K094039
Pg. 1 of 2

ATTACHMENT 2

510(k) SUMMARY

510(k) Owner: Fidia Farmaceutici, S.p.A.
Via Ponte dell Fabbrica 3/A
35031 Abano Terme
PADOVA, ITALY

Contact: Dr. Giusi LoCastro
Regulatory Affairs
Phone: +39-049-8232906
Fax: + 39-049-8232398

MAY - 7 2010

Date Summary Prepared: May 4, 2010

Device:
Trade Name: HYALO GYN®
Common/Classification Name: Lubricant, Patient, Vaginal, Latex Compatibile
Product Code NUC
Classification: 21 C.F.R. § 884.5300

Predicate Device: Glycerin & Paraben Free Astroglide
Biofilm, Inc.
K072647

Device Description: HYALO GYN is a colorless, odorless, transparent, aqueous, hydrating gel that contains "Hydeal-D®" (a partial benzyl ester of hyaluronic acid), propylene glycol, a carbomer, preservatives (methyl-p-hydroxybenzoate and propyl-p-hydroxybenzoate), and sodium hydroxide (to balance the pH). The hyaluronic acid is manufactured using a bacterial fermentation process. HYALO GYN is intended for use as a personal lubricant. HYALO GYN is compatible with latex condoms: lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin. HYALO GYN has a pH of 5.5-6.5 and a shelf life of 3 years.

HYALO GYN acts as a moisturizer and lubricant because of the strong hydrating properties of its hyaluronic acid derivative component. The carbomer and propylene glycol, combined with the hyaluronic acid derivative, enable HYALO GYN to achieve its thick, viscous gel form, and the mucoadhesive properties of the product allow it to adhere to the vaginal mucosa, enhancing the residence time, thus hydrating and protecting this tissue.

Intended Use:	Hyalo Gyn is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with condoms: lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin.
Technological Characteristics:	HYALO GYN is substantially equivalent to the predicate device with regard to intended use and technological characteristics. Hydeal-D has been used in legally marketed devices, and no new questions of safety or effectiveness are presented. In addition, the other components (carbomer, propylene glycol, preservatives, and water) meet the specifications defined in the United States Pharmacopoeia (USP) or National Formulary (NF), where applicable.
Biocompatibility Data	Cytotoxicity studies demonstrate that HYALO GYN is not cytotoxic. An acute intraperitoneal toxicity study on HYALO GYN indicated that the lethal dose is >10 ml/kg but <20 ml/kg. A skin sensitization study provides evidence for the lack of a sensitizing effect. Vaginal tolerance testing demonstrated that HYALO GYN is a minimal vaginal irritant in the rabbit model.
Performance Data -- Nonclinical	Condom compatibility testing demonstrates that HYALO GYN is compatible with latex, polyurethane, and natural skin condoms. No macroscopic signs and no statistically significant differences were observed in tensile strength, elongation at break, and breaking force between treated and non-treated groups of condoms. Stability studies conducted in accordance with the ICH Q1A guidelines confirm a shelf-life of 36 months.
Performance Data -- Clinical	A pilot, open, uncontrolled clinical study was conducted in Italy to assess the safety and effectiveness of HYALO GYN. A total of 80 women were enrolled at a single site. They were instructed to use the test product every three days for 30 days. Follow-up visits were performed on Days 7 and 21, with the final visit taking place three days after the last application of test product. The results obtained in this study demonstrated that the test material had moisturizing effects on the vaginal mucosa. Safety was considered to be excellent as demonstrated by the absence of adverse events and the investigator's overall assessment of tolerability score (98.7%). There were no alterations of the vaginal ecosystem.
Conclusions	Based on the biocompatibility testing, nonclinical performance testing, and the clinical data provided in this 510(k), it is concluded that HYALO GYN is safe and effective as a vaginal lubricant and moisturizer, and at least as safe and effective as legally marketed vaginal lubricants. Further, the lack of adverse events reported over 8 years of postmarket experience with HYALO GYN outside of the U.S. demonstrate the safe and effective use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAY - 7 2010

Fidia Farmaceutici S.p.A
% Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Avenue, N.W.
WASHINGTON DC 20004

Re: K094039
Trade Name: HYALO GYN®
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 7, 2010
Received: April 7, 2010

Dear Dr. Segal:

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.

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" (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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094039

Device Name: HYALO GYN®

Indications for Use: HYALO GYN is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This product is compatible with condoms: lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K094039

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAY - 7 2010

Fidia Farmaceutici S.p.A
% Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Avenue, N.W.
WASHINGTON DC 20004

Re: K094039
Trade Name: HYALO GYN®
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 7, 2010
Received: April 7, 2010

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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" (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,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094039

Device Name: HYALO GYN®

Indications for Use: HYALO GYN is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This product is compatible with condoms: lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K094039

DB1/64550482.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 26, 2010

FIDIA FARMACEUTICI SPA
VIA PONTE DELLA FABBRICA 3/A
ABANO TERME, PADUA (PD)
ITALY 35031
ATTN: GIUSI LOCASTRO

510k Number: K094039
Product: HYALO GYN

Extended Until: 04/26/2010

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

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). 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.

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

173

Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004
Tel: 202.739.3000
Fax: 202.739.3001
www.morganlewis.com

Morgan Lewis
COUNSELORS AT LAW

Sharon A. Segal, Ph.D.
Director of Regulatory Science
202.739.5427
ssegal@MorganLewis.com

K 94

March 25, 2010

FDA CDRH DMC
MAR 25 2010
Received

BY HAND DELIVERY

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -- W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Re: K094039
HYALO GYN® Vaginal Moisturizer
Request for Extension to Respond to February 26, 2010 Additional Information Letter

Dear Mr. Pollard:

On behalf of Fidia Farmaceutici, S.p.A. ("Fidia"), Morgan Lewis requests an extension of one month (*i.e.,* until April 26, 2010) to respond to your February 26, 2010 Additional Information letter for the subject Premarket Notification for HYALO GYN. Fidia requires this additional time to compile the data and information requested.

Please contact me at 202-739-5427 or by e-mail at ssegal@morganlewis.com if you have any questions.

Sincerely,

Sharon A. Segal, Ph.D.
Director of Regulatory Science

174

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 26 2010

Fidia Farmaceutici S.p.A
% Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Avenue, N.W.
WASHINGTON DC 20004

Re: K094039
Trade Name: Hyalo Gyn® Vaginal Moisturizer and Lubricant
Dated: December 30, 2009
Received: December 30, 2009

Dear Dr. Segal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

Device Description

(b) (4)

175

(b) (4)

Predicate Device Comparison

(b) (4)

Biocompatibility testing

(b) (4)

(b) (4)

Condom Compatibility

(b) (4)

(b) (4)

[redacted]

Shelf-life

(b) (4)

[redacted]

Labeling

(b) (4)

[redacted]

Administrative Issue

(b) (4)

[redacted]

(b) (4)

[redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

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 additional information 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.

180

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of the letter, please contact M. Ashraf Hossain, M.B.B.S., Ph.D., at (301) 796-6536. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Colin M. Pollard

Colin M. Pollard
Chief, Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and
Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 31, 2009

FIDIA FARMACEUTICI SPA
VIA PONTE DELLA FABBRICA 3/A
ABANO TERME, PADUA (PD)
ITALY 35031
ATTN: GIUSI LOCASTRO

510k Number: K094039
Received: 12/30/2009
Product: HYALO GYN

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "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).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

K094039

Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004
Tel: 202.739.3000
Fax: 202.739.3001
www.morganlewis.com

Morgan Lewis
COUNSELORS AT LAW

Sharon A. Segal, Ph.D.
Director of Regulatory Science
202.739.5427
ssegal@morganlewis.com

FDA CDRH DMC

DEC 30 2009

Received

December 30, 2009

BY HAND DELIVERY

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

Re: Traditional Premarket 510(k) Notification for Fidia Farmaceutici S.p.A.s HYALO GYN®

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and on behalf of Fidia Farmaceutici S.p.A. ("Fidia") Morgan, Lewis & Bockius LLP ("Morgan Lewis") is submitting the enclosed premarket Traditional Premarket Notification ("510(k)") for its HYALO GYN, a colorless, transparent aqueous hydrating gel that is intended for use as a personal lubricant. This device is regulated under product code NUC (21 C.F.R. § 884.5300), as a Class II Patient vaginal latex compatible lubricant.

Contact Person: Dr. Giusi LoCastro
Regulatory Affairs
Fidia Farmaceutici S.p.A.
Phone: +39-049-8232906
Fax: + 39-049-8232398

K30
CN
+1

Basis for Submission: New device

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic	X	

K30

Question	YES	NO
source?		
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software/		X
Does the submission include clinical information?	X	
Is the device implanted?		X

The existence of this premarket notification and the data and other information that it contains are confidential. The protection afforded to such confidential information by 18 U.S.C. 1905, 21 U.S.C. 331(j), 5 U.S.C. 552, and other applicable laws is hereby claimed.

Further, in accordance with the Medical Device User Fee and Modernization Act of 2002 ("MDUFMA"), FAB has submitted the appropriate application fee. A copy of the User Fee Cover Sheet is provided with the enclosed 510(k).

If you have any questions regarding this notification or require additional information, please contact me at 202.739.5427 or by e-mail at ssegal@morganlewis.com.

Sincerely,

Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan Lewis

Enclosures

cc: Dr. Giusi LoCastro

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010 See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) 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)	2. CONTACT NAME
FIDIA FARMACEUTICI SPA Via Ponte della Fabbrica 3/A Abano Terme Italy 35031 IT	Giusi Lo Castro 2.1 E-MAIL ADDRESS glocastro@fidiapharma.it 2.2 TELEPHONE NUMBER (include Area code) 00390498232906
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.3 FACSIMILE (FAX) NUMBER (include Area code) 00390498232398

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:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 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

[X] 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?

[X] 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.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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 [X] NO

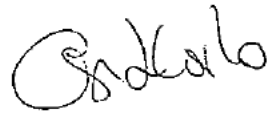
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) 20-Nov-2009

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Fidia farmaceutici S.p.A



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
12/30/2009	(b) (4) 3	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☑ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☑ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Fidia Farmaceutici S.p.A.	9610200		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(+39) 049-8232906		
Street Address	**FAX Number *(including area code)***		
Via Ponte dell Fabbrica, 3/A	(+39) 049-8232398		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Abano Terme (Padova)	Padova	35031	Italy
Contact Name			
Giusi LoCastro			
Contact Title	**Contact E-mail Address**		
Regulatory Affairs	glocastro@fidiapharma.it		

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/Postal Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Media Arts (301) 443-1090 EF

320

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

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

SECTION D2 REASON FOR APPLICATION - IDE

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

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☑ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NUC	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K072647	Glycerin & Paraben Free Astroglide	Biofilm, Inc.
2	K073251	HYALOMATRIX PA	Fidia Advanced Biopolymers S.r.l.
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Personal lubricant

	Trade or Proprietary or Model Name for This Device	Model Number
1	HYALO GYN	
2		
3		
4		
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

- [x] Laboratory Testing
- [x] Animal Trials
- [x] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NUC	21 C.F.R. 884.5300	☐ Class I ☑ Class II ☐ Class III ☐ Unclassified
Classification Panel		

Indications *(from labeling)*

HYALO GYN is intended as a moisturizer for vaginal dryness and personal lubricant to supplement the body's own natural lubrication fluids. HYALO GYN also reduced friction during sexual intercourse enhancing the comfort and ease of intimate sexual activity with or without a condom.

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

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

☑ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name Fidia Farmaceutici S.p.A.		Establishment Registration Number 3003668467	
Division Name *(if applicable)*		Phone Number *(including area code)* (+39) 049-8232906	
Street Address Via Ponte della Fabbrica, 3/A		FAX Number *(including area code)* (+39) 049-8232398	
City Abano Terme (Padova)		State / Province Padova	ZIP/Postal Code 35031	Country Italy
Contact Name Giusi LoCastro	Contact Title Regulatory Affairs		Contact E-mail Address glocastro@fidiapharma.it	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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/Postal 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:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
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

HYALO GYN®

Premarket Notification [510(k)]

Submitted by:

Fidia Farmaceutici, S.p.A.
Abano Terme, Italy

December 30, 2009

Table of Contents

List of Attachments

Attachment 12 (Declaration of Conformity for Applicator and Plunger)
Attachment 13 (Report on Compatibility with Condoms)
Attachment 14 (Evaluation of the Tolerability and Efficacy of HYALGEL VAGINAL (HYALOgin™) for the Treatment of Vaginal Dryness and Irritation)

510(k)

1.0 Indications for Use Statement

The Indications for Use Statement for HYALO GYN is provided in Attachment 1.

2.0 510(k) Summary

The 510(k) summary for HYALO GYN is provided in Attachment 2.

3.0 Truthful and Accuracy Statement

The Truthful and Accuracy Statement is provided in Attachment 3.

4.0 Class III Summary and Certification

This section does not apply.

5.0 Financial Certification or Disclosure Statement

FDA Form 3454 ("Certification of Financial Interests and Arrangements of Clinical Investigators") is provided in Attachment 4.

6.0 Executive Summary

6.1 Brief Device Description

HYALO GYN[1] is a colorless, transparent, aqueous, hydrating gel that contains "Hydeal-D®, a hyaluronic acid derivative (Hydeal-D is the same product as HYAFF 11p50), propylene glycol, carbopol 974P, preservatives (methyl-p-hydroxybenzoate and propyl-p-hydroxybenzoate), and sodium hydroxide (to balance the pH). The hyaluronic acid is manufactured using a bacterial fermentation process. HYALO GYN is intended for use as a personal lubricant. HYALO GYN is compatible with latex, polyurethane, and "natural skin" condoms as demonstrated in testing conducted according to ASTM D3492-03 and ASTM D412-98a.

[1] HYALO gyn also is marketed under the tradename "HYALOFEMME" outside of the U.S. The only difference between the two products is that HYALO gyn is packaged with 10 single-use, disposable vaginal application applicators, and HYALOFEMME is packaged with one re-usable vaginal applicator. Fidia intends to market only HYALO gyn in the U.S. Please note that the test substance used in the biocompatibility studies reported in this submission is referred to as "Hyalofemme."

6.2 Device Comparison Table

A substantial equivalence table comparing the HYALO GYN to the predicate devices is provided below.

Table 6-1: Substantial Equivalence Comparison Table

	New Device	Predicate Device	Predicate Device
510(k) #	To be determined	K072647	K073251
Company	Fidia Farmaceutici, S.p.A.	Biofilm, Inc.	Fidia Advanced Biopolymers S.r.l.
Name	HYALO GYN®	Glycerin & Paraben Free Astroglide®	HYALOMATRIX PA®
Intended Use	(b) (4)	Glycerin and Paraben Free Astroglide® is a personal lubricant, for penile, anal, or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with latex condoms.	HYALOMATRIX PA is indicated for the management of wounds including partial and full-thickness wounds; second and third-degree burns; pressure ulcers; venous ulcers; diabetic ulcers; chronic vascular ulcers; tunneled/undetermined wounds; surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence); trauma wounds (abrasions, lacerations, skin tears); and draining wounds. The device is intended for one-time use.
Materials		• Water • Butylene glycol • Xylitol	• HYAFF 11 (benzyl ester of hyaluronic acid derived from bacterial fermentation)
Visual Appearance		Clear, non-greasy, high viscosity liquid	White bilayered non-woven pads with 150µm layer of semipermeable silicone
Water Solubility		Soluble	Not Applicable
Latex condom compatibility		Compatible	Not Applicable
Sterile		No	Yes

6.3 Summary of Biocompatibility Testing

(b) (4)

6.4 Summary of Performance Testing

(b) (4)

7.0 Device Description

(b) (4)

7.1 Physical Appearance

HYALO GYN is a clear, colorless gel.

7.2 Materials

(b) (4)

(b) (4)

Table 7-1. Composition of HYALO GYN

Component	Amount per 100 g
(b) (4)	

Finished product specifications for HYALO GYN are provided in Section 7.3.2 below.

HYALO GYN is packaged with 10 applicators and a plunger with plunger rod for application (see Section 7.4 below).

7.3 Product Specifications

(b) (4)

7.3.2 Finished Product Specifications

The finished product specifications are provided in Table 7-3.

Table 7-3. Finished Product Specifications

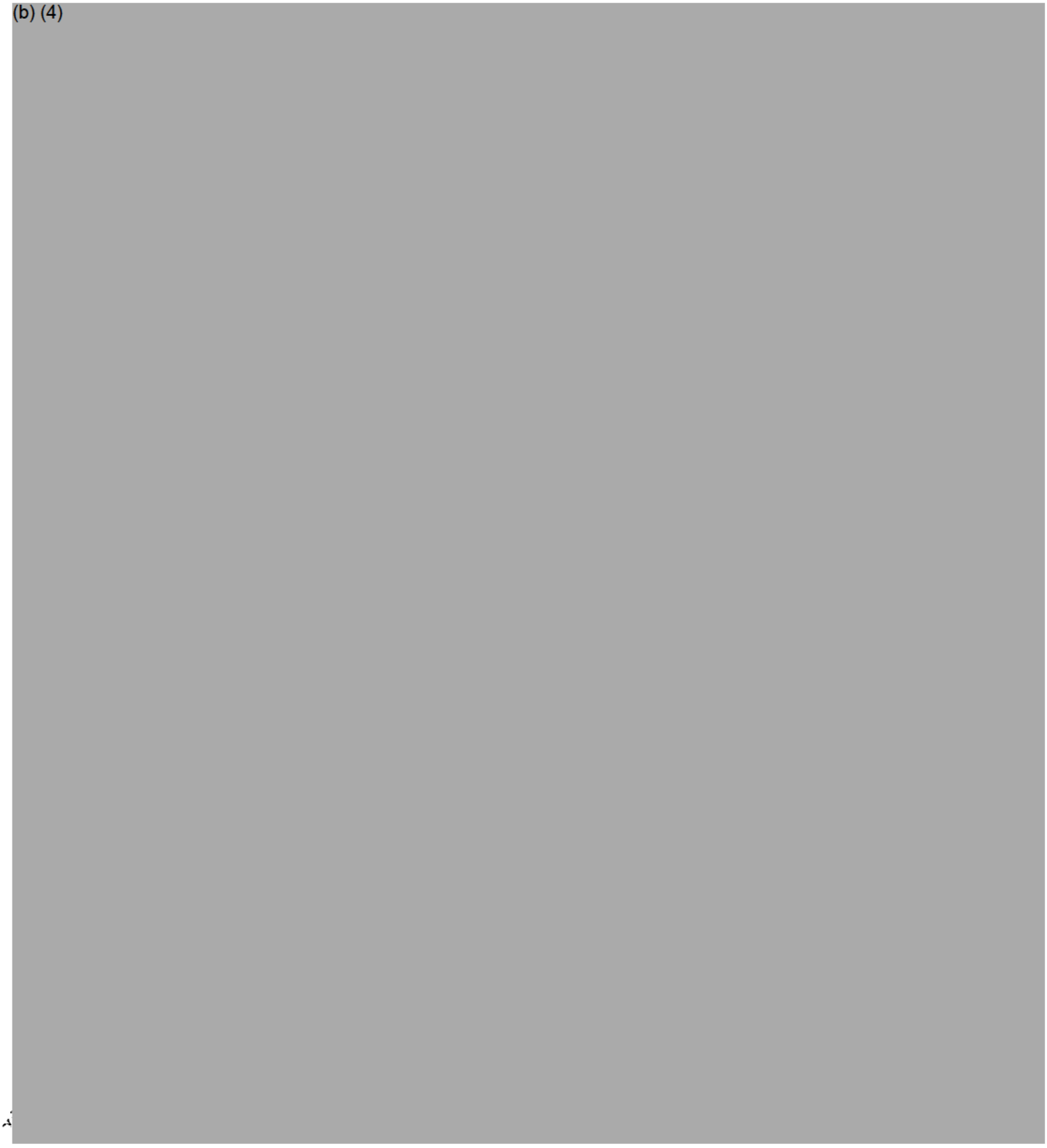
(b) (4)

7.4 Packaging

(b) (4)

7.5 Device Manufacture

(b) (4)



(b) (4)

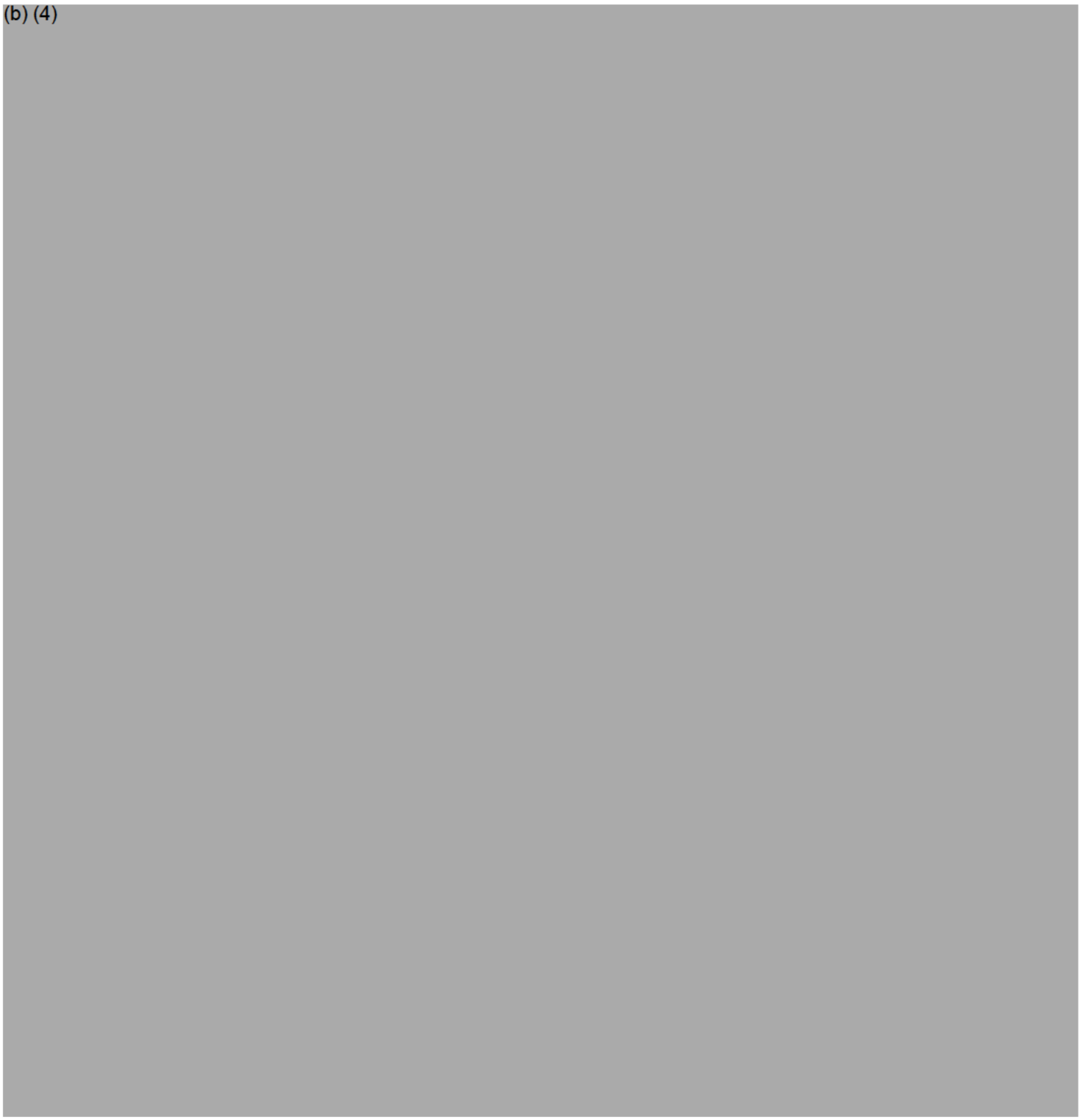
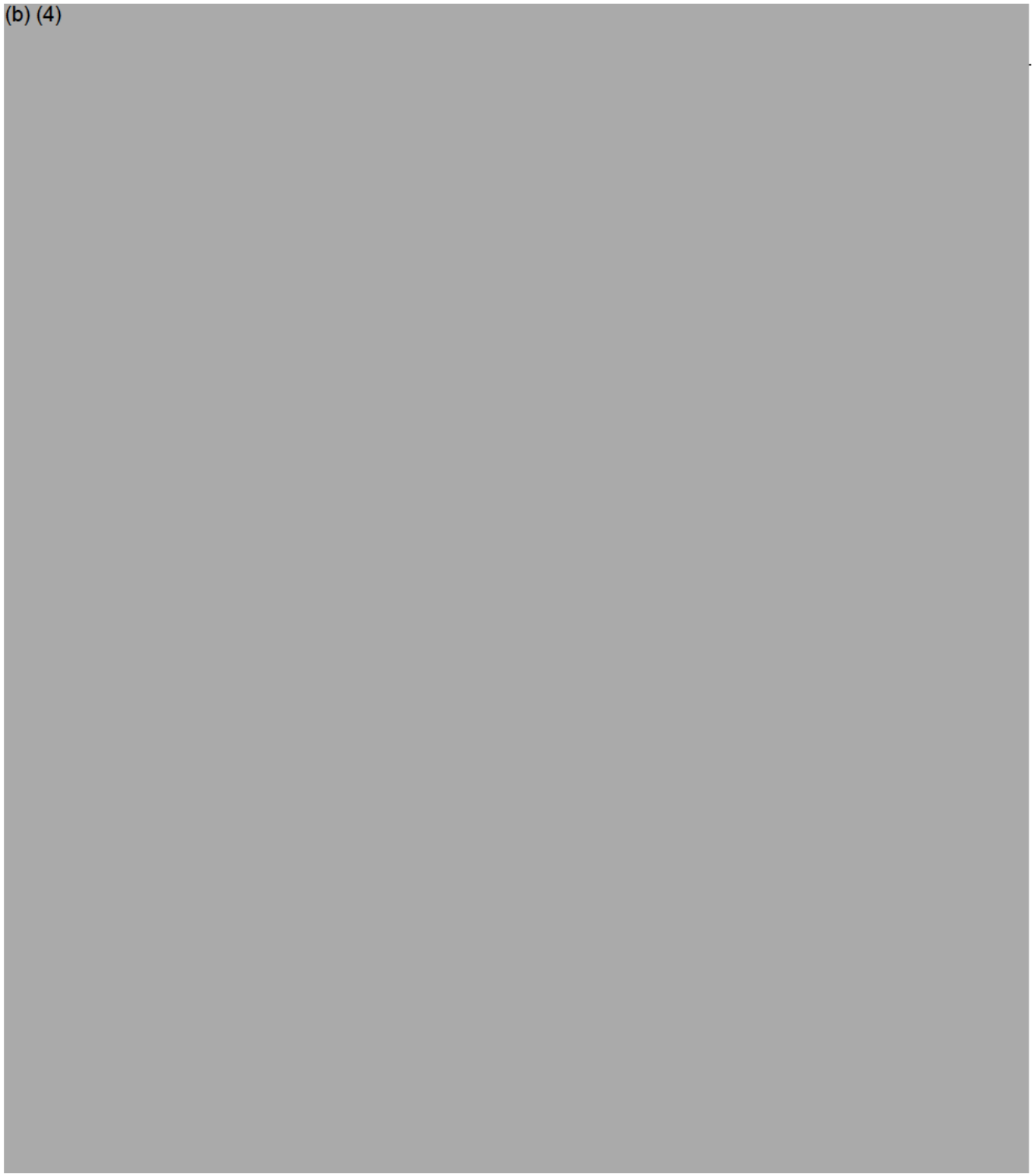


Figure 7-2.
Manufacturing Flow Chart for Hydeal-D/HYAFF 11p50

7.5.2 HYALO GYN Production

(b) (4)



8.0 Substantial Equivalence Discussion

8.1 Predicate Devices

Glycerin & Paraben Free Astroglide
Biofilm, Inc.
K072647

HYALOMATRIX PA®
Fidia Advanced Biopolymers S.r.l.
K073251

8.2 Comparison with Predicate Devices

HYALO GYN is substantially equivalent to Glycerin & Paraben Free Astroglide with regard to the indications for use. HYALO GYN and Glycerin & Paraben Free Astroglide are both intended for use as a personal moisturizer and lubricant, to supplement the body's natural lubrication, and enhance the ease and comfort of intimate sexual activity. Glycerin & Paraben Free Astroglide is a personal lubricant for the penis, anus, and vagina, while HYALO GYN is intended for use only in the vagina. HYALO GYN and Glycerin & Paraben Free Astroglide also are both glycerin-free.

(b) (4)

(b) (4)

9.0 Proposed Labeling

The proposed labeling for HYALO GYN is provided in Attachment 8.

10.0 Sterilization and Shelf life

HYALO GYN will be supplied non-sterile.

The efficacy of the preservatives used in HYALO GYN has been tested and confirmed, and the study report is provided in Attachment 9.

(b) (4)

11.0 Biocompatibility

The biocompatibility of HYALO GYN, was assessed in both *in vitro* and *in vivo* studies. These studies are summarized below in Table 11-1, and the final study reports are provided in Attachment 11.

In accordance with FDA's Blue Book Guidance G95-1 ("Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' "), the following biocompatibility studies were conducted:

- Cytotoxicity
- Sensitization
- Irritation (vaginal mucosa)
- Acute systemic toxicity

(b) (4)

(b) (4)

Table 11-1. Summary of Biocompatibility Testing on HYALO GYN/HYALOFEMME[2]

12.0 Software

This section does not apply.

13.0 Electromagnetic Compatibility and Electrical Safety

This section does not apply.

14.0 Performance Testing -- Bench

(b) (4)

15.0 Performance Testing -- Animal

This section does not apply.

16.0 Performance Testing -- Clinical

(b) (4)

(b) (4)

ATTACHMENT 1

Indications for Use

510(k) Number (if known): _____

Device Name: HYALO GYN

Indications for Use: HYALO GYN is intended as a moisturizer for vaginal dryness and personal lubricant to supplement the body's own natural lubrication fluids. HYALO GYN also reduces friction during sexual intercourse enhancing the comfort and ease of intimate sexual activity with or without a condom.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

ATTACHMENT 2

510(k) SUMMARY

510(k) Owner: Fidia Farmaceutici, S.p.A.
Via Ponte dell Fabbrica 3/A
35031 Abano Terme
PADOVA, ITALY

Contact: Dr. Giusi LoCastro
Regulatory Affairs
Phone: +39-049-8232906
Fax: + 39-049-8232398

Date Summary Prepared: December 30, 2009

Device:
Trade Name: HYALO GYN®
Common/Classification Name: Lubricant, Patient, Vaginal, Latex Compatibile
Product Code NUC
Classification: 21 C.F.R. § 884.5300

Predicate Devices:
Glycerin & Paraben Free Astroglide
Biofilm, Inc.
K072647

HYALOMATRIX PA®
Fidia Advanced Biopolymers S.r.l.
K073251

Device Description: HYALO GYN is a colorless, transparent, aqueous, hydrating gel that contains "Hydeal-D®," a hyaluronic acid derivative, propylene glycol, a carbomer, preservatives (methyl-p-hydroxybenzoate and propyl-p-hydroxybenzoate), and sodium hydroxide (to balance the pH). The hyaluronic acid is manufactured using a bacterial fermentation process. HYALO GYN is intended for use as a personal lubricant. HYALO GYN is compatible with latex condoms

Intended Use: HYALO GYN is intended as a moisturizer for vaginal dryness and personal lubricant to supplement the body's own natural lubrication fluids. HYALO GYN also reduces friction during sexual intercourse enhancing the comfort and ease of intimate sexual activity with or without a condom.

Technological Characteristics:	HYALO GYN is substantially equivalent to the predicate devices with regard the intended use and/or technological characteristics. Hydeal-D has been used in legally marketed predicate devices, and no new questions of safety or effectiveness are presented by the technological differences between HYALO GYN and its predicate devices.
Biocompatibility Data	Cytotoxicity studies demonstrate that HYALO GYN is not cytotoxic. An acute intraperitoneal toxicity study on HYALO GYN indicated that the lethal dose is >10 ml/kg but <20 ml/kg. A skin sensitization study provides evidence for the lack of a sensitizing effect. Vaginal tolerance testing demonstrated that HYALO GYN is a minimal to mild vaginal irritant. HYALO GYN is latex condom compatible.

ATTACHMENT 3

Truthful and Accuracy Statement
[As Required by 21 C.F.R. § 807.87(k)]

I certify that, in my capacity as Chairman of Fidia Farmaceutici S.p.A., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____
(Signature)

Antonio Germani
(Typed Name)

_____
(Date)

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

ATTACHMENT 4

FDA Form 3454

ATTACHMENT 5

Technical Information on Aluminum Tube

ATTACHMENT 6

Technical Information on Vaginal Applicator Plunger

ATTACHMENT 7

Technical Information on Internal Coatings

ATTACHMENT 8

Proposed Labeling for HYALO GYN

ATTACHMENT 9

Preservative Efficacy Study Report

ATTACHMENT 10

Stability Data for HYALO GYN

ATTACHMENT 11

Biocompatibility Study Reports

ATTACHMENT 12

Declaration of Conformity for Applicator and Plunger

ATTACHMENT 13

Report on Compatibility with Condoms

ATTACHMENT 14

Evaluation of the Tolerability and Efficacy of HYALGEL VAGINAL (HYALOgin™) for the Treatment of Vaginal Dryness and Irritation

ATTACHMENT 1

Indications for Use

510(k) Number (if known): _____

Device Name: HYALO GYN

Indications for Use: HYALO GYN is intended as a moisturizer for vaginal dryness and personal lubricant to supplement the body's own natural lubrication fluids. HYALO GYN also reduces friction during sexual intercourse enhancing the comfort and ease of intimate sexual activity with or without a condom.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

ATTACHMENT 2

510(k) SUMMARY

510(k) Owner:	Fidia Farmaceutici, S.p.A. Via Ponte dell Fabbrica 3/A 35031 Abano Terme PADOVA, ITALY	
	Contact:	Dr. Giusi LoCastro Regulatory Affairs
	Phone:	+39-049-8232906
	Fax:	+ 39-049-8232398
Date Summary Prepared:	December 30, 2009	
Device:	Trade Name:	HYALO GYN®
	Common/Classification Name:	Lubricant, Patient, Vaginal, Latex Compatibile Product Code NUC
	Classification:	21 C.F.R. § 884.5300
Predicate Devices:	Glycerin & Paraben Free Astroglide Biofilm, Inc. K072647	
	HYALOMATRIX PA® Fidia Advanced Biopolymers S.r.l. K073251	
Device Description:	HYALO GYN is a colorless, transparent, aqueous, hydrating gel that contains "Hydeal-D®," a hyaluronic acid derivative, propylene glycol, a carbomer, preservatives (methyl-p-hydroxybenzoate and propyl-p-hydroxybenzoate), and sodium hydroxide (to balance the pH). The hyaluronic acid is manufactured using a bacterial fermentation process. HYALO GYN is intended for use as a personal lubricant. HYALO GYN is compatible with latex condoms	
Intended Use:	HYALO GYN is intended as a moisturizer for vaginal dryness and personal lubricant to supplement the body's own natural lubrication fluids. HYALO GYN also reduces friction during sexual intercourse enhancing the comfort and ease of intimate sexual activity with or without a condom.	

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Biocompatibility Data	Cytotoxicity studies demonstrate that HYALO GYN is not cytotoxic. An acute intraperitoneal toxicity study on HYALO GYN indicated that the lethal dose is >10 ml/kg but <20 ml/kg. A skin sensitization study provides evidence for the lack of a sensitizing effect. Vaginal tolerance testing demonstrated that HYALO GYN is a minimal to mild vaginal irritant. HYALO GYN is latex condom compatible.

ATTACHMENT 3

Truthful and Accuracy Statement
[As Required by 21 C.F.R. § 807.87(k)]

I certify that, in my capacity as Chief Executive Officer of Fidia Farmaceutici S.p.A., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Antonio Germani

December 30, 2009

(Premarket Notification [510(k)] Number)

ATTACHMENT 4

FDA Form 3454

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☐ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		

☒ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Antonio Germani	Chief Executive Officer
FIRM/ORGANIZATION: Fidia Farmaceutici S.p.A.	
SIGNATURE: Antonio Germani	DATE *(mm/dd/yyyy)*: December 30, 2009

Paperwork Reduction Act Statement

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. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

PSC Graphics (301) 443-1090 EF

MCA

365

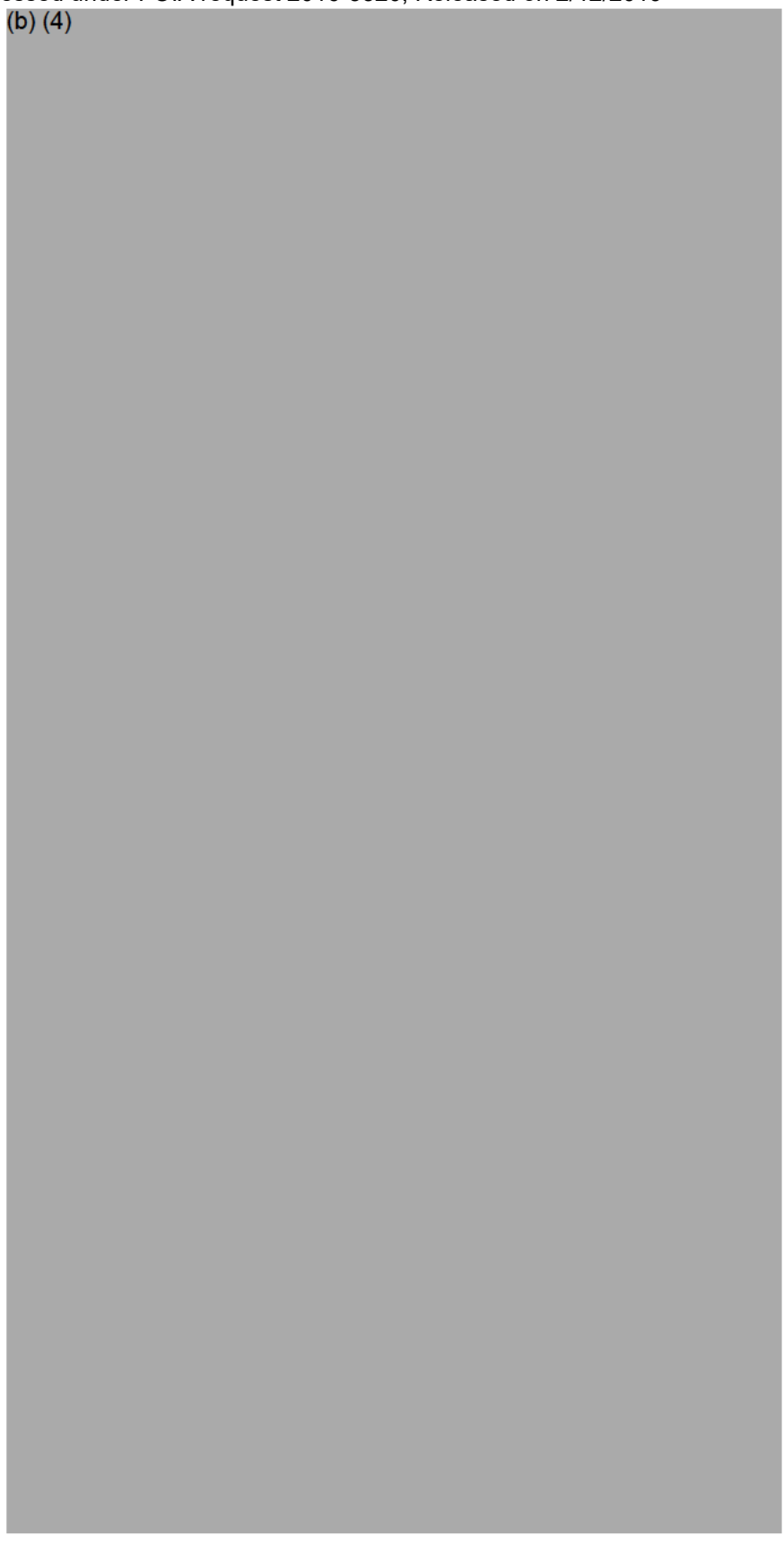
Fidia
Advanced
Biopolymers

List of clinical investigators

(b) (4)

[redacted]

(b) (4)



Fidia
Advanced
Biopolymers

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367

ATTACHMENT 5

Technical Information on Aluminum Tube

ATTACHMENT 6

Technical Information on Vaginal Applicator Plunger

ATTACHMENT 7

Technical Information on Internal Coatings

ATTACHMENT 8

Proposed Labeling for HYALO GYN

(b)(4) Proposed labeling

(b)(4) Proposed labeling

ATTACHMENT 9

Preservative Efficacy Study Report

ATTACHMENT 10

Stability Data for HYALO GYN

ATTACHMENT 11

Biocompatibility Study Reports

ATTACHMENT 13

Report on Compatibility with Condoms

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

COVER SHEET MEMORANDUM

From: Reviewer Name M. Ashraf Hossain

Subject: 510(k) Number K094039(S)

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/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold)

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

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 N, see http://eroom.fda.gov/eRoomReg/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)?			✓
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, 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
884.5300	II	NUC

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

Additional Product Codes: HIS

Review: Colin M Pollard (Branch Chief) OGDB (Branch Code) 5/6/10 (Date)

Final Review: (Division Director) 5/7/10 (Date)

5

K094039

510(k) SUMMARY REQUIREMENTS CHECKLIST 21 CFR 807.92				
All 510(k) summaries shall contain the following information:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared	✓		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	✓		
3	An identification of the legally marketed device(s) to which the submitter claims equivalence.	✓		
4	A description of the device that is the subject of the 510(k), including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)	✓		
5	A statement of the indications for use of the device that is the subject of the 510(k), including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is indicated. Or, if the indication statements are different from those of the legally marketed device(s) identified in paragraph (3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device, and why the differences do not affect the safety and effectiveness of the device when used as indicated.	✓		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source, etc.) as the predicate device(s) identified in paragraph(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified in paragraph (3) of this section.	✓		
510(k) summaries for those 510(k)s in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence	✓		
8	A summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. (There can not be any patient identifier information in the summary.)	✓		
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in paragraph(3) of this section.	✓		

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K094039/S1 Hyalo Gyn Personal Lubricant

Date: May 6, 2010
To: The Record Office: ODE
Division: DRARD
From: M. Ashraf Hossain, MBBS, PhD.; Staff Fellow, OGDB

510(k) Holder/ Manufacturer: Fidia Farmaceutici S.p.A.
Via Ponte della Fabbrica 3/A
Abano Terme,
PADOVA ITALY 35031 IT
Attn: Giusi Locastro, Regulatory Affairs

Device Name: Hyalo Gyn® Vaginal Moisturizer and Lubricant

Contact: Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Avenue
Washington DC 20004

Phone: 202-739-5427
Fax: 202-739-3001
Email: ssegal@morganlewis.com

I. PURPOSE AND SUBMISSION SUMMARY

(b) (4)

[redacted]

3

(b) (4)

[redacted]

II. ADMINISTRATIVE REQUIREMENTS

Fidia has provided a 510(k) Summary, Indications for Use (IFU), and Truthful and Accurate-statements as well as FDA-3654 standards form. Administrative requirements have been met.

III. DEVICE DESCRIPTION

(b) (4)

[redacted]

(b) (4)

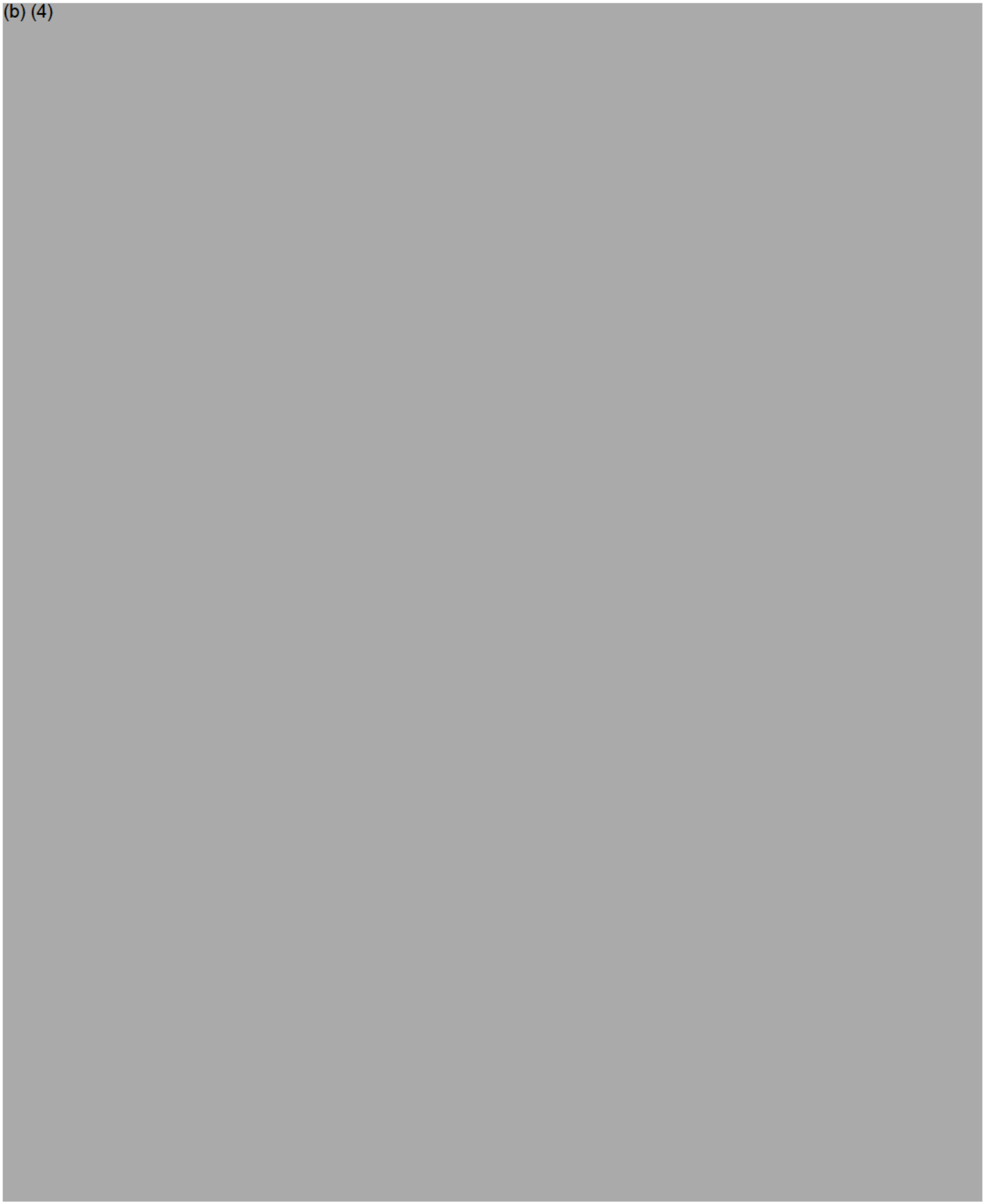
(b) (4)

(b) (4)

VII. STERILIZATION/SHELF LIFE

(b) (4)

(b) (4)



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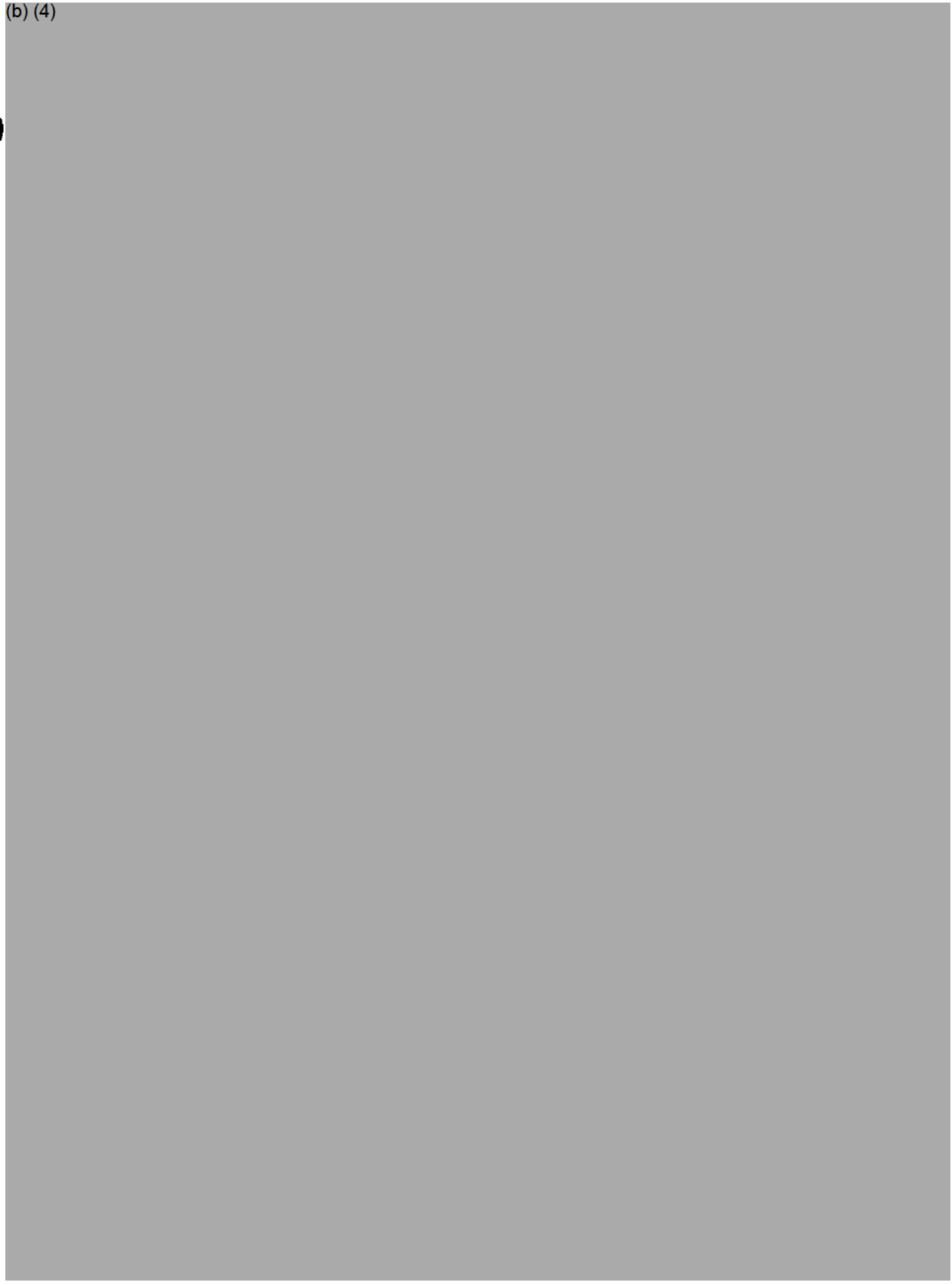
[redacted]

VIII. BIOCOMPATIBILITY/ MATERIAL SAFETY

(b) (4)

[redacted]

(b) (4)



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(b) (4)

The biocompatibility testing (material safety) information is acceptable.

IX. PERFORMANCE TESTING

(b) (4)

[redacted]

(b) (4)

X. Clinical Performance

(b) (4)

(b) (4)

[redacted]

XI. SUBSTANTIAL EQUIVALENCE DISCUSSION

	Yes	No	
1. Same Indication Statement?	✓		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	✓		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		✓	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	✓		If **NO** = Request Data
9. Data Demonstrate Equivalence?	✓		Final Decision: SE
* Yes-responses to questions 2, 4, 6 and 9, and every no-response requires an explanation.			

(b) (4)

Question 5.

Response:

Question 9.

Response:

XII. CONTACT HISTORY

(b) (4)

XIII. CONCLUSION

(b) (4)

[redacted]

XIV. RECOMMENDATION

Regulation Number: 21 CFR 884.5300
Regulation Name: Lubricant, Patient, Vaginal, Latex Compatible
Regulatory Class: Class II
Product Code: NUC

I recommend that Hyalo Gyn® Vaginal Moisturizer and Lubricant (K094039) is determined substantially equivalent to the predicate device Glycerine and paraben-free Astroglide personal lubricant (K072647, by Biofilm).

5/06/10

M. Ashraf Hossain, MBBS, PhD. Date
Reviewer

Colin M Pollard 5/6/10

Colin M. Pollard Date
Chief, Ob-Gyn Devices Branch

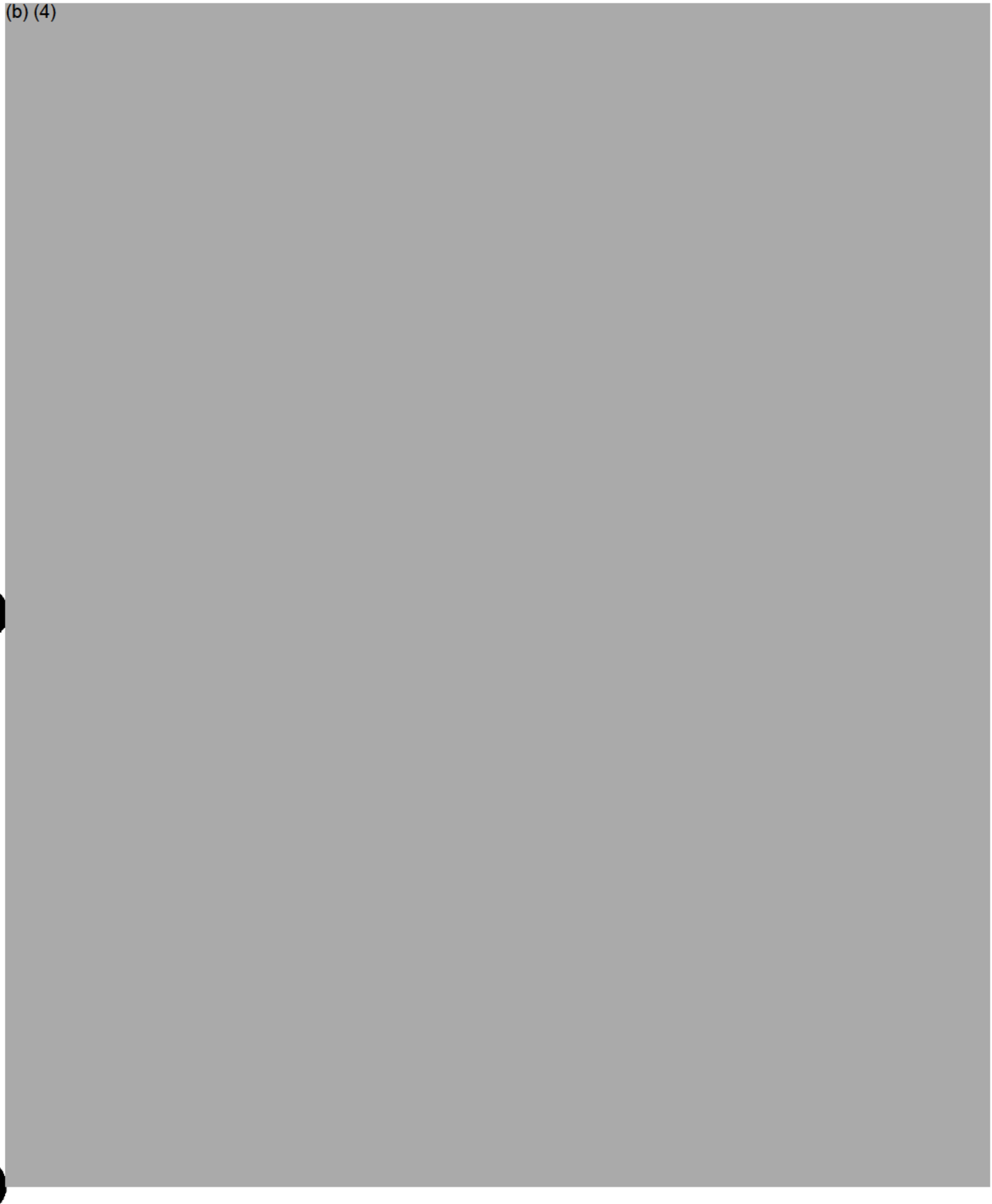
/ Concur
/ / Do not concur

Appendix 1. Table.

(b) (4)

Appendix 2. Review of Sponsor Responses to AI Letter Dated February 26, 2010.

(b) (4)



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Predicate Device Comparison

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Biocompatibility testing

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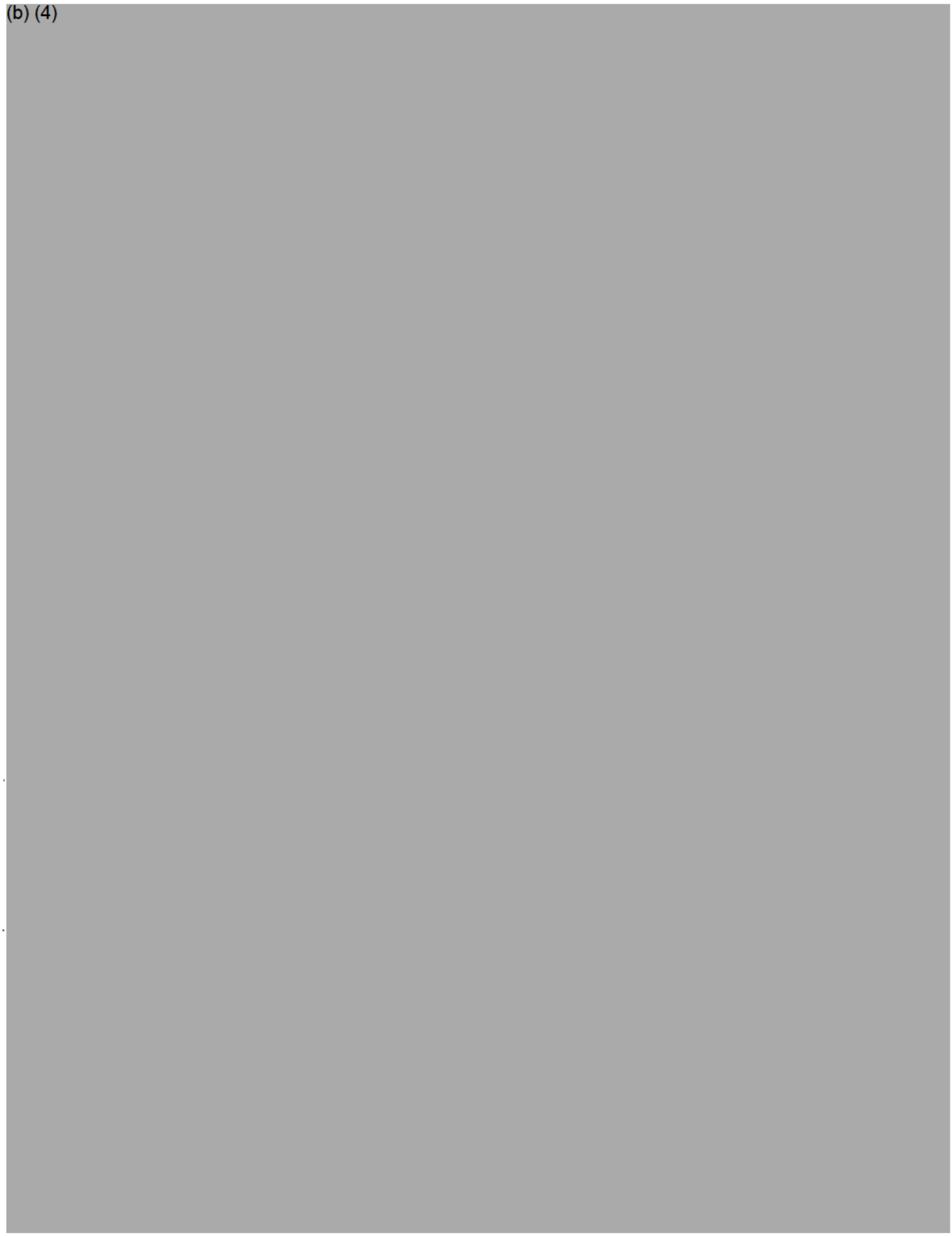
(b) (4)



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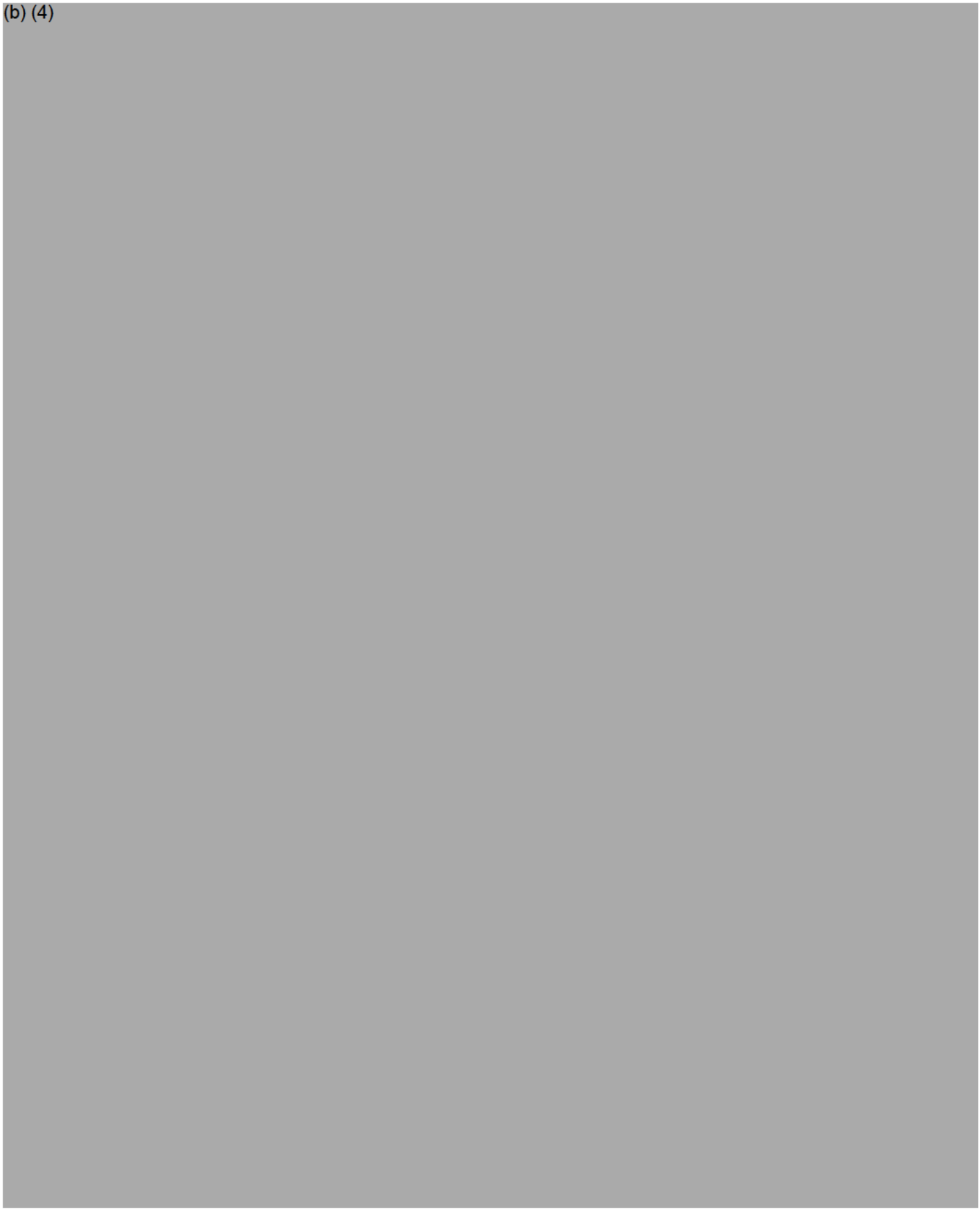


(b) (4)

[redacted]

Condom Compatibility

(b) (4)

[redacted]

(b) (4)

Shelf-life

(b) (4)

(b) (4)

[redacted]

Administrative Issue

(b) (4)

[redacted]

(b) (4)

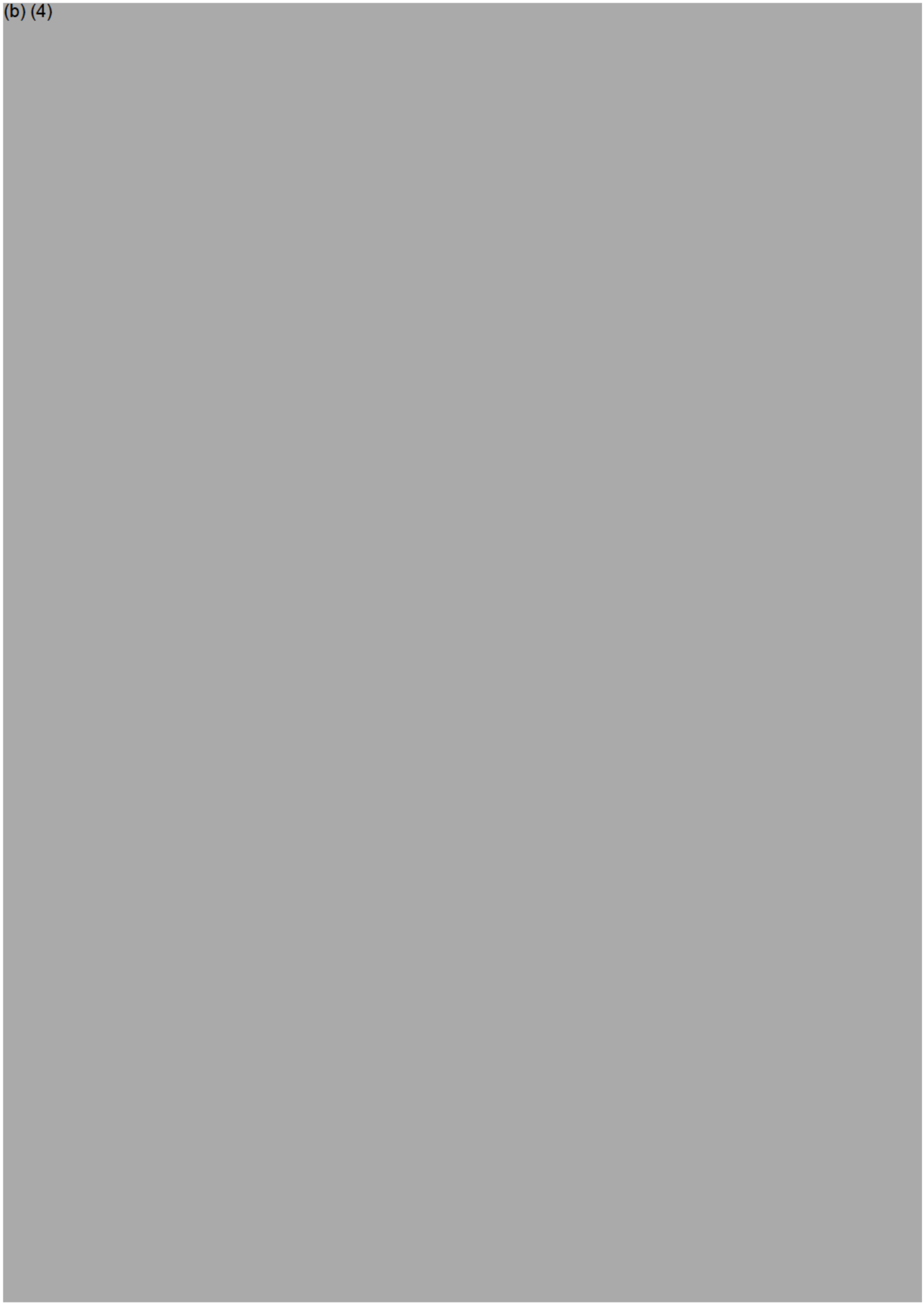
Pollard, Colin M.

From: Segal, Ph.D., Sharon A. [ssegal@morganlewis.com]
Sent: Friday, May 07, 2010 9:44 AM
To: Pollard, Colin M.
Cc: glocastro@fidiapharma.it; Hossain, Mohammad A
Subject: RE: K094039 -- labeling
Attachments: (64816490)_(2)_K094039 - Revised Product Information and Box Labeling (2) (May 7, 2010).DOC

(b) (4)

[redacted]

(b) (4)



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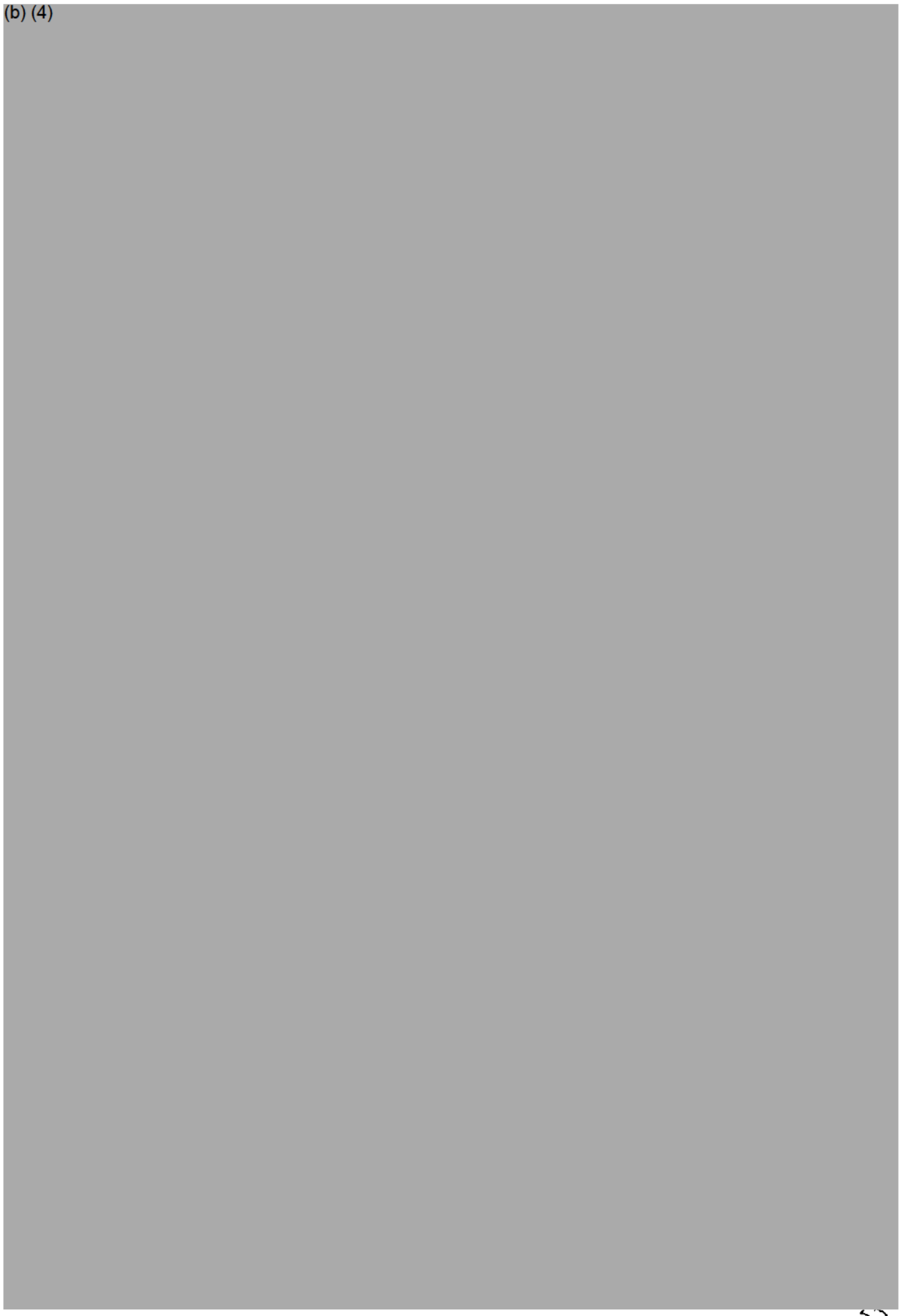

(b) (4)

From: Segal, Ph.D., Sharon A. [mailto:ssegal@morganlewis.com]
Sent: Thursday, May 06, 2010 3:47 PM
To: Hossain, Mohammad A
Cc: Pollard, Colin M.; glocastro@fidiapharma.it
Subject: RE: K094039 -- 510k Summary

(b) (4)

message.

DISCLAIMER
This e-mail message is intended only for the personal use of the recipient(s) named above. This message may be an attorney-client communication and as such privileged and confidential. If you are not an intended recipient, you may not review, copy or distribute this message. If you have received this communication in error, please notify us immediately by e-mail and delete the original message.

DISCLAIMER
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HYALO GYN®

Product Information

HYALO GYN® is a clear, colorless gel with strong hydrating properties that contains Hydeal-D®, a hyaluronic acid derivative.

Composition

Principal component: Hydeal-D® (hyaluronic acid derivative)
Other components: Propylene glycol, carbomer (Carbopol 974P), methyl p-hydroxy-benzoate, propyl p-hydroxybenzoate, sodium hydroxide, and purified water.

Indications for Use

HYALO GYN® is a personal lubricant, for penile and / or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.
This product is compatible with condoms: lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin.

Contraindications

Proven individual hypersensitivity towards the product.

Warnings and Precautions

1. In cases of vaginal infection, consult your doctor before using this product.
2. The product can be used during menstruation.
3. Each applicator is for single use only.
4. If the packaging proves to be damaged, do not use the product.
5. Keep out of reach of children.
6. Keep in a cool, dry place (<40°C).
7. Do not use the product after the expiration date shown on the packaging.
8. If irritation occurs, discontinue use and see a doctor.
9. This is not a spermicide and does not provide protection against pregnancy.
10. Slippery, avoid spill.
11. Safety and effectiveness of this product has not been evaluated in pregnant women.

Directions for Use

How to prepare the applicator for use:
Each package contains 10 single-use applicators consisting of a piston, and one opaque plastic plunger.

How to apply the product

1. Screw the applicator (complete with plunger) onto the opening of the tube.
2. Pull the plunger back until the piston is about halfway up the applicator.
3. Squeeze the tube and fill the applicator up to the piston.

4. Unscrew the applicator form the tube and, after thoroughly washing your hands and the area around your vagina, insert it into the vagina while assuming a crouching or supine (laying down) position.
5. Push the plunger until all the gel has been expelled.
6. Extract the applicator. The applicators are for single use only and must be discarded after use.
7. In cases of severe dryness, it is advisable to expel a small amount of gel from the applicator before use, so that the tip is lubricated before being introduced into the vagina.

Frequency of Use
The frequency with which the product should be used depends on how dry the vaginal mucosa is. One application every three days for a period of thirty days is recommended, unless otherwise recommended by your health care provider.

Manufactured by
Fidia Farmaceutici S.p.A.
Via Ponte della Fabbrica 3/A
35031 Abano Terme (PD) -- Italy

HYALO GYN® BOX (Top panel only)

HYALO GYN®

Vaginal lubricating gel containing Hydeal-D®

Keep in a cool, dry place (T<40°C)
KEEP OUT OF REACH OF CHILDREN
If irritation occurs, discontinue use and see a doctor
This is not a spermicide and does not provide protection against pregnancy
Slippery, avoid spill
Safety and effectiveness of this product has not been evaluated in pregnant women

Manufactured by:
Fidia Farmaceutici, S.p.A.
Via Ponte dell Fabbrica 3/A
35031 Abano Terma (PD) - Italy

Distributed by:

Hossain, Mohammad A

From: Segal, Ph.D., Sharon A. [ssegal@morganlewis.com]
Sent: Thursday, May 06, 2010 5:00 PM
To: Hossain, Mohammad A
Subject: RE: K094039 -- labeling

(b) (4)

[redacted]

Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW | Washington, DC 20004
Direct: 202.739.5427 | Main: 202.739.3000 | Fax: 202.739.3001
ssegal@morganlewis.com | www.morganlewis.com
Assistant: Anne-Marie J. Drakes | 739-5747 | adrakes@morganlewis.com

---

From: Hossain, Mohammad A [mailto:Mohammad.Hossain@fda.hhs.gov]
Sent: Thursday, May 06, 2010 4:57 PM
To: Segal, Ph.D., Sharon A.
Subject: RE: K094039 -- labeling

(b) (4)

[redacted]

M. Ashraf Hossain, MBBS, PhD.
Staff Fellow
FDA/CDRH/ODE/DRARD/OGDB

41

5/6/2010

10903 New Hampshire Avenue W066-G110
Silver Spring, Maryland 20993-0002

Phone: 301-796-6536
Email mohammad.hossain@fda.hhs.gov

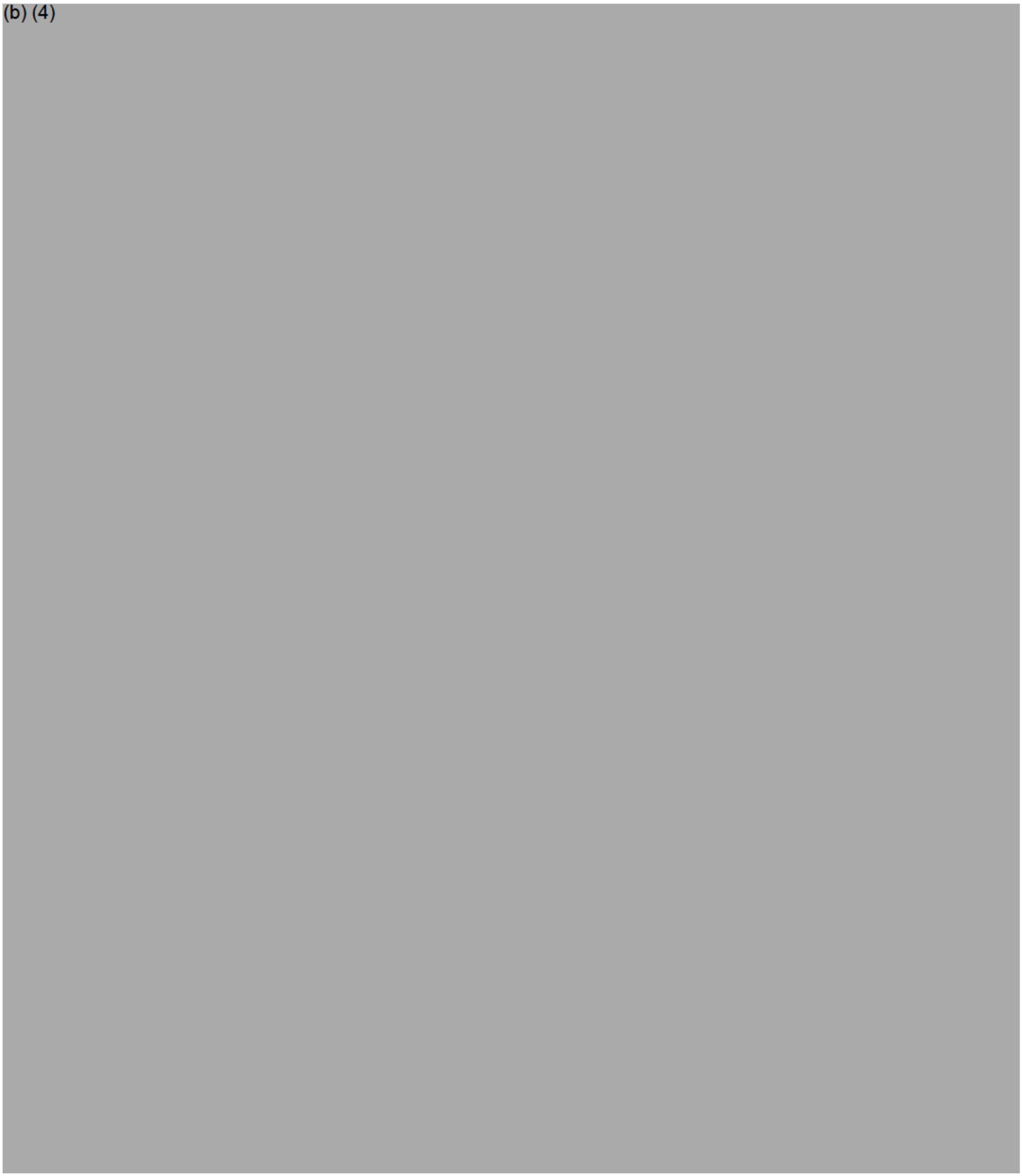
From: Segal, Ph.D., Sharon A. [mailto:ssegal@morganlewis.com]
Sent: Thursday, May 06, 2010 3:47 PM
To: Hossain, Mohammad A
Cc: Pollard, Colin M.; glocastro@fidiapharma.it
Subject: RE: K094039 -- 510k Summary

(b) (4)

[redacted]

Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW | Washington, DC 20004
Direct: 202.739.5427 | Main: 202.739.3000 | Fax: 202.739.3001
ssegal@morganlewis.com | www.morganlewis.com
Assistant: Anne-Marie J. Drakes | 739-5747 | adrakes@morganlewis.com

(b) (4)



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(b)(4) Biocompatibility Assessment

(b)(4) Biocompatibility Assessment

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(b)(4) Biocompatibility Assessment

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(b)(4) Biocompatibility Assessment

Hossain, Mohammad A

From: Segal, Ph.D., Sharon A. [ssegal@morganlewis.com]
Sent: Friday, April 23, 2010 12:39 PM
To: Hossain, Mohammad A
Cc: glocastro@fidiapharma.it
Subject: RE: K094039 -- Response to April 15 additional information request

(b) (4)

[redacted]

Thank you.

Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW | Washington, DC 20004
Direct: 202.739.5427 | Main: 202.739.3000 | Fax: 202.739.3001
ssegal@morganlewis.com | www.morganlewis.com
Assistant: Anne-Marie J. Drakes | 739-5747 | adrakes@morganlewis.com

[redacted]

From: Hossain, Mohammad A [mailto:Mohammad.Hossain@fda.hhs.gov]
Sent: Friday, April 23, 2010 12:12 PM
To: Segal, Ph.D., Sharon A.
Subject: RE: K094039 -- Response to April 15 additional information request

(b) (4)

[redacted]

M. Ashraf Hossain, MBBS, PhD.
Staff Fellow
FDA/CDRH/ODE/DRARD/OGDB

[redacted]

5/6/2010

31

10903 New Hampshire Avenue W066-G110
Silver Spring, Maryland 20993-0002

Phone: 301-796-6536
Email mohammad.hossain@fda.hhs.gov

From: Segal, Ph.D., Sharon A. [mailto:ssegal@morganlewis.com]
Sent: Friday, April 23, 2010 10:18 AM
To: Hossain, Mohammad A
Cc: Pollard, Colin M.; Bailey, Michael T; Ghosh, Molly; glocastro@fidiapharma.it
Subject: K094039 -- Response to April 15 additional information request

Dear Dr. Hossain,

(b) (4)

Best regards,
Sharon Segal

Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW | Washington, DC 20004
Direct: 202.739.5427 | Main: 202.739.3000 | Fax: 202.739.3001
ssegal@morganlewis.com | www.morganlewis.com
Assistant: Anne-Marie J. Drakes | 739-5747 | adrakes@morganlewis.com

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you have received this communication in error, please notify us immediately by e-mail and delete the original message.

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INTERACTIVE REVIEW MEMO

Type of Interaction:	Teleconference
Date:	April 19, 2010
Reviewer:	M. Ashraf Hossain, MBBS, PhD. Staff Fellow, OGDB
RE: K094039_S1	Hyalo Gyn Gel
510(k)-holder:	Fidia Farmaceutici, Italy (Fidia) C/O Morgan ,Lewis & Bockius, LLP Washington, DC
Participants:	M. Ashraf Hossain, Michael Bailey, Molly Ghosh and Colin Pollard (from the FDA) and Sharon Segal from Morgan-Lewis.

(b) (4)

[redacted]

(b) (4)

INTERACTIVE REVIEW MEMO

Type of Interaction:	Teleconference
Date:	April 22, 2010
Reviewer:	M. Ashraf Hossain, MBBS, PhD. Staff Fellow, OGDB
RE: K094039_S1	Hyalo Gyn Gel
510(k)-holder:	Fidia Farmaceutici, Italy (Fidia) C/O Morgan ,Lewis & Bockius, LLP Washington, DC
Participants:	M. Ashraf Hossain, Michael Bailey, and Molly Ghosh (from the FDA); Abrecht Poth and (b) (4)) and Sharon Segal from Morgan-Lewis.

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[redacted]

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(b) (4)

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

COVER SHEET MEMORANDUM

From: Reviewer Name M. Ashraf Hossain

Subject: 510(k) Number K094039

To: The Record

Please list CTS decision code A I

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

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 N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
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)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, 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.)			✓

7/2/07

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 884.5300 **Class*** II **Product Code** NUC

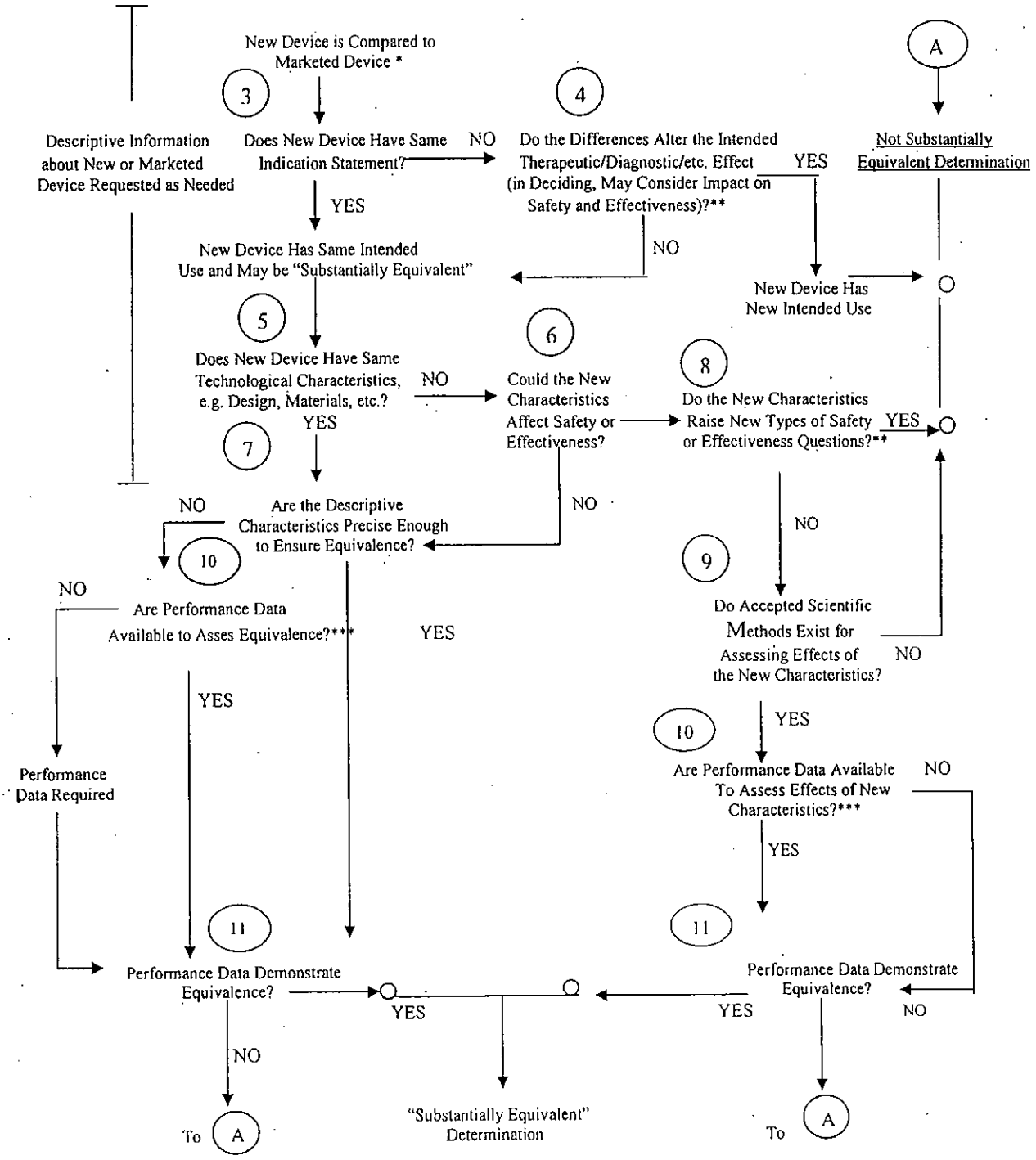
(*If unclassified, see 510(k) Staff)

Additional Product Codes: H.I.S

Review: Colleen M Pollard (Branch Chief) OGDB (Branch Code) 2/26/10 (Date)

Final Review: _____ (Division Director) _____ (Date)

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



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

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K094039 Hyalo Gyn Personal Lubricant

To: The Record Office: ODE
Division: DRARD/OGDB

From: M. Ashraf Hossain, MBBS, PhD.; Staff Fellow

510(k) Holder/ Manufacturer: Fidia Farmaceutici S.p.A.
Via Ponte della Fabbrica 3/A
Abano Terme,
PADOVA ITALY 35031 IT
Attn: Giusi Locastro, Regulatory Affairs

Device Name: Hyalo Gyn® Personal Lubricant

Contact: Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Avenue
Washington DC 20004

Phone: 202-739-5427
Fax: 202-739-3001
Email: ssegal@morganlewis.com

I. Purpose and Submission Summary:

Fidia Farmaceutici S.p.A. (Fidia) of Padova, Italy, submitted this original traditional 510(k) to introduce Hyalo Gyn® gel into interstate commerce. Fidia states that this personal lubricant is compatible with condoms.

(b) (4)

II. Administrative Requirements

(b) (4)

[redacted]

(b) (4)

[redacted]

IV. Indications for Use

(b) (4)

[redacted]

(b) (4)

V. Predicate Device Comparison

Fidia states that the subject device Hyalo Gyn® *gel* has similar intended use as well as technological characteristics to the predicates, identified in this submission as:

- K072647, Glycerine- and paraben-free Astroglide (manufactured by Biofilm), and
- K0673251, Hyalomatrix PA (manufactured by Fidia Advanced Polymers S.r.l.).

(b) (4)

	Subject Device Hyalo Gyn®	Predicate Hyalomatrix PA	Predicate G&P-Free Astroglide
	K094039	K073251	K072647
Manufacturer	(b) (4)	Fidia Advanced Polymers	BioFilm, Inc.
Intended Use	(b) (4)	Wound dressing pad	Personal lubricant
Condom compatibility	(b)	N/A	Yes
Availability	(b) (4)	Rx	OTC
Appearance	(b) (4)	Pads with silicone	Clear, highly viscous
Viscosity	(b) (4)	N/A	Unknown
pH	(b)	4.0-6.0	3.5-6.0
Flavor	(b	No	No
Container material	(b) (4)	Unknown	HDPE Plastic (?)
Water solubility	(b)	N/A	Yes
Chemical ingredients	(b) (4) 1(b) % (b) (4) (b) (4) (b) (4) (b) (4) (b) (4)	Hydeal-D Benzyl ester of hyaluronic acid HYAFF11 ≥88%	Purified Water 59.6% Butylene glycol 20.0% Xylitol (60%) 10.0% Propylene glycol 10.0% Polyquaternium-15 0.4%
Microbial Tests	(b)	Passed	Passed
Sterility status	(b) (4)	Sterile	Non-sterile

Per 880.5300, lubricant, patient, vaginal, latex compatible device is intended as a moisturizer for vaginal dryness and personal lubrication of the vaginal entry to enhance condom use and to

111

facilitate ease and comfort during intimate sexual activity. (b) (4)

(b) (4)

VI. Packaging and Labeling

(b) (4)

(b) (4)

(b) (4)

(b) (4)

[redacted]

VII. Stability/Shelf Life

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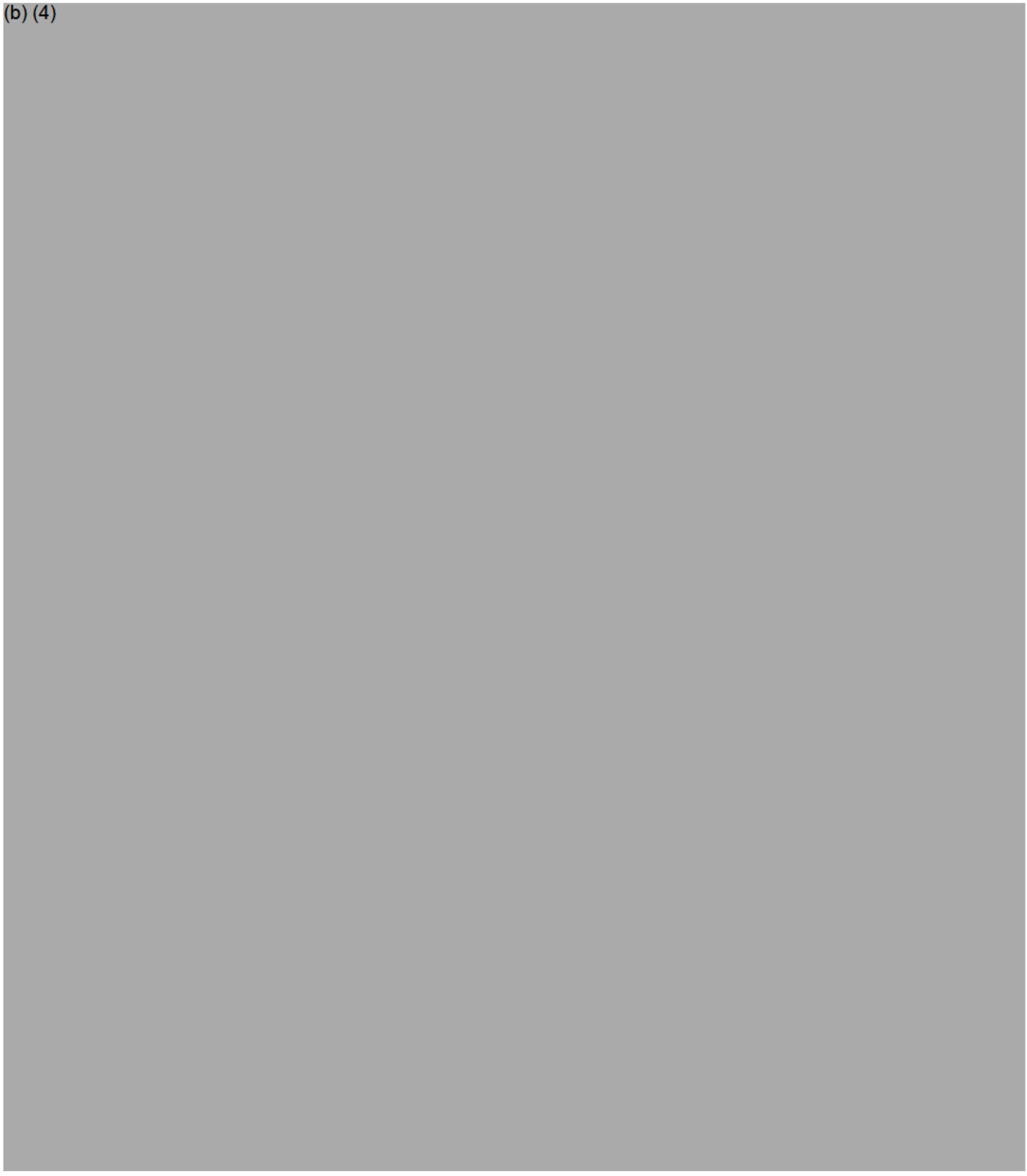
[redacted]

(b) (4)

VIII. Material Safety (Toxicity Testing)

(b) (4)

(b) (4)



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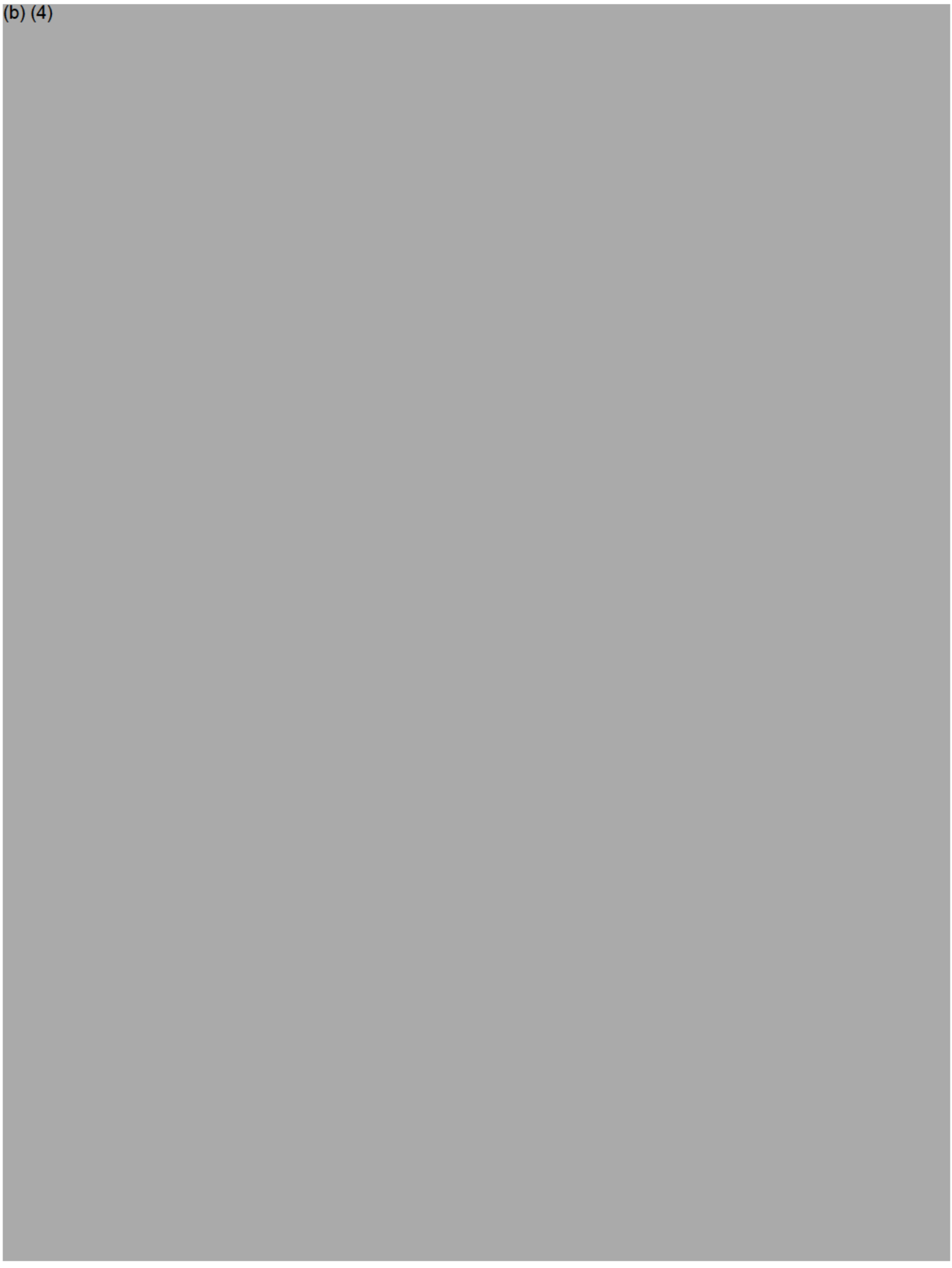

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IX. Performance Testing

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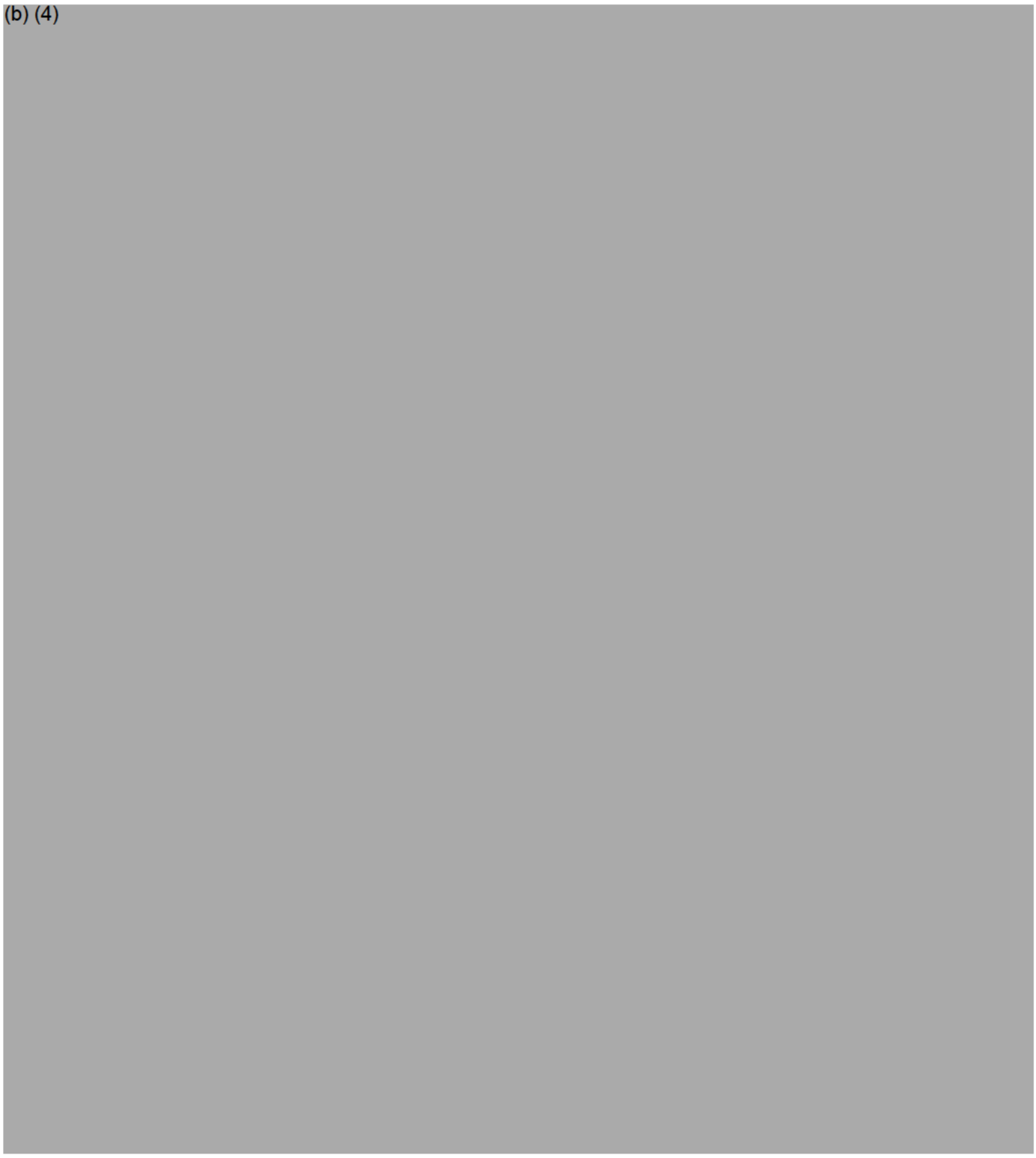

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Clinical Performance

(b) (4)

(b) (4)

[redacted]

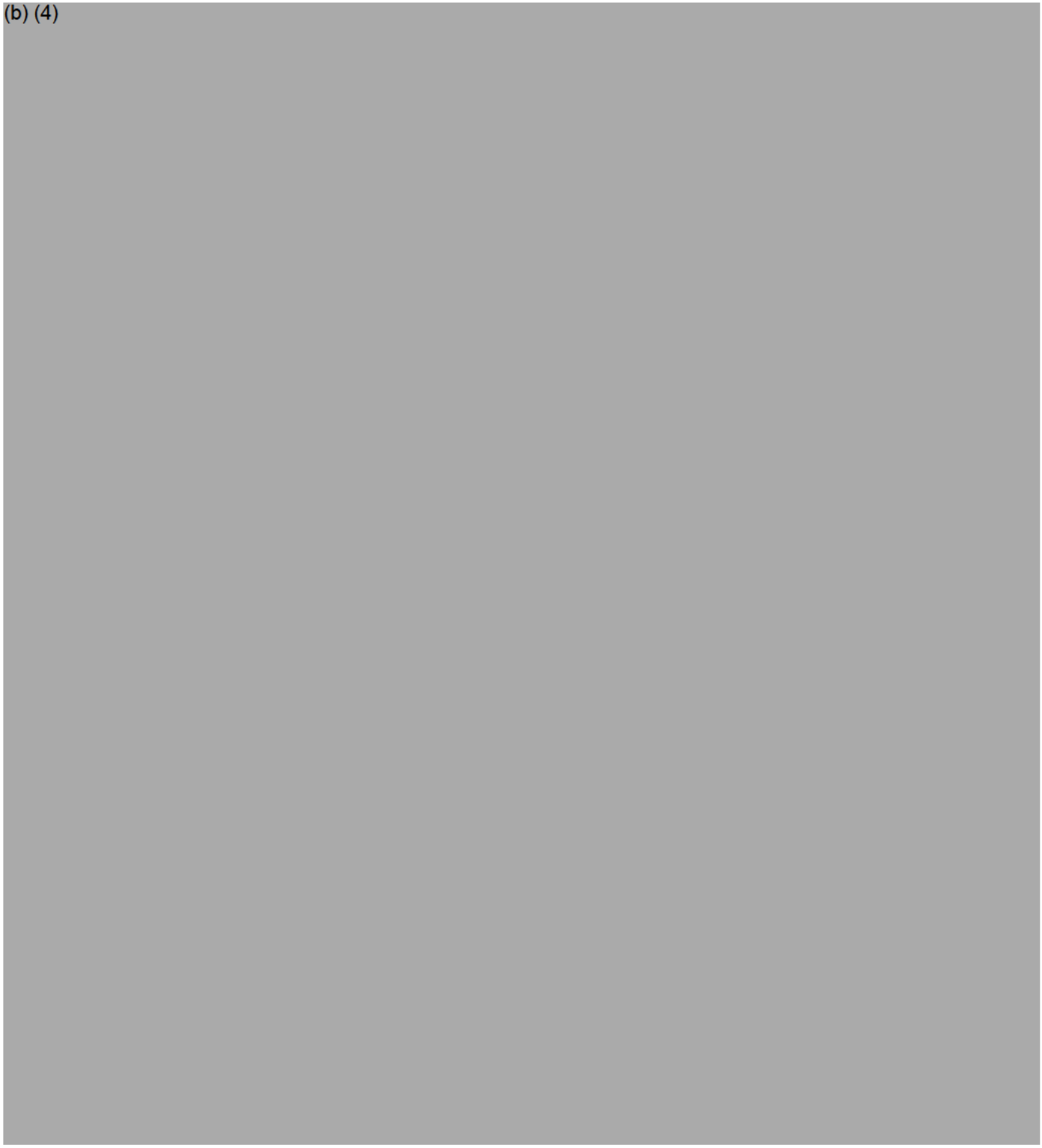
X. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	✓		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	✓		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		✓	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?		✓	If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

We will address the "NO" responses [to Q# 5 and 8] issues at the time of a SE or NSE decision.

XI. Deficiencies

(b) (4)



Biocompatibility testing

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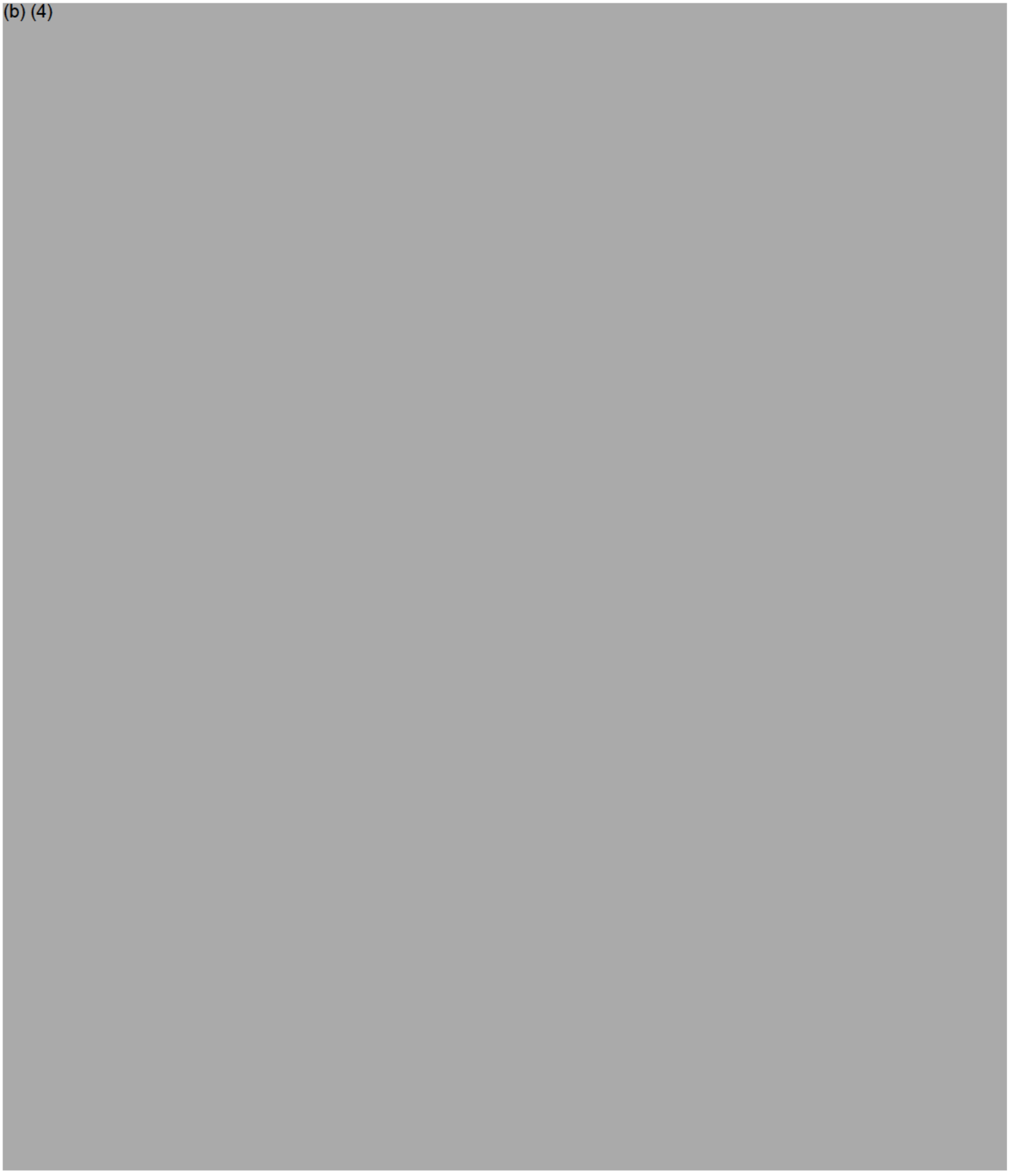

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Condom Compatibility

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Shelf-life

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Labeling

(b) (4)

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[redacted]

Administrative Issue

(b) (4)

[redacted]

XII. Contact History

(b) (4)

[redacted]

XIII. Recommendation

Place this document on hold, pending response to my letter requesting additional information.

M. Ashraf Hossain 2/26/10
Reviewer

2/26/10
Date

Colin M. Pollard
Chief, Obstetrics and Gynecology Devices Branch

2/26/10
Date

Appendix 1. Table. Performance of Hyalo Gyn lubricant (Condom Compatibility)

(b) (4)

Public Health Service

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandums

Date: February 22, 2010

From: Michael T. Bailey, Ph.D.
Ob/Gyn Devices Branch, DRARD (HFZ-470)

To: M. Ashraf Hossain
DRARD/OGDB

Subject: K094039 – Fidia Hyalogyn Lubricant

(b) (4)

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ASHRAF - ADD OUTLINE HERE

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_____ Dated: _____

Michael T. Bailey, Ph.D.
Prepared: 2/22/10 MTB

Updated 2/01/10

OFFICE OF DEVICE EVALUATION
CLINICAL REVIEW

From: Jill Brown
OGDB, DRARD, ODE

To: M. Ashraf Hossain, Reviewer Requesting Consult
OGDB, DRARD, ODE

CC: Colin Pollard, Branch Chief

Subject: K094039
HYALO GYN®
Fidia Farmaceutici

Date: January 29, 2010; revised February 1, 2010

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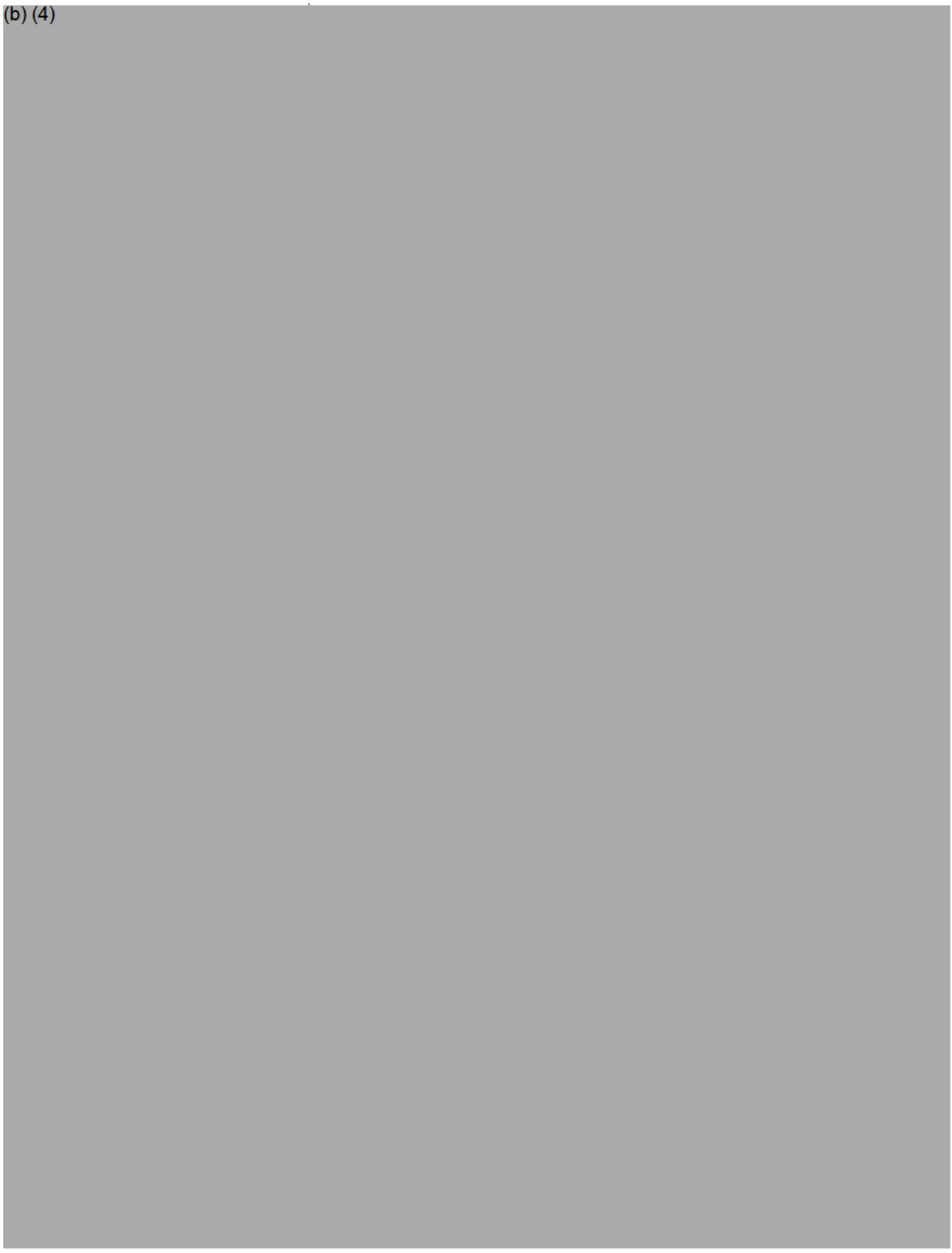

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REVIEW CONCLUSIONS/DISCUSSION

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Labeling comments

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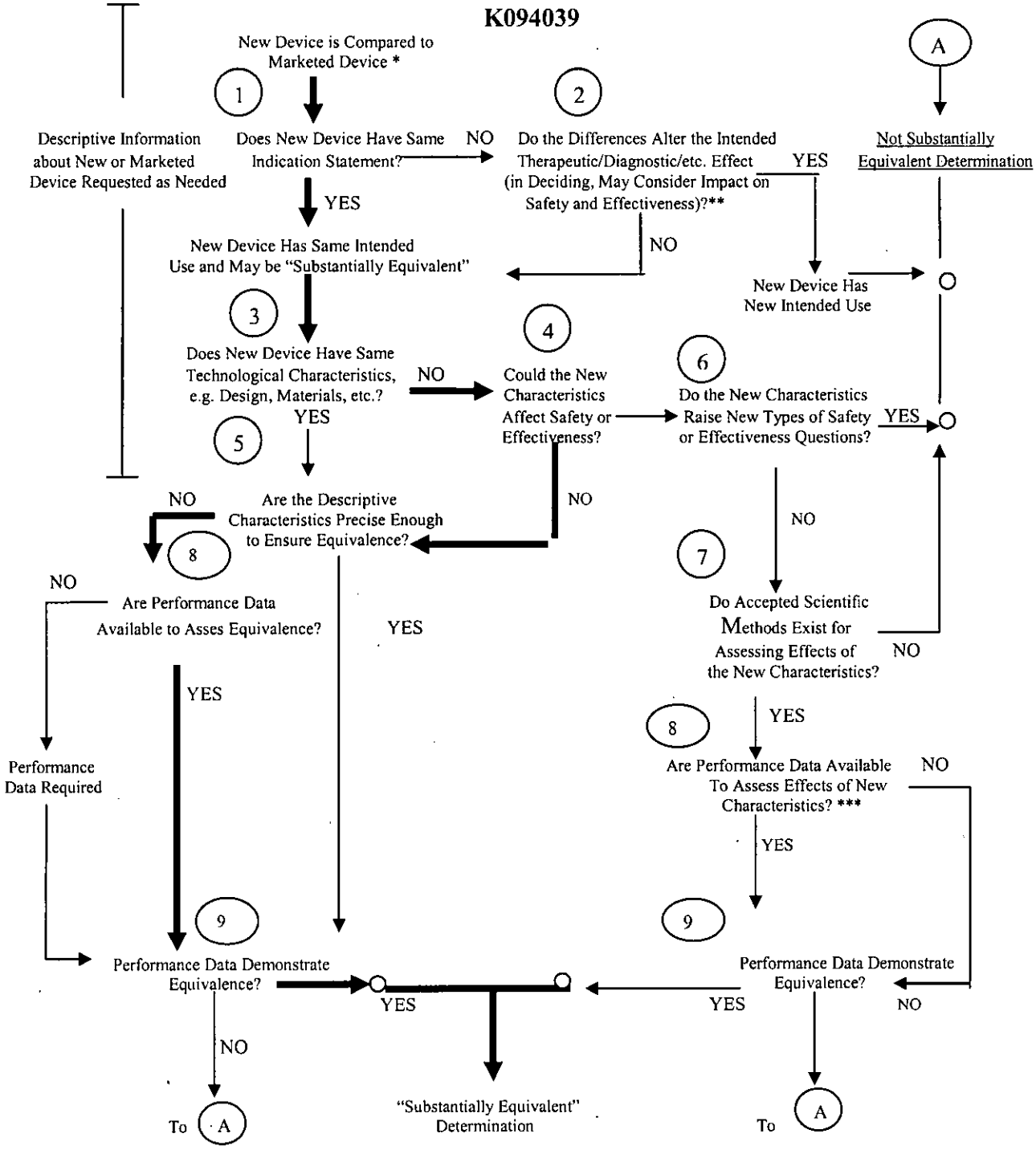
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS
K094039



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

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 07, 2010

FIDIA FARMACEUTICI SPA
VIA PONTE DELLA FABBRICA 3/A
ABANO TERME, PADUA (PD)
ITALY 35031
ATTN: GIUSI LOCASTRO

510k Number: K094039

Product: HYALO GYN

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. Pleaseremember 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

90

K094039(5)

Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004
Tel: 202.739.3000
Fax: 202.739.3001
www.morganlewis.com

Morgan Lewis
COUNSELORS AT LAW

FDA CDRH DMC

APR 07 2010

Received

K-38

April 7, 2010

BY HAND DELIVERY

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

Re: K094039
Trade Name: HYALO GYN® Vaginal Moisturizer and Lubricant
Response to February 26, 2010 Additional Information Request

Dear Mr. Pollard:

On behalf of Fidia Farmaceutici S.p.A. ("Fidia"), Morgan Lewis submits the attached response to the subject Additional Information request for K094039. Each of the information requests is repeated in bold, italicized text for ease of review, followed by Fidia's response.

Please contact me at 202.739.5427 or by e-mail at ssegal@morganlewis.com if there are any questions or additional information is required.

Sincerely,

Sharon A. Segal, Ph.D.
Director of Regulatory Science

Attachments

c: Dr. Giusi LoCastro

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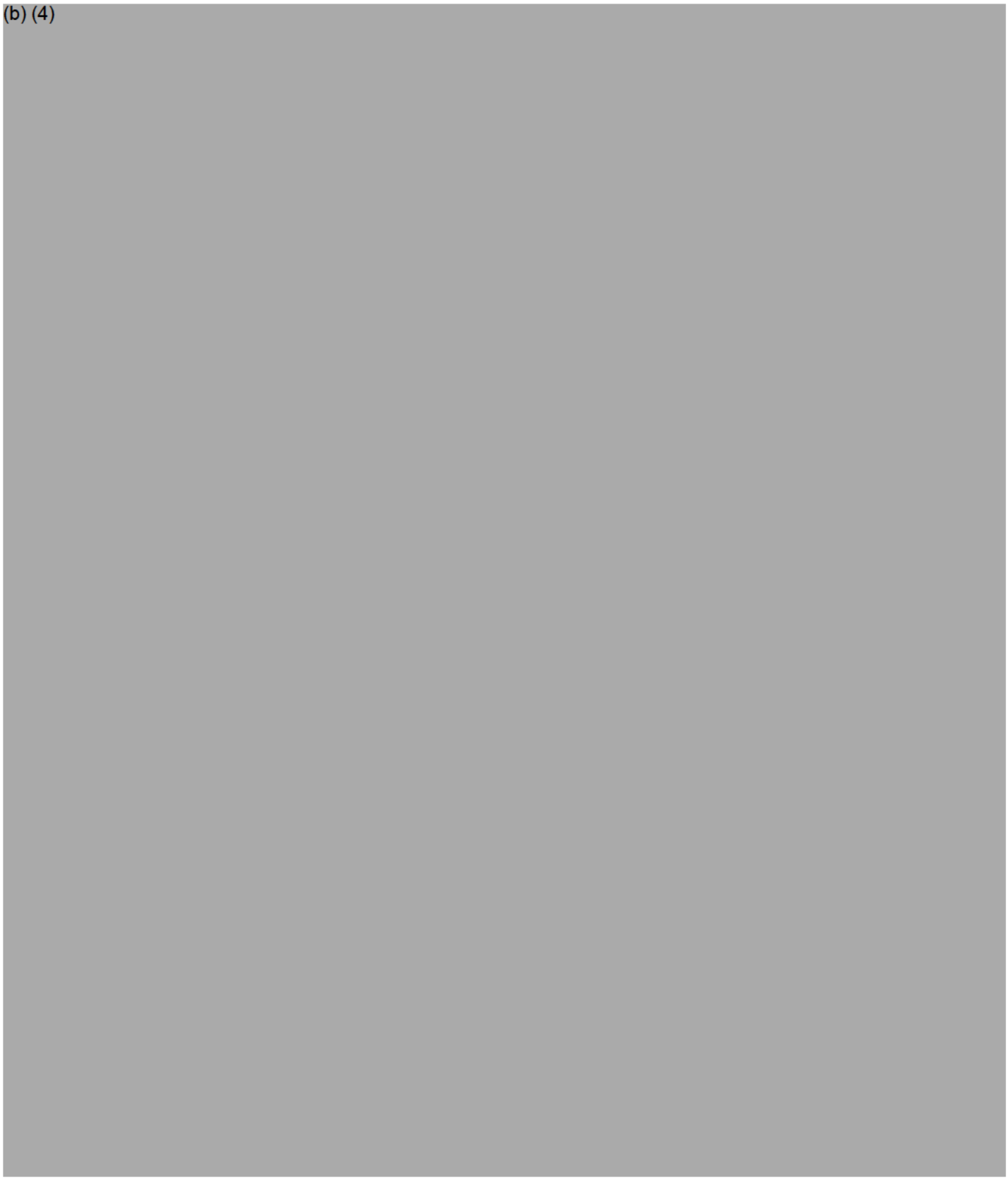

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Technological Characteristics:

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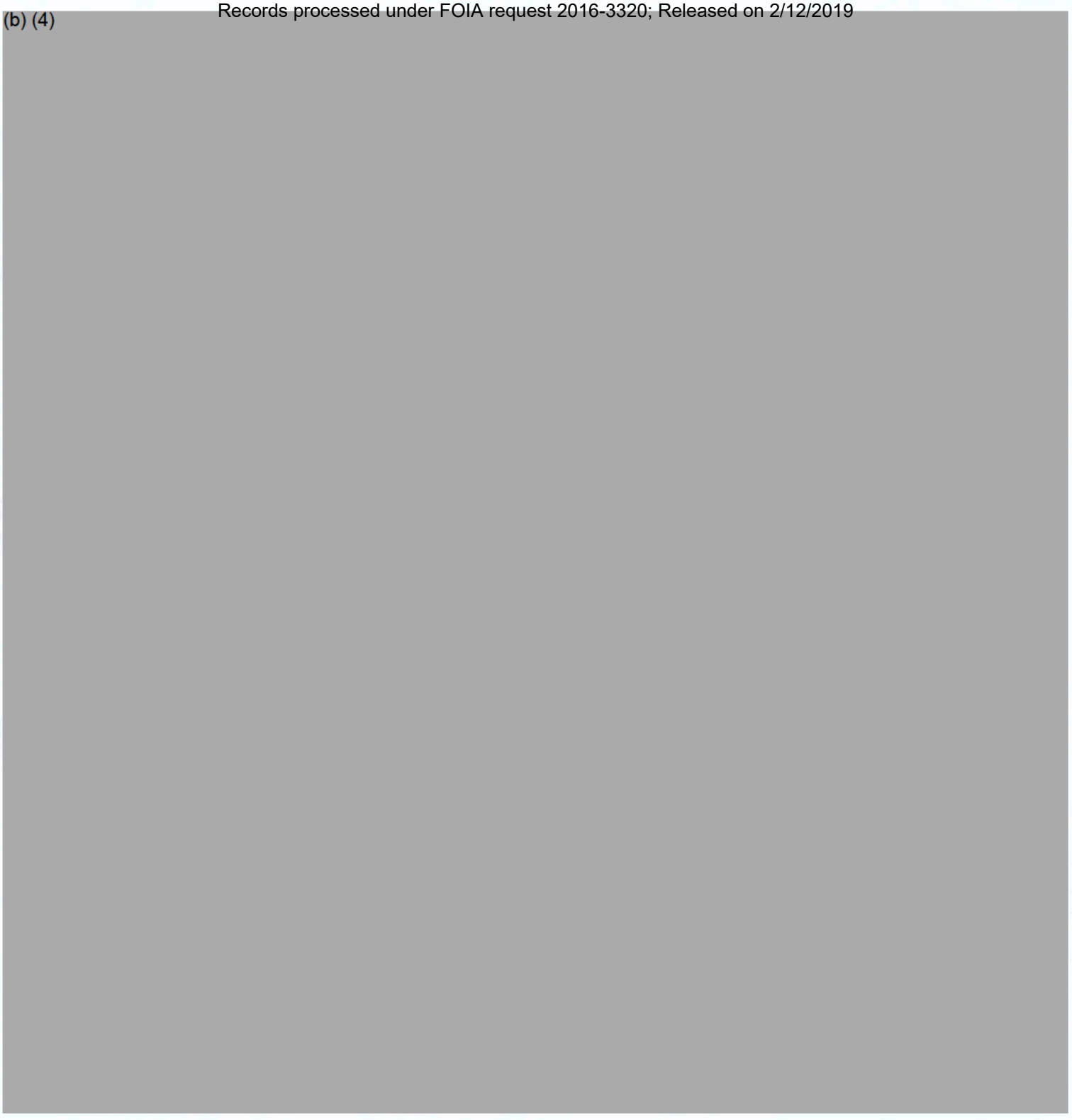

Table 6-1: Substantial Equivalence Comparison Table

	New Device	Predicate Device
510(k) #	K094039	K072647
Company	Fidia Farmaceutici, S.p.A.	Biofilm, Inc.
Name	HYALO GYN®	Glycerin & Paraben Free Astroglide®
Intended Use	(b) (4)	Glycerin and Paraben Free Astroglide® is a personal lubricant, for penile, anal, or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with latex condoms.
Materials		• Water • Butylene glycol • Xylitol
Visual Appearance		Clear, non-greasy, high viscosity liquid
Water Solubility		Soluble
Latex condom compatibility		Compatible
Sterile		No

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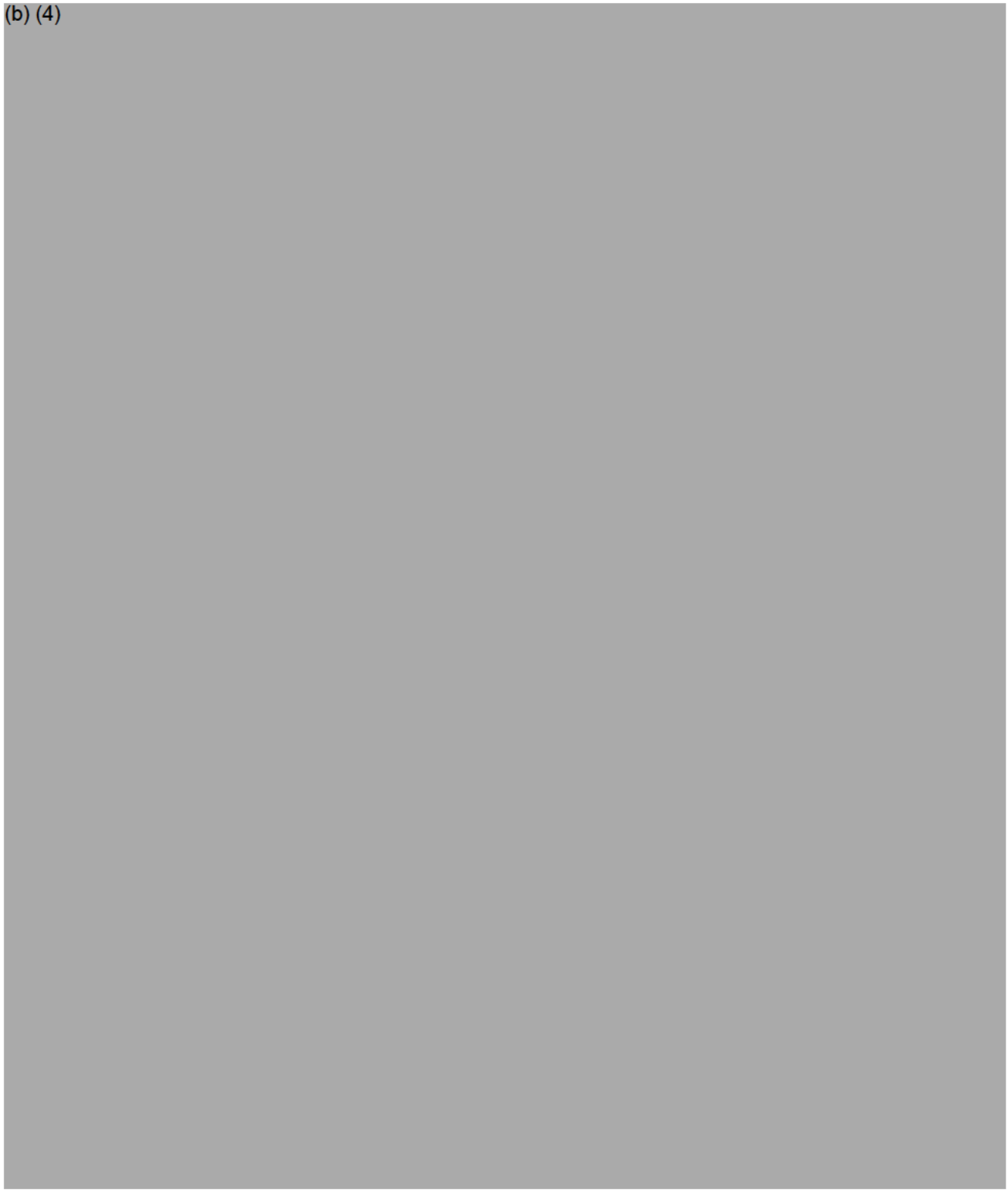

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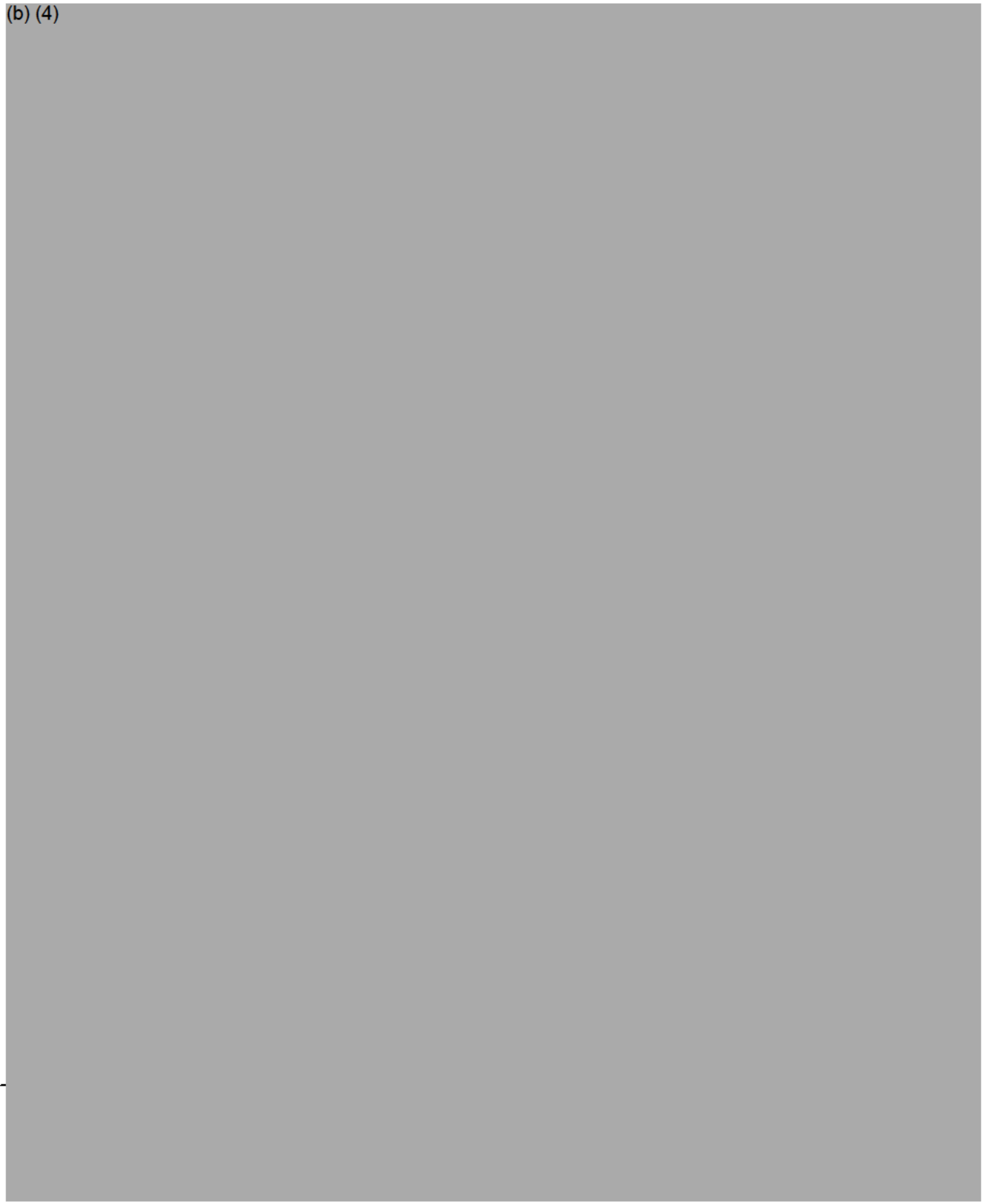

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ATTACHMENT 1
Pritchard et al. 1996

ELSEVIER

International Journal of Pharmaceutics 129 (1996) 137–145

international journal of pharmaceutics

Evaluation of the bioadhesive properties of hyaluronan derivatives: detachment weight and mucociliary transport rate studies.

Kelly Pritchard[a], Alison B. Lansley[a,*], Gary P. Martin[a], Mark Helliwell[a], Christopher Marriott[a], Luca M. Benedetti[b]

[a] *Department of Pharmacy, King's College London, Manresa Road, London SW3 6LX, UK*
[b] *Fidia Advanced Biopolymers, Via Ponte della Fabbrica 3/a, 35031 Abano Terme (PD), Italy*

Received 4 June 1995; accepted 23 August 1995

Abstract

Hyaluronan of various molecular weights, and microspheres made from several of its esters, were assessed for adhesiveness in vitro by means of detachment weight and mucociliary transport rate. Microspheres made from esters of alginic acid and gellan gum were also evaluated. The results were compared with those obtained from Carbopol 974 which was used as a positive control. Hyaluronan and its autocross-linked esters displayed comparable adhesion to Carbopol in both studies. All microsphere preparations were less adhesive than Carbopol ($p < 0.05$, Mann-Whitney U-test) when tested for detachment weight (using mucosal epithelium) and mucociliary transport rate. Adhesion to a mucus gel was similar for most preparations. Hyaluronan has been shown to possess excellent adhesion in vitro. Although formulation of hyaluronan into microspheres tends to reduce its inherent adhesive properties, the microspheres formed displayed significantly decreased mucociliary clearance. The inclusion of drug into such a biodegradable and biocompatible dosage form is an attractive prospect for transmucosal delivery.

Keywords: Bioadhesion; Carbopol; Detachment force; Epithelia; Hyaluronan; Microsphere; Mucoadhesion; Mucociliary transport rate; Mucus

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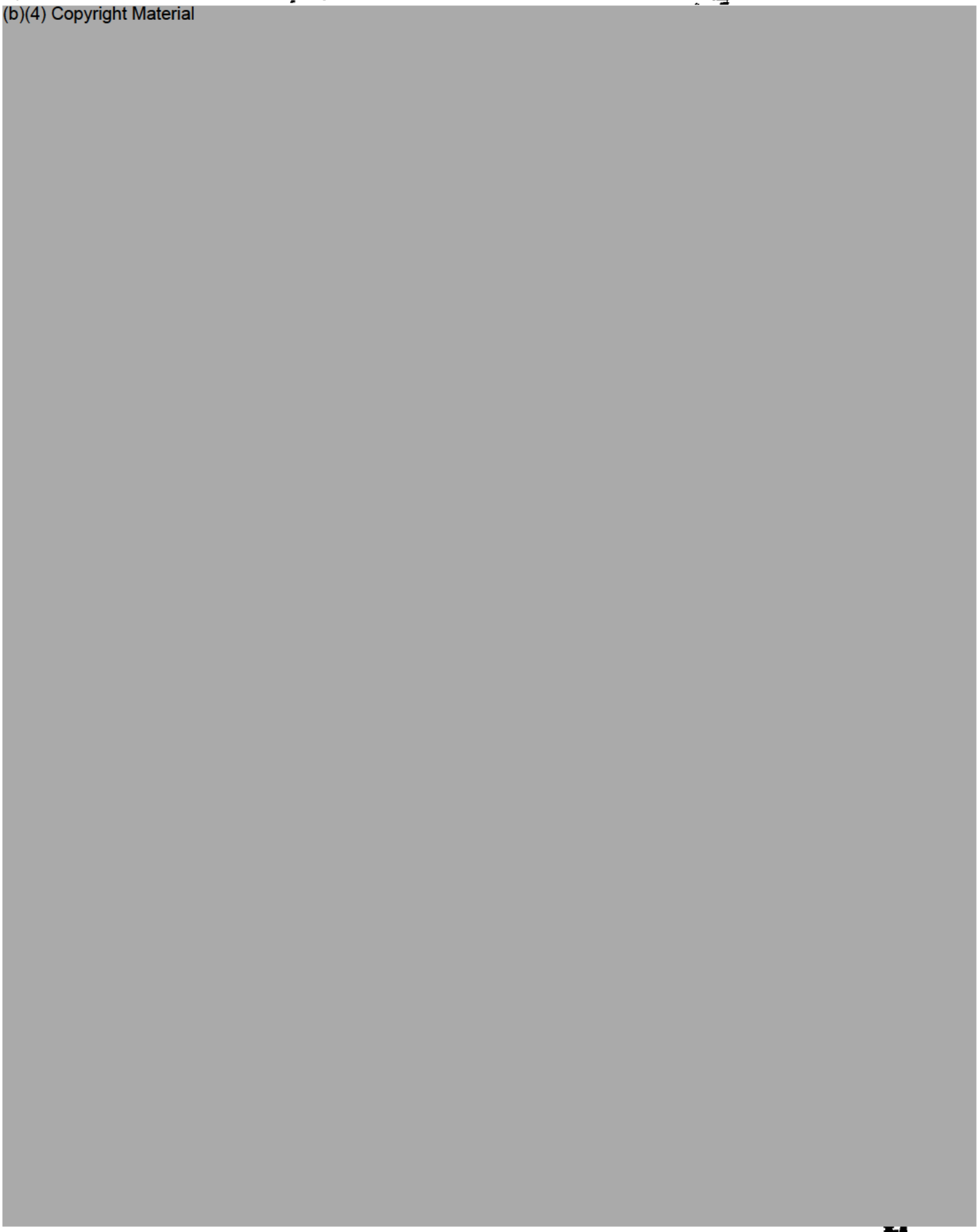

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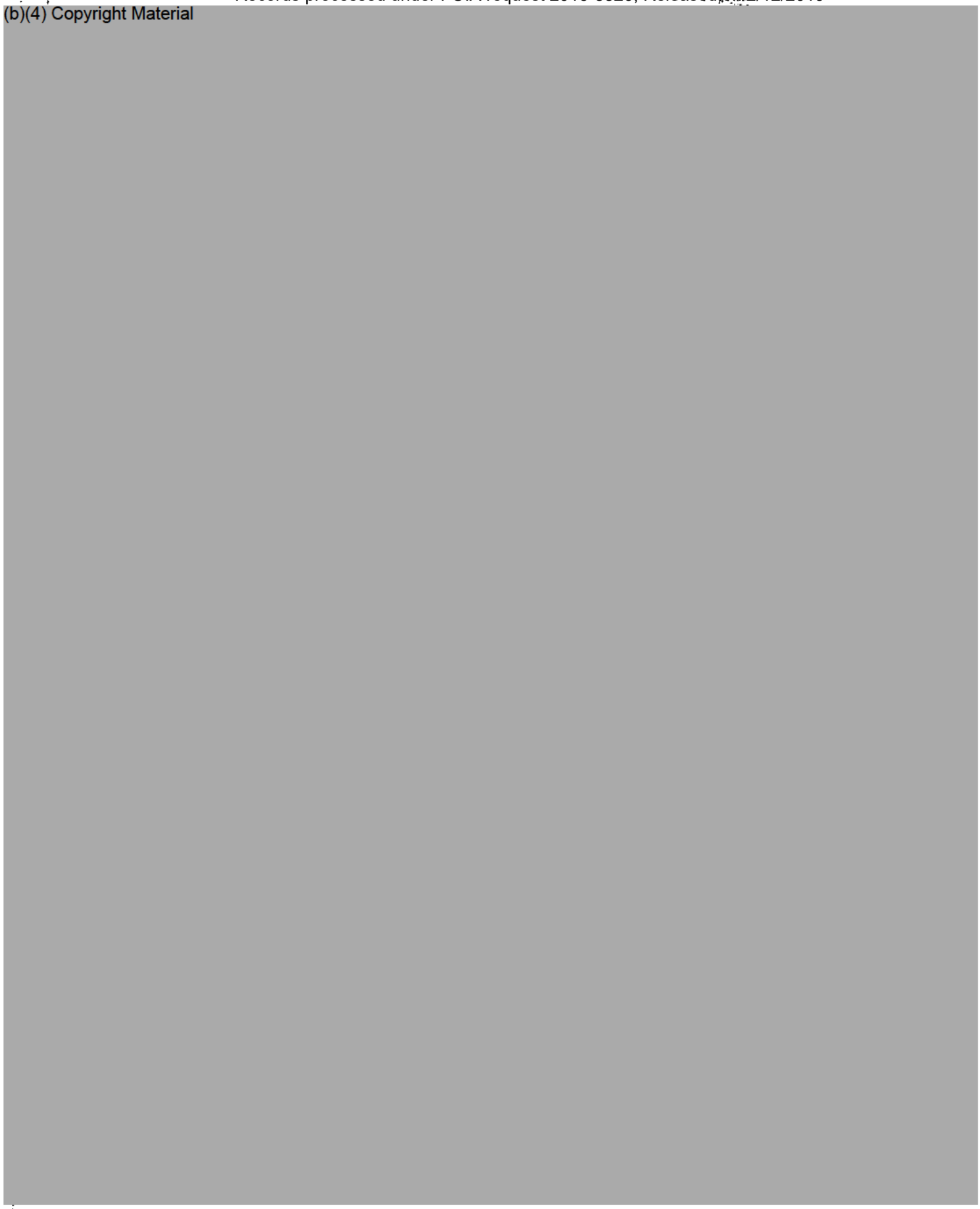

ATTACHMENT 2
Robinson and Bologna 1994

Journal of Controlled Release, 28 (1994) 87–94

COREL 00925

SSDI 0168-3659(93)E0110-2

Vaginal and reproductive system treatments using a bioadhesive polymer

Joseph R. Robinson[a,*] and William J. Bologna[b]

[a]School of Pharmacy, University of Wisconsin, 425 N Charter Street, Madison, WI 53706, USA
[b]Columbia Research Laboratories-Paris, 92, Avenue D'Lena, Paris 75116, France

(Received 20 May 1993; accepted in revised form 22 July 1993)

Polycarbophil, a lightly cross-linked polyacrylic acid, can remain on vaginal tissue for 3–4 days and hence serve as a platform for drug delivery. Intrinsic properties of the polymer such as acidic pKa and polyelectrolyte nature of the ionized form of the polymer can alter the local pH and hydration level of the tissue to effectively treat local pathologies. Clinical assessment of local tissue pH, in postmenopausal women, shows a reduction in pH from about 6 to 4 and maintenance of this acidic pH for about 3–4 days after the last dose. This acidic pH is an unfavorable environment for pathogens. In addition a low viscosity gel of the polymer is an effective treating agent for dry vagina, a common condition of postmenopausal females and those female cancer patients on estrogen blockers. Hydration of the vaginal tissue occurs through an increase in vaginal blood flow as determined by a laser Doppler study. In addition, the polymer appears to be an effective delivery system for the spermicidal/antiviral agent nonoxynol-9. By virtue of its ability to adhere to vaginal tissue while retaining nonoxynol-9 in its gel structure, it is an excellent extended effect spermicide. Moreover, the ability of the polymer to attach to lymphocytes, while carrying nonoxynol-9, makes it a targeted drug delivery system and useful as an AIDS prophylaxis, as well as a treating agent for other sexually transmitted diseases. Finally, employing the polymer gel with natural progesterone allows extended vaginal delivery of the drug to achieve the clinical endpoint of a fully secretory endometrium with low serum levels of the drug. The lower serum drug levels translate into reduced side effects.

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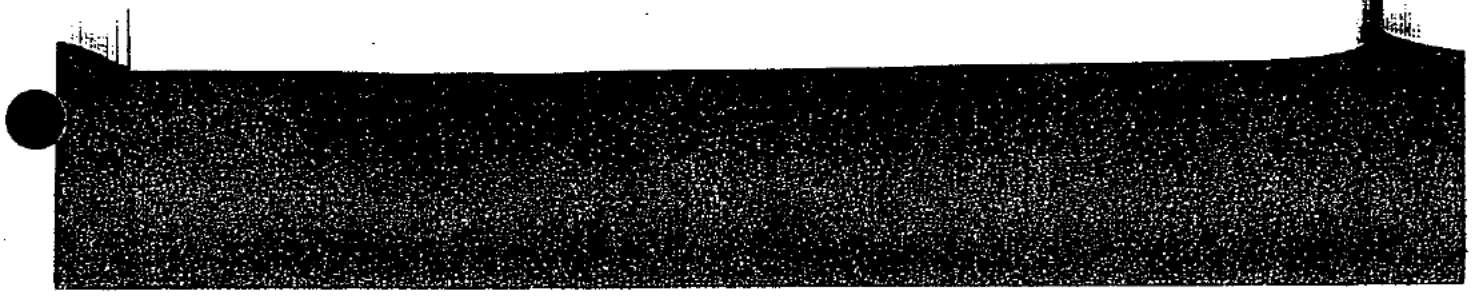

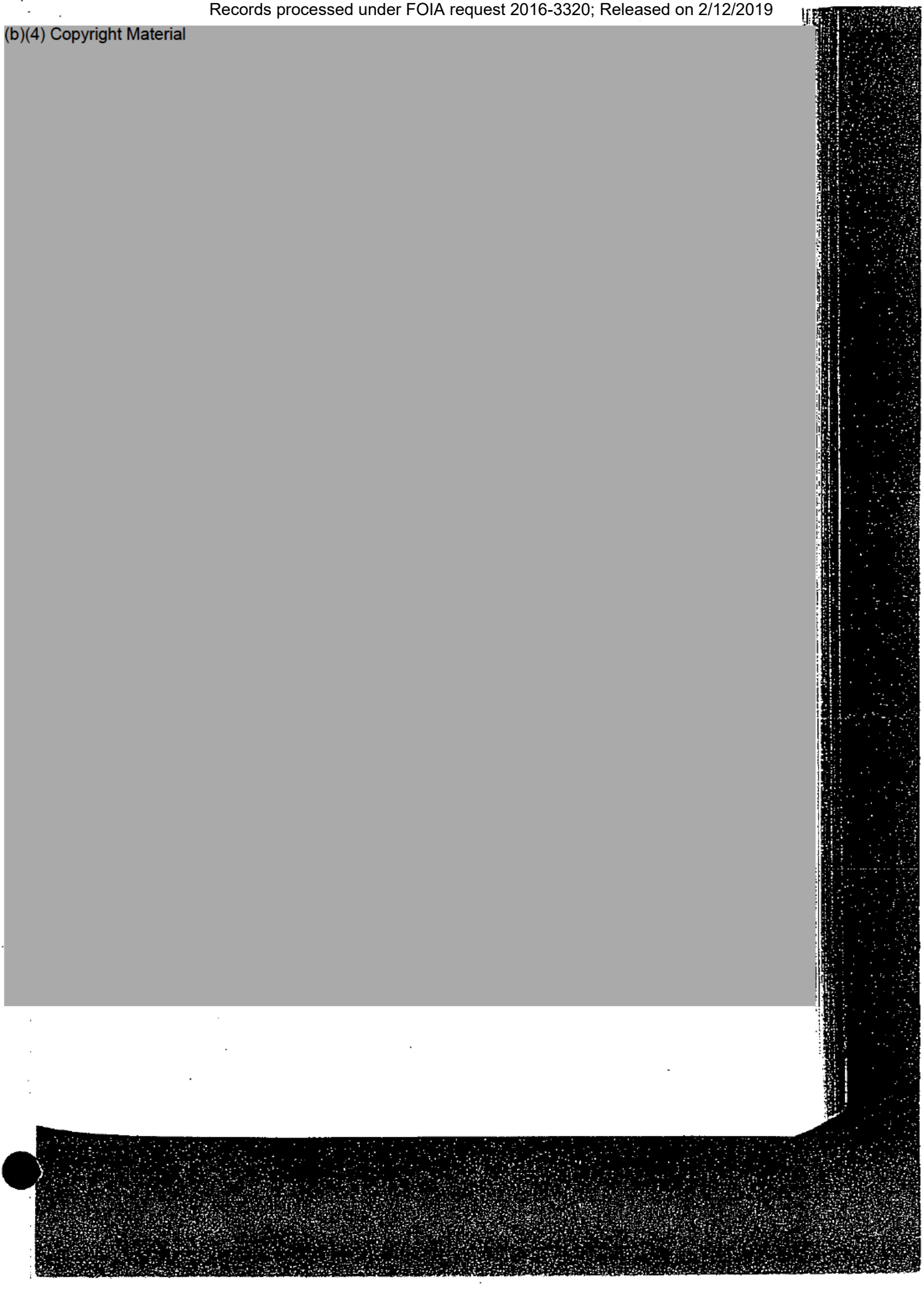

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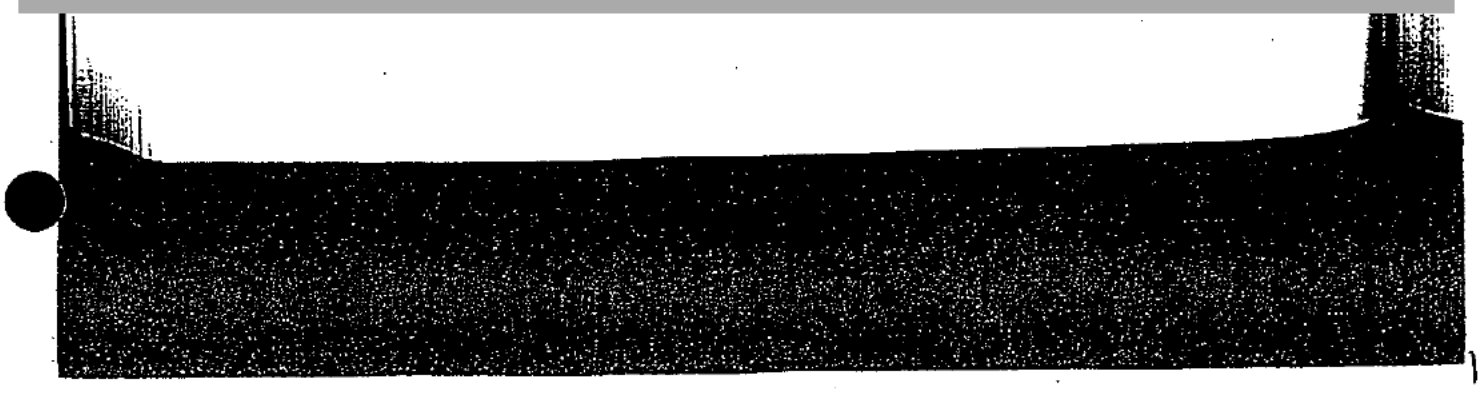

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ATTACHMENT 3
Borzacchiello and Ambrosio 2001

J. Biomater. Sci. Polymer Edn. Vol. 12, No. 3, pp. 307–316 (2001)

Network formation of low molecular weight hyaluronic acid derivatives

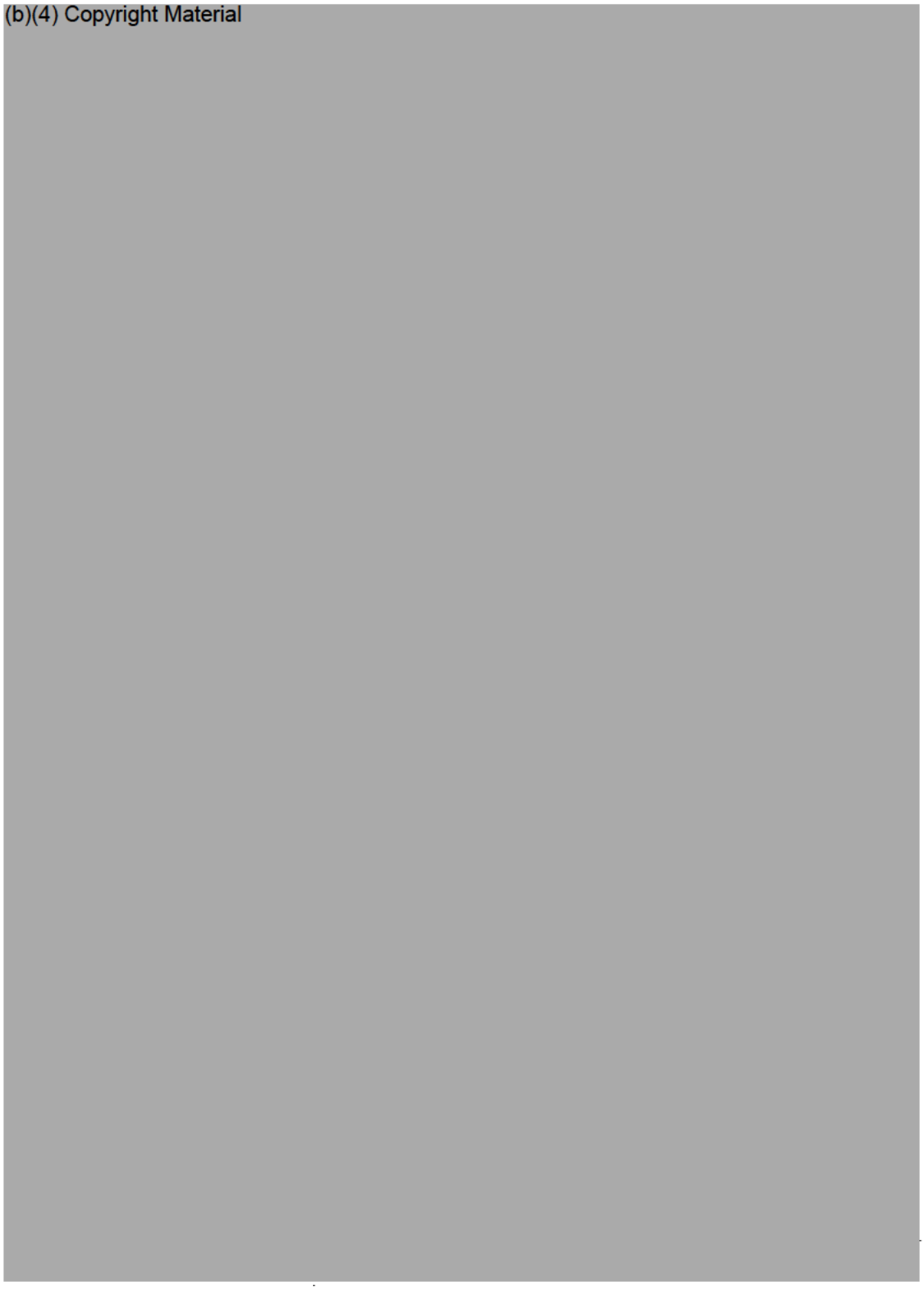
A. BORZACCHIELLO* and L. AMBROSIO

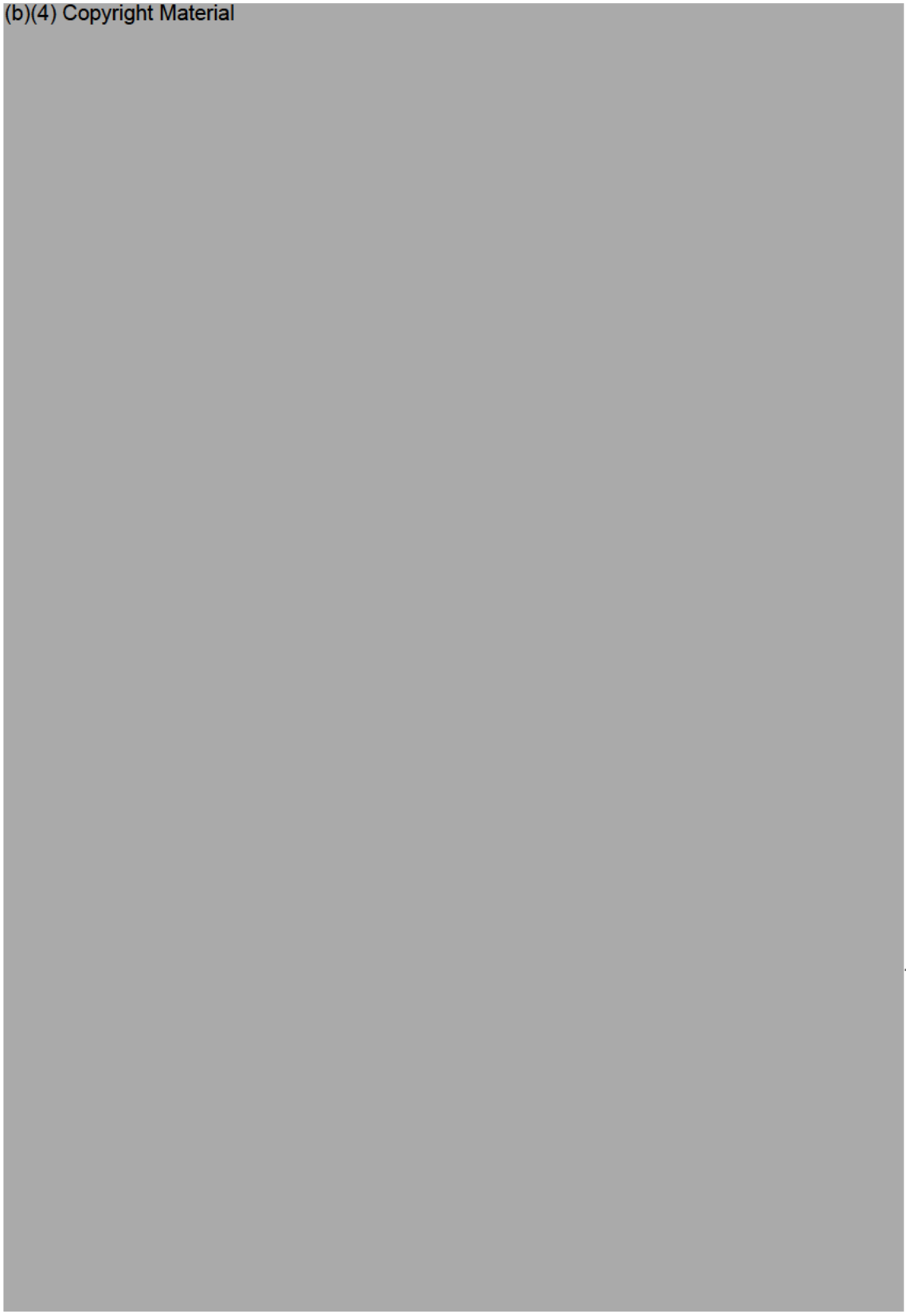
Institute of Composite Materials Technology-CNR, Interdisciplinary Research Center in Biomaterials (CRIB), University of Naples 'Federico II', P.le Tecchio 80, 80125, Naples, Italy

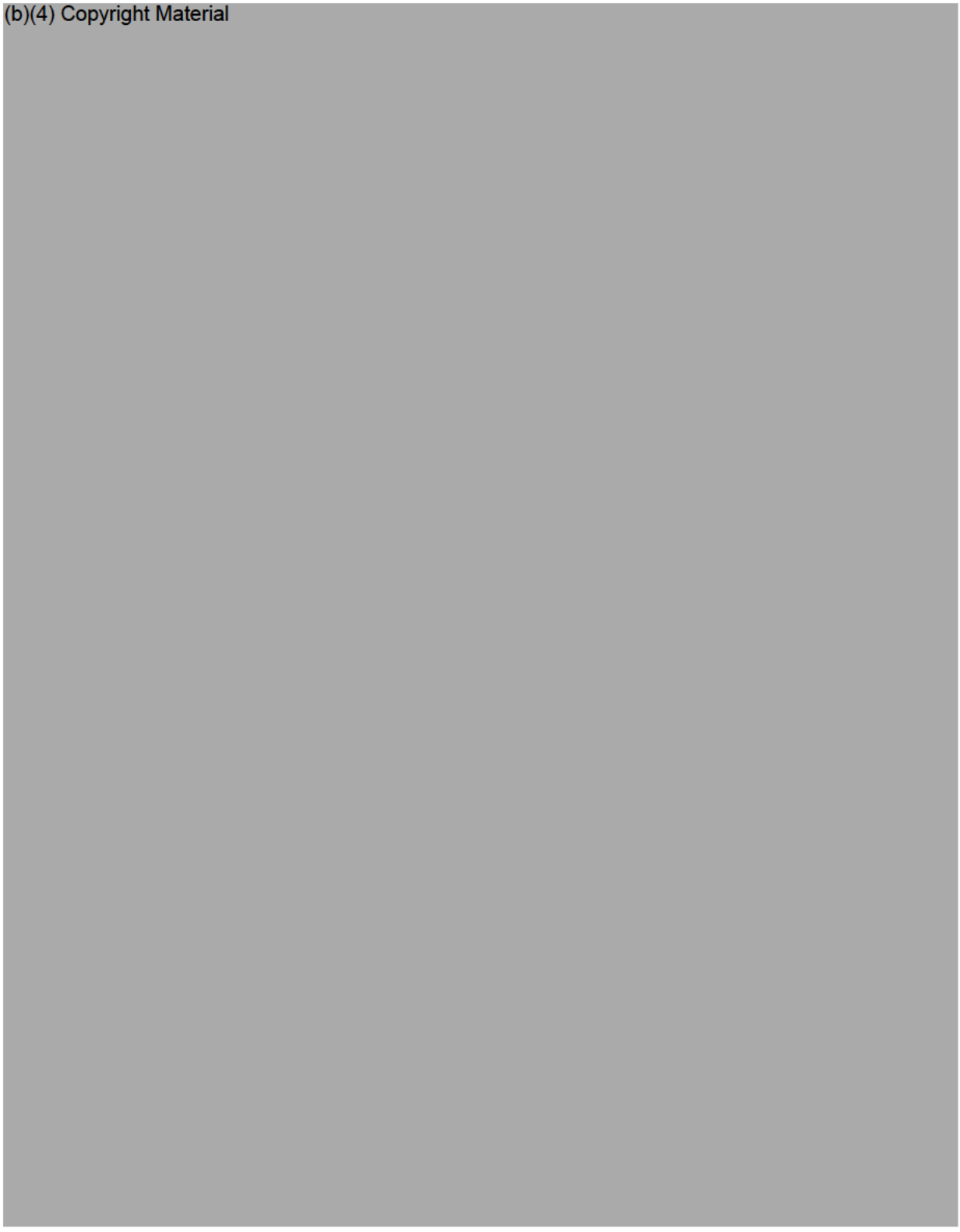
Received 5 June 2000; accepted 24 November 2000

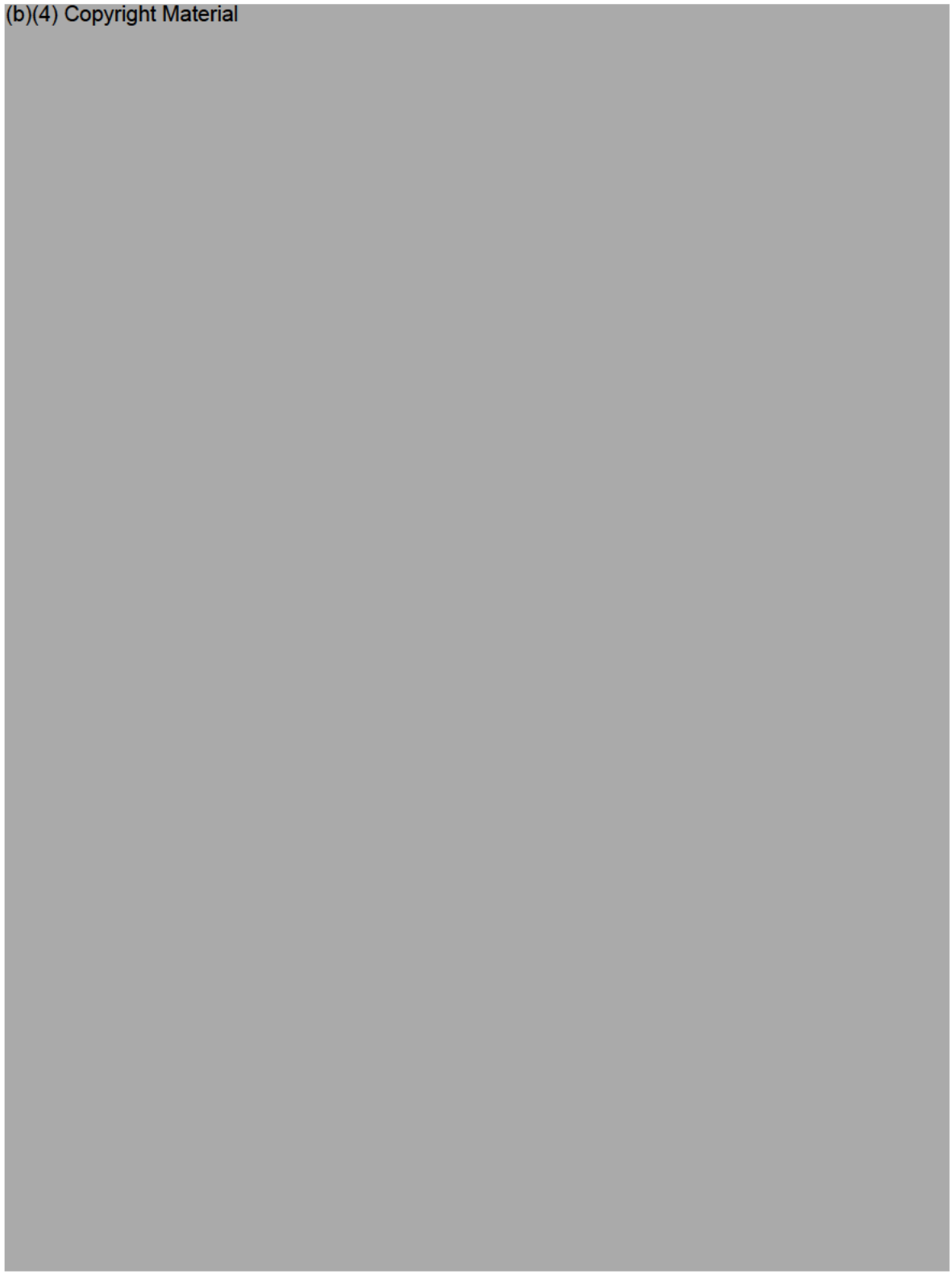
Abstract—The oscillatory and steady shear rheological properties of the benzyl esters of hyaluronic acid (HA), partially esterified (Hyaff11p50), at low molecular weight (150 kDa) were evaluated and compared to the properties of HA at the same molecular weight. At concentrations up to 40 mg cm^{-3} both Hyaff11p50 solutions and HA solutions, behaved as viscous fluids. At higher concentrations, HA ester solutions exhibited an elastic response typical of weak gels, whereas HA exhibited a viscous behaviour. A solid-like response was also observed by lowering the temperature. These results indicate that hyaluronic acid ester solutions can form a weak gel network. The rheological properties of HA derivatives changed significantly compared to HA solutions. The improved elasticity and residence times of these solutions expand the possible applications of hyaluronic acid in the biomedical field.

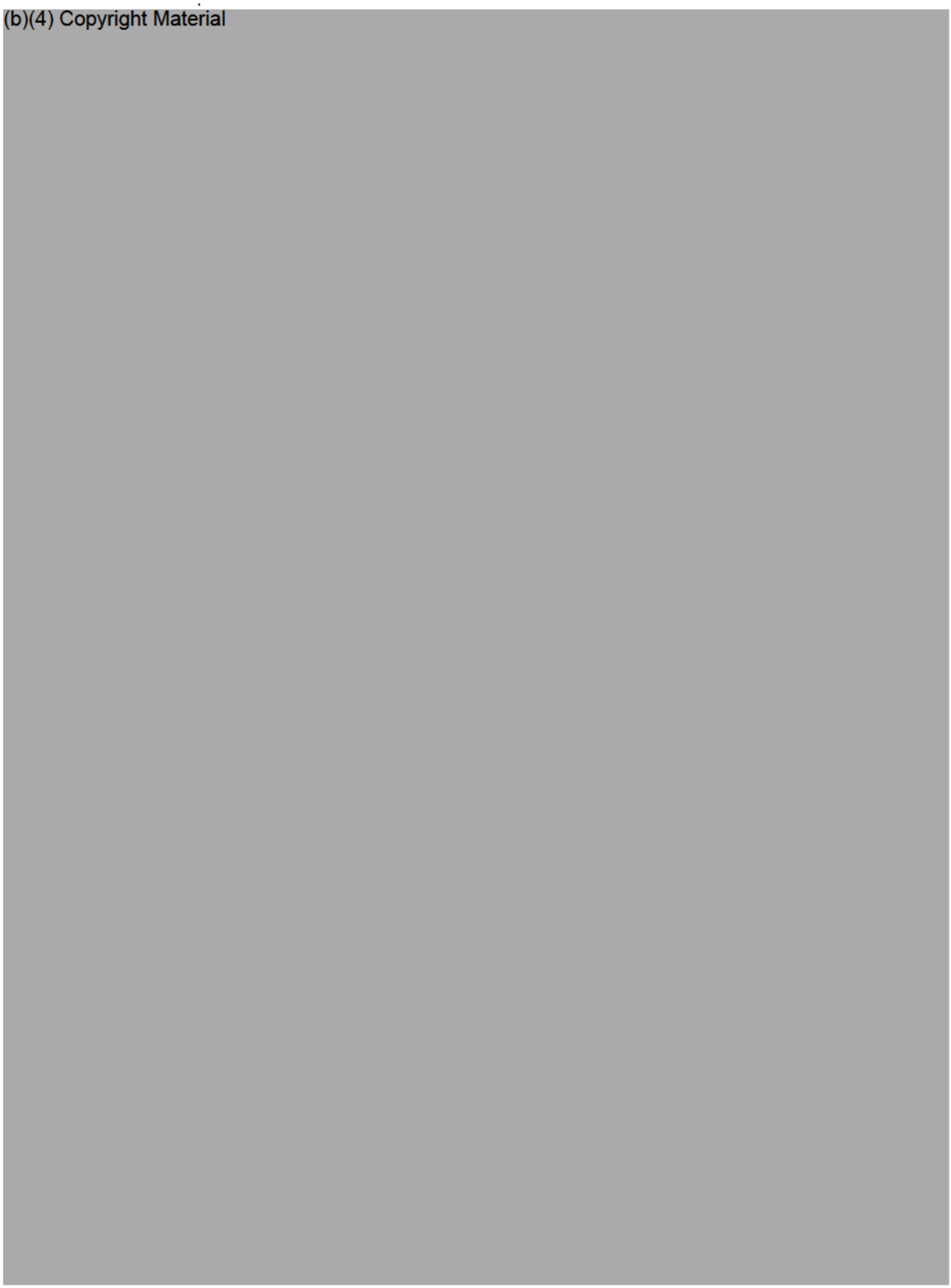
Key words: Hyaluronic acid; hyaluronic acid derivatives; rheology; viscosity; viscoelasticity; concentration; temperature; network.











ATTACHMENT 4
1996 Ovarectomized Rat Study

ATTACHMENT 5
Postmarket Data

ATTACHMENT 6
Revised Labeling

HYALO GYN®

Product Information

HYALO GYN® is a clear, colorless gel with strong hydrating properties that contains Hydeal-D®, a hyaluronic acid derivative. Hyaluronic acid occurs naturally in the body and is responsible for maintaining a correct level of hydration in body tissues.

Composition
Principal component: Hydeal-D® (hyaluronic acid derivative)
Other components: Propylene glycol, carbomer (Carbopol 974P), methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, sodium hydroxide, and purified water.

Indications for Use
HYALO GYN® is a personal lubricant, for penile and / or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual actitity and supplement the body's natural lubrication.
This product is compatible with condoms: lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin.

Contra-indications
Proven individual hypersensitivity towards the product.

Warnings and Precautions
1. In cases of vaginal infection, consult your doctor before using the product.
2. The product can be used during menstruation and does not influence the results of gynecological tests.
3. Each applicator is for single use only.
4. If the packaging proves to be damaged, do not use the product.
5. Keep out of reach of children.
6. Keep in a cool, dry place (<40°C).
7. Do not use the product after the expiration date shown on the packaging.
8. If irritation occurs, discontinue use and see a doctor.
9. This is not a spermicide.
10. Slippery, avoid spill.
11. Safety and effectiveness of this product has not been evaluated in pregnant women.

Directions for Use
How to prepare the applicator for use:
Each package contains 10 single-use applicators consisting of a piston, and one opaque plastic plunger.

How to apply the product

1. Screw the applicator (complete with plunger) onto the opening of the tube.
2. Pull the plunger back until the piston is about halfway up the applicator.
3. Squeeze the tube and fill the applicator up to the piston.
4. Unscrew the applicator from the tube and, after thoroughly washing your hands and the area around your vagina, insert it into the vagina while assuming a crouching or supine (laying down) position.
5. Push the plunger until all the gel has been expelled.
6. Extract the applicator. The applicators are for single use only and must be discarded after use.
7. In cases of severe dryness, it is advisable to expel a small amount of gel from the applicator before use, so that the tip is lubricated before being introduced into the vagina.

Frequency of use

The frequency with which the product should be used depends on how dry the vaginal mucosa is. One application every three days for a period of thirty days is recommended, unless otherwise recommended by your health care provider.

Manufactured by
Fidia Farmaceutici S.p.A.
Via Ponte della Fabbrica 3/A
35031 Abano Terme (PD) – Italy

[redacted]

150

BOX LABELING

152

TUBE LABELING

HYALO GYN®

Vaginal lubricating gel
containing Hydeal-D®

30 g tube

How to use Screw the single dose applicator (complete with plunger) onto the opening of the tube and fill the applicator up to half-way. After thoroughly washing your hands and the area around your vagina, insert gel into the vagina by pushing down on the plunger while assuming a crouching or supine (laying down) position.

Keep in a cool, dry place (<40°C).
KEEP OUT OF REACH OF CHILDREN.

Manufactured by Fidia Farmaceutici S.p.A.
Via Ponte della Fabbrica 3/A
35031 Abano Terme (PD) – Italy

Lot n. Exp. date

154

ATTACHMENT 8
Revised Indications for Use Statement

Indications for Use

510(k) Number (if known): K094039

Device Name: HYALO GYN®

Indications for Use: HYALO GYN is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This product is compatible with condoms: lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

FORM FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM D3492-03 (2003) Standard Specification for Rubber Contraceptives (Male Condoms)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 9-56 (2008)	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

159

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Paperwork Reduction Act Statement

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1 (2003) Biological evaluation of medical devices - Part 1: Evaluation and testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
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Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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PSC Graphics (301) 443-1090 EF

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-1 (2003) Biological evaluation of medical devices - Part 1: Evaluation and testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2	Categorization by nature of body contact	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option selected: 4.2.2 Surface-contacting devices - Skin and mucosal membranes

DESCRIPTION
Test was performed on the final product on the basis of the nature, degree, duration, frequency, contact to human.

JUSTIFICATION
The selection and evaluation of any material or device intended for use in humans requires a structured programme of assessment

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-5 (1999) Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-64	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-5 (1999) Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.3	Preparation of material for direct-contact tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option selected: direct-contact test

DESCRIPTION
Direct deposition of the device

JUSTIFICATION
Type of test selected on the basis of physical-chemical characteristics of the device

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10 (2002) Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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165

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-10 (2002) Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option selected: 6.3 Animal skin irritation test

DESCRIPTION
Repeated-exposure test

JUSTIFICATION
to assess the tolerability of the device after repeated topical administration

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10 (2002) Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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167

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-10 (2002) Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed hypersensitivity tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: 7.4 Maximization test for delayed hypersensitivity

DESCRIPTION
Test was conducted according to 7.4

JUSTIFICATION
to assess the cutaneous allergenic potential of the device

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-11 (2004) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-118 (2006)	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-11 (2004) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.5	Acute systemic toxicity	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option selected: Acute intraperitoneal application

DESCRIPTION
Intraperitoneal injection of the device

JUSTIFICATION
This route of administration provides information about hazard assessment

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-12 (2007) Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-135	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-12 (2007) Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Preparation of extract samples	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option selected: estimation in exaggerated-use conditions or risk assessment in actual use

DESCRIPTION
Extraction method of the device

JUSTIFICATION
to provide a measure of the hazard potential (for risk-estimation in exaggerated-use conditions) of the device

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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172