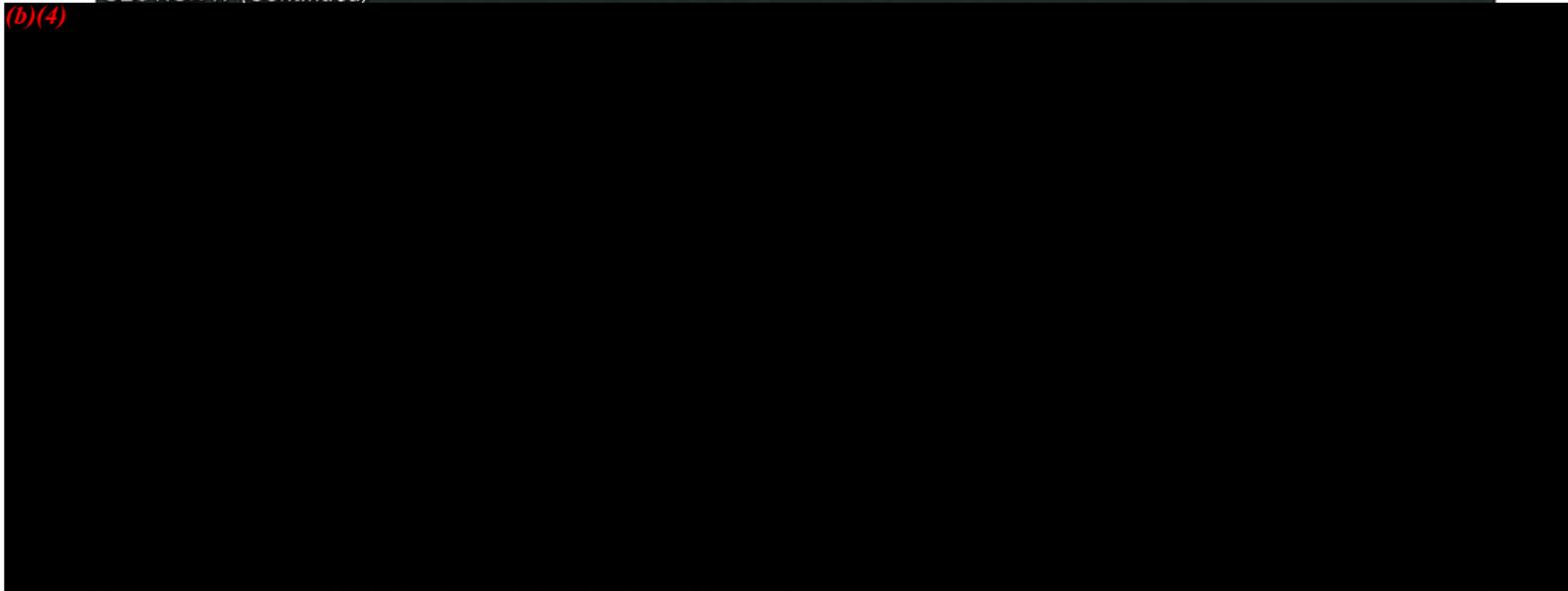
MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)



<p>Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.</p>	<p>FDA Document Number (if known)</p>
---	---------------------------------------

SECTION H (Continued)



(b)(4)

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	<p>Facility Establishment Identifier (FEI) Number</p>	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
<p>Company / Institution Name</p>		<p>Establishment Registration Number</p>	
<p>Division Name (if applicable)</p>		<p>Phone Number (including area code)</p>	
<p>Street Address</p>		<p>FAX Number (including area code)</p>	
<p>City</p>	<p>State / Province</p>	<p>ZIP Code</p>	<p>Country</p>
<p>Contact Name</p>	<p>Contact Title</p>	<p>Contact E-mail Address</p>	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	<p>Facility Establishment Identifier (FEI) Number</p>	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
<p>Company / Institution Name</p>		<p>Establishment Registration Number</p>	
<p>Division Name (if applicable)</p>		<p>Phone Number (including area code)</p>	
<p>Street Address</p>		<p>FAX Number (including area code)</p>	
<p>City</p>	<p>State / Province</p>	<p>ZIP Code</p>	<p>Country</p>
<p>Contact Name</p>	<p>Contact Title</p>	<p>Contact E-mail Address</p>	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 1350 Piccard Drive, Room 400
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.



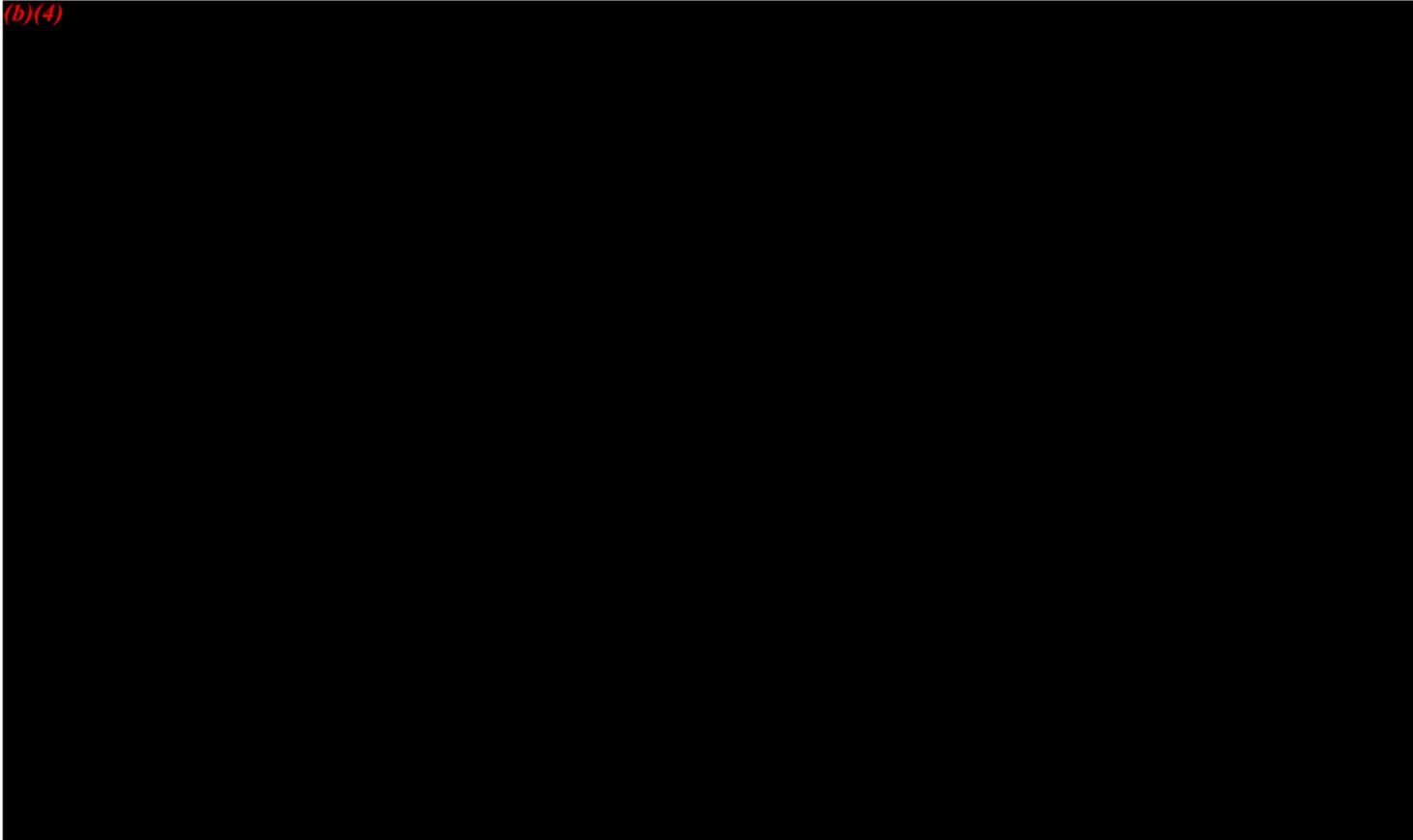
April 25, 2012

RESPONSE TO INQUIRIES

Re: K112909 / S001

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution

(b)(4)



Should you have any questions or require further information regarding this response please do not hesitate to contact me. I can be reached at 585-338-6706 or Tricia.M.Garrett@bausch.com. As an alternative, please feel free to contact Jennifer Murray at 585-338-8460 or Jennifer.B.Murray@Bausch.com to ensure we work expeditiously throughout this review period. Thank you.

A handwritten signature in blue ink that reads "Tricia Garrett".

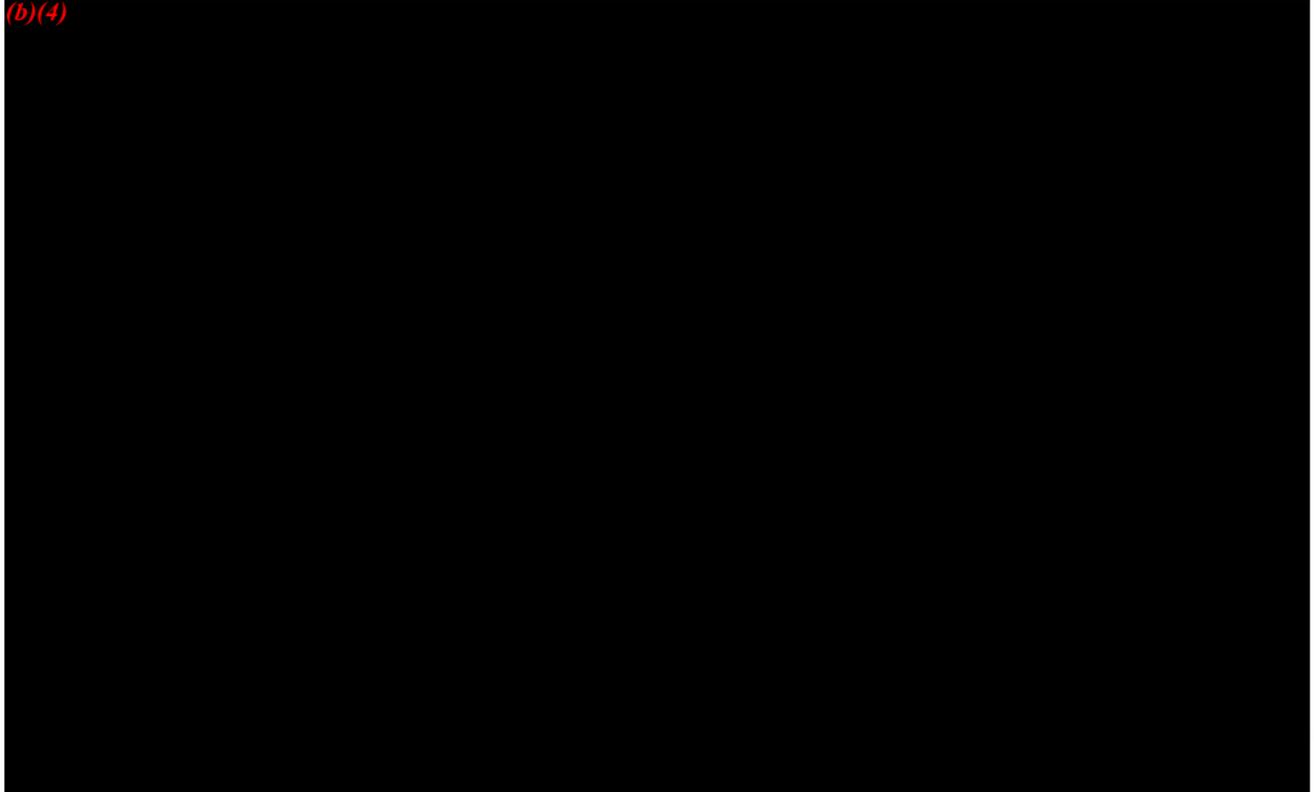
Tricia Garrett
Senior Specialist, Global Regulatory Affairs
(585) 338-6706
(585) 338-0702
Tricia.M.Garrett@Bausch.com

The following Attachments are included in this submission:

Attachment Number	Description	Supporting Query Number
1.	(b)(4)	1

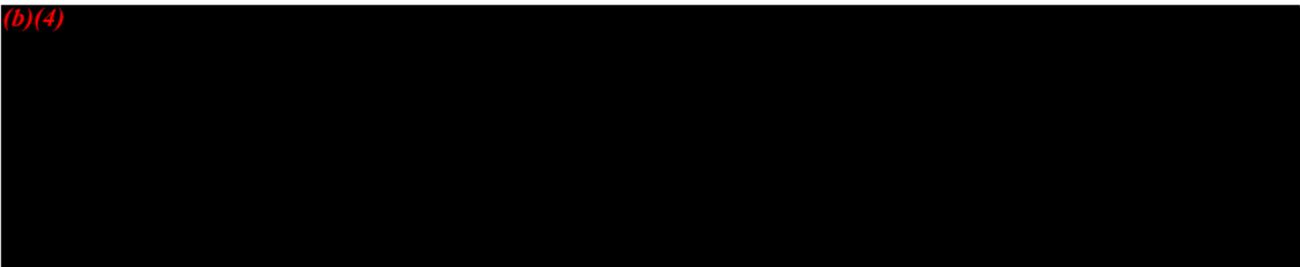
Clinical:

(b)(4)



Sterility:

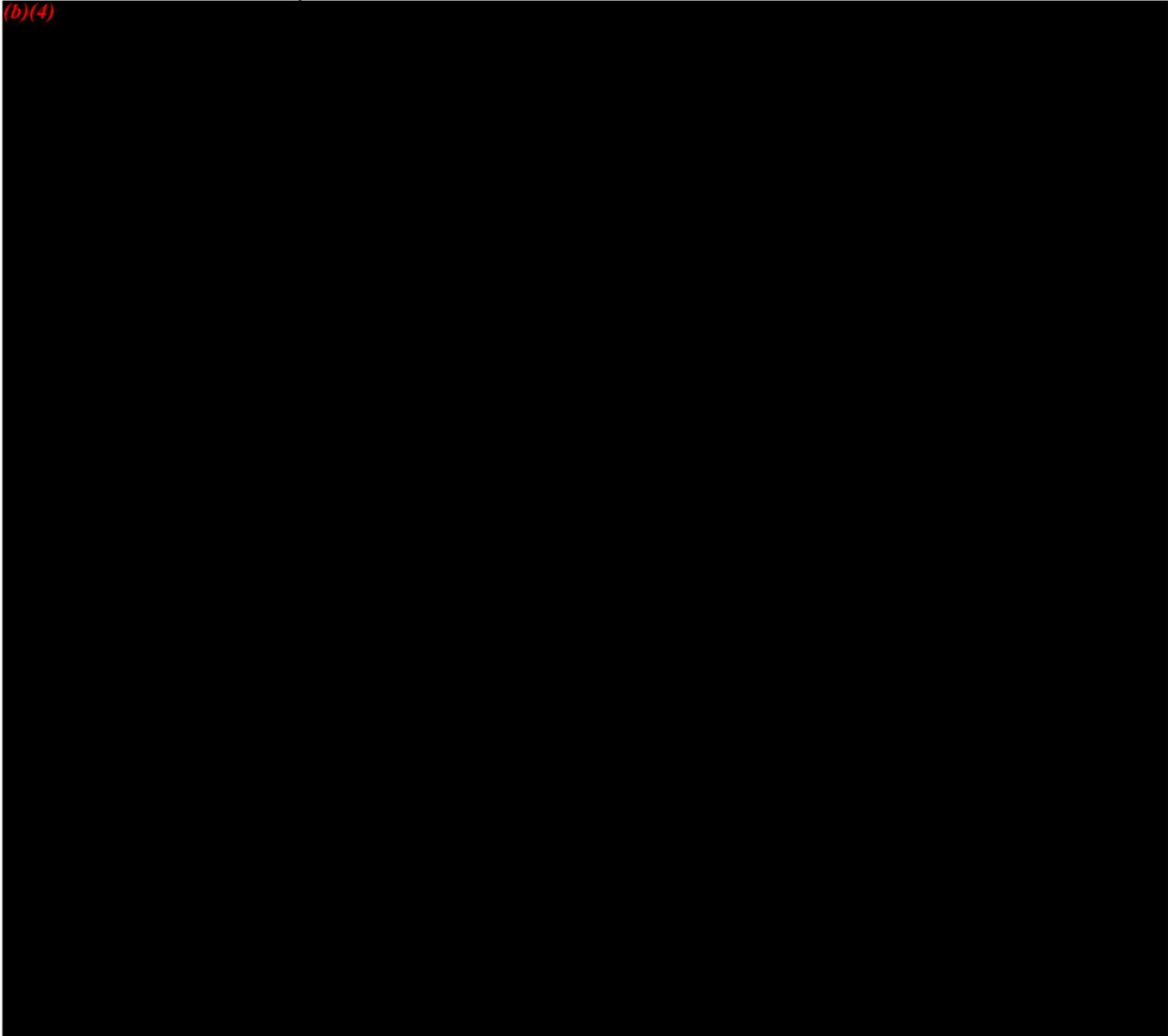
(b)(4)



7

Bausch + Lomb Response for Question 2

(b)(4)



(b)(4)

LABORATORY REPORT

**BAUSCH
& LOMB**

(b)(4)

TITLE: Total Protein Analysis of Clinically Worn Lenses (b)(4) – A Safety and Efficacy Study of a New Contact Lens Cleaning and Disinfecting Solution- (b)(4) (b)(4)
To: (b)(4)
(b)(4)

SUMMARY

(b)(4)

[Redacted Summary Content]

(b)(4)