

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22548Orig1s000

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

Department of Health and Human Services Food and Drug Administration		Form Approved: OMB No. 0910-0513 Expiration Date: 7/31/10 See OMB Statement on Page 3.	
PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT <i>For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use</i>		NDA NUMBER 22-548	
		NAME OF APPLICANT/NDA HOLDER Allergan, Inc.	
<i>The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.</i>			
TRADE NAME (OR PROPOSED TRADE NAME) TRADENAME (gatifloxacin ophthalmic solution) 0.5%			
ACTIVE INGREDIENT(S) gatifloxacin		STRENGTH(S) 0.5%	
DOSAGE FORM Ophthalmic solution			
This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4). Within thirty (30) days after approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. The information submitted in the declaration form submitted upon or after approval will be the <i>only</i> information relied upon by FDA for listing a patent in the Orange Book.			
For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.			
FDA will not list patent information if you submit an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.			
For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.			
1. GENERAL			
a. United States Patent Number 6,333,045		b. Issue Date of Patent 25 December 2001	c. Expiration Date of Patent 20 August 2019
d. Name of Patent Owner Senju Pharmaceutical Co., Ltd 2-5-8, Hirano-machi, Chuo-ku, Osaka Japan Kyorin Pharmaceutical Co., Ltd (see address to the right)		Address (of Patent Owner) 5 Kanda Surugadai, 2-chome, Chiyoda-ku	
		City/State Tokyo, Japan 101-8311	
		ZIP Code	FAX Number (if available) (033) 293-3453
		Telephone Number (033) 293-3423	E-Mail Address (if available)
e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States)  John Wurst		Address (of agent or representative named in 1.e.) 2525 Dupont Drive	
		City/State Irvine, California	
		ZIP Code 92612	FAX Number (if available) (714) 246-4249
		Telephone Number (714) 246-5475	E-Mail Address (if available) wurst_john@allergan.com
f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

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2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement? Yes No

2.2 Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement? Yes No

2.3 If the answer to question 2.2 is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b). Yes No

2.4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in 2.3.

2.5 Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.) Yes No

2.6 Does the patent claim only an intermediate? Yes No

2.7 If the patent referenced in 2.1 is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.) Yes No

3. Drug Product (Composition/Formulation)

3.1 Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement? Yes No

3.2 Does the patent claim only an intermediate? Yes No

3.3 If the patent referenced in 3.1 is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.) Yes No

4. Method of Use

Sponsors must submit the information in section 4 for each method of using the pending drug product for which approval is being sought that is claimed by the patent. For each pending method of use claimed by the patent, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? Yes No

4.2 Patent Claim Number(s) (as listed in the patent) 6-8	Does (Do) the patent claim(s) referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
---	--

4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the proposed labeling.)
---	--

5. No Relevant Patents

For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. Yes

6. Declaration Certification

6.1 *The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.*

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide Information below)

Date Signed

Joanne Lemmo

4 May 09

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

NDA Applicant/Holder

NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official

Patent Owner

Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name

Joanne Lemmo

Address

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City/State

Irvine, CA

ZIP Code

92612

Telephone Number

(714) 246-5844

FAX Number (if available)

(714) 246-4051

E-Mail Address (if available)

lemmo_joanne@allergan.com

The public reporting burden for this collection of information has been estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDER (HFD-007)
5600 Fishers Lane
Rockville, MD 20857

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**PATENT INFORMATION SUBMITTED WITH THE FILING
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*For Each Patent That Claims a Drug Substance
(Active Ingredient), Drug Product (Formulation and Composition)
and/or Method of Use*

NDA NUMBER
22-548

NAME OF APPLICANT/NDA HOLDER
Allergan, Inc.

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.

TRADE NAME (OR PROPOSED TRADE NAME)

TRADENAME (gatifloxacin ophthalmic solution) 0.5%

ACTIVE INGREDIENT(S)

gatifloxacin

STRENGTH(S)

0.5%

DOSAGE FORM

Ophthalmic solution

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For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number 5,880,283	b. Issue Date of Patent 9 March 1999	c. Expiration Date of Patent 5 December 2015
d. Name of Patent Owner Kyorin Pharmaceutical Co., Ltd.	Address (of Patent Owner) 5 Kanda Surugadai, 2-chome, Chiyoda-ku	
	City/State Tokyo, Japan 101-8311	
	ZIP Code	FAX Number (if available) (033) 293-3453
	Telephone Number (033) 293-3423	E-Mail Address (if available)
e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States)	Address (of agent or representative named in 1.e.) 2525 Dupont Drive	
	City/State Irvine, California	
	ZIP Code 92612	FAX Number (if available) (714) 246-4249
 John Wurst	Telephone Number (714) 246-5475	E-Mail Address (if available) wurst_john@allergan.com
f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

2. Drug Substance (Active Ingredient)

- 2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement? Yes No
- 2.2 Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement? Yes No
- 2.3 If the answer to question 2.2 is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b). Yes No
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4. Method of Use

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- 4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? Yes No
- 4.2 Patent Claim Number(s) (as listed in the patent) Yes No
 Does (Do) the patent claim(s) referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? Yes No

<p>4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.</p>	<p>Use: (Submit indication or method of use information as identified specifically in the proposed labeling.)</p>
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5. No Relevant Patents

For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. Yes

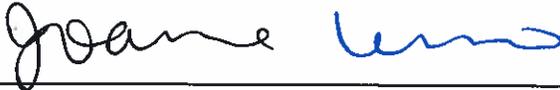
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Date Signed



4 May 09

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Check applicable box and provide information below.

NDA Applicant/Holder

NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official

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Name

Joanne Lemmo

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2525 Dupont Drive

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TRADENAME (gatifloxacin ophthalmic solution) 0.5%

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DOSAGE FORM
Ophthalmic solution

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1. GENERAL

a. United States Patent Number 4,980,470	b. Issue Date of Patent 25 December 1990	c. Expiration Date of Patent 15 December 2009
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d. Name of Patent Owner Kyorin Pharmaceutical Co., Ltd.	Address (of Patent Owner) 5 Kanda Surugadai, 2-chome, Chiyoda-Ku	
	City/State Tokyo, Japan 101-8311	
	ZIP Code	FAX Number (if available) (033) 293-3453
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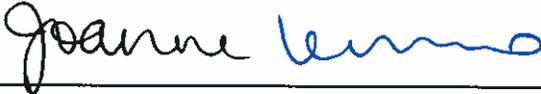
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4 May 09

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NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official

Patent Owner

Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name

Joanne Lemmo

Address

2525 Dupont Drive

City/State

Irvine, CA

ZIP Code

92612

Telephone Number

(714) 246-5844

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E-Mail Address (if available)

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EXCLUSIVITY SUMMARY

NDA # 022548

SUPPL #

HFD # 520

Trade Name ZYMAXID

Generic Name (gatifloxacin ophthalmic solution) 0.5%

Applicant Name Allergan, Inc.

Approval Date, If Known 05/18/2010

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES NO

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3, SE4, SE5, SE6, SE7, SE8

505(b)(1)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES NO

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

N/A

d) Did the applicant request exclusivity?

YES NO

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

3 years

e) Has pediatric exclusivity been granted for this Active Moiety?

YES NO

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES NO

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# 021061

TEQUIN (gatifloxacin) tablets, injection--1999

NDA# 021493

ZYMAR (gatifloxacin ophthalmic solution) 0.3%--2003

NDA#

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

NDA#

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. (Caution: The questions in part II of the summary should only be answered "NO" for original approvals of new molecular entities.)

IF "YES," GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDAs AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of

summary for that investigation.

YES NO

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES NO

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES NO

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES NO

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES NO

If yes, explain:

- (c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Study 198782-004 and Study 198782-005

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

- a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

- b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

Study 198782-004 and Study 198782-005

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1
IND # 059408 YES !
! ! NO
! Explain:

Investigation #2
IND # 059408 YES !
! ! NO
! Explain:

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1
!
!
YES ! NO
Explain: ! Explain:

Investigation #2
!
!
YES ! NO
Explain: ! Explain:

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES NO

If yes, explain:

Name of person completing form: Constantine J. Markos, Pharm.D., R.Ph.
Title: Regulatory Health Project Manager
Date: 04/20/2010

Name of Office/Division Director signing form: Wiley A. Chambers, M.D.
Title: Acting Division Director

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22548	ORIG-1	ALLERGAN	GATIFLOXACIN OPHTHALMIC SOLUTION 0.5%

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CONSTANTINE J MARKOS
05/19/2010

WILEY A CHAMBERS
05/24/2010



1.3.3 Debarment Certification

Allergan, Inc. hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.

Joanne B. Lemmo
Senior Manager
Regulatory Affairs

27 April 2009

Date

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION ¹		
NDA # 022548 BLA #	NDA Supplement # BLA STN #	If NDA, Efficacy Supplement Type:
Proprietary Name: ZYMAXID Established/Proper Name: Gatifloxacin Dosage Form: Ophthalmic Solution 0.5%		Applicant: Allergan, Inc. Agent for Applicant (if applicable):
RPM: Constantine J. Markos, Pharm.D., R.Ph.		Division: Division of Anti-Infective and Ophthalmology Products
<p>NDA: NDA Application Type: <input checked="" type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2) Efficacy Supplement: <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)</p> <p>(A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). Consult page 1 of the 505(b)(2) Assessment or the Appendix to this Action Package Checklist.)</p>		<p>505(b)(2) Original NDAs and 505(b)(2) NDA supplements: Listed drug(s) referred to in 505(b)(2) application (include NDA/ANDA #(s) and drug name(s)):</p> <p>Provide a brief explanation of how this product is different from the listed drug.</p> <p><input type="checkbox"/> If no listed drug, check box and explain:</p> <p><u>Two months prior to each action, review the information in the 505(b)(2) Assessment and submit the draft to CDER OND IO for clearance. Finalize the 505(b)(2) Assessment at the time of the approval action.</u></p> <p><u>On the day of approval, check the Orange Book again for any new patents or pediatric exclusivity.</u></p> <p><input checked="" type="checkbox"/> No changes <input type="checkbox"/> Updated Date of check: 05/18/2010</p> <p>If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.</p>
❖ Actions		
<ul style="list-style-type: none"> • Proposed action • User Fee Goal Date is <u>05/30/2010</u> 		<input checked="" type="checkbox"/> AP <input type="checkbox"/> TA <input type="checkbox"/> CR
<ul style="list-style-type: none"> • Previous actions (<i>specify type and date for each action taken</i>) 		<input checked="" type="checkbox"/> None
❖ If accelerated approval, were promotional materials received? Note: For accelerated approval (21 CFR 314.510/601.41), promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf). If not submitted, explain _____		<input type="checkbox"/> Received

¹ The **Application Information** section is (only) a checklist. The **Contents of Action Package** section (beginning on page 5) lists the documents to be included in the Action Package.

❖ Application Characteristics ²	
<p>Review priority: <input checked="" type="checkbox"/> Standard <input type="checkbox"/> Priority Chemical classification (new NDAs only):</p> <p><input type="checkbox"/> Fast Track <input type="checkbox"/> Rx-to-OTC full switch <input type="checkbox"/> Rolling Review <input type="checkbox"/> Rx-to-OTC partial switch <input type="checkbox"/> Orphan drug designation <input type="checkbox"/> Direct-to-OTC</p> <p>NDAs: Subpart H BLAs: Subpart E <input type="checkbox"/> Accelerated approval (21 CFR 314.510) <input type="checkbox"/> Accelerated approval (21 CFR 601.41) <input type="checkbox"/> Restricted distribution (21 CFR 314.520) <input type="checkbox"/> Restricted distribution (21 CFR 601.42) Subpart I Subpart H <input type="checkbox"/> Approval based on animal studies <input type="checkbox"/> Approval based on animal studies</p> <p><input type="checkbox"/> Submitted in response to a PMR <input type="checkbox"/> Submitted in response to a PMC <input type="checkbox"/> Submitted in response to a Pediatric Written Request</p> <p>Comments:</p>	
❖ BLAs only: <i>RMS-BLA Product Information Sheet for TBP</i> has been completed and forwarded to OBPS/DRM (<i>approvals only</i>)	<input type="checkbox"/> Yes, date
❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 (<i>approvals only</i>)	<input type="checkbox"/> Yes <input type="checkbox"/> No
❖ Public communications (<i>approvals only</i>)	
• Office of Executive Programs (OEP) liaison has been notified of action	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
• Press Office notified of action (by OEP)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
• Indicate what types (if any) of information dissemination are anticipated	<input checked="" type="checkbox"/> None <input type="checkbox"/> HHS Press Release <input type="checkbox"/> FDA Talk Paper <input type="checkbox"/> CDER Q&As <input type="checkbox"/> Other

² Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA. For example, if the application is a pending BLA supplement, then a new *RMS-BLA Product Information Sheet for TBP* must be completed.

❖ Exclusivity	
<ul style="list-style-type: none"> Is approval of this application blocked by any type of exclusivity? 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
<ul style="list-style-type: none"> NDA and BLAs: Is there existing orphan drug exclusivity for the “same” drug or biologic for the proposed indication(s)? <i>Refer to 21 CFR 316.3(b)(13) for the definition of “same drug” for an orphan drug (i.e., active moiety). This definition is NOT the same as that used for NDA chemical classification.</i> 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If, yes, NDA/BLA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 5-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 3-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 6-month pediatric exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> NDAs only: Is this a single enantiomer that falls under the 10-year approval limitation of 505(u)? <i>(Note that, even if the 10-year approval limitation period has not expired, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date 10-year limitation expires:
❖ Patent Information (NDAs only)	
<ul style="list-style-type: none"> Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought. If the drug is an old antibiotic, skip the Patent Certification questions. 	<input checked="" type="checkbox"/> Verified <input type="checkbox"/> Not applicable because drug is an old antibiotic.
<ul style="list-style-type: none"> Patent Certification [505(b)(2) applications]: Verify that a certification was submitted for each patent for the listed drug(s) in the Orange Book and identify the type of certification submitted for each patent. 	21 CFR 314.50(i)(1)(i)(A) <input type="checkbox"/> Verified 21 CFR 314.50(i)(1) <input type="checkbox"/> (ii) <input type="checkbox"/> (iii)
<ul style="list-style-type: none"> [505(b)(2) applications] If the application includes a paragraph III certification, it cannot be approved until the date that the patent to which the certification pertains expires (but may be tentatively approved if it is otherwise ready for approval). 	<input type="checkbox"/> No paragraph III certification Date patent will expire
<ul style="list-style-type: none"> [505(b)(2) applications] For each paragraph IV certification, verify that the applicant notified the NDA holder and patent owner(s) of its certification that the patent(s) is invalid, unenforceable, or will not be infringed (review documentation of notification by applicant and documentation of receipt of notice by patent owner and NDA holder). <i>(If the application does not include any paragraph IV certifications, mark “N/A” and skip to the next section below (Summary Reviews)).</i> 	<input type="checkbox"/> N/A (no paragraph IV certification) <input type="checkbox"/> Verified

- [505(b)(2) applications] For **each paragraph IV** certification, based on the questions below, determine whether a 30-month stay of approval is in effect due to patent infringement litigation.

Answer the following questions for **each** paragraph IV certification:

- (1) Have 45 days passed since the patent owner's receipt of the applicant's notice of certification?

Yes No

(Note: The date that the patent owner received the applicant's notice of certification can be determined by checking the application. The applicant is required to amend its 505(b)(2) application to include documentation of this date (e.g., copy of return receipt or letter from recipient acknowledging its receipt of the notice) (see 21 CFR 314.52(e)).

If "Yes," skip to question (4) below. If "No," continue with question (2).

- (2) Has the patent owner (or NDA holder, if it is an exclusive patent licensee) submitted a written waiver of its right to file a legal action for patent infringement after receiving the applicant's notice of certification, as provided for by 21 CFR 314.107(f)(3)?

Yes No

If "Yes," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip the rest of the patent questions.

If "No," continue with question (3).

- (3) Has the patent owner, its representative, or the exclusive patent licensee filed a lawsuit for patent infringement against the applicant?

Yes No

(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)).

If "No," the patent owner (or NDA holder, if it is an exclusive patent licensee) has until the expiration of the 45-day period described in question (1) to waive its right to bring a patent infringement action or to bring such an action. After the 45-day period expires, continue with question (4) below.

- (4) Did the patent owner (or NDA holder, if it is an exclusive patent licensee) submit a written waiver of its right to file a legal action for patent infringement within the 45-day period described in question (1), as provided for by 21 CFR 314.107(f)(3)?

Yes No

If "Yes," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (Summary Reviews).

If "No," continue with question (5).

<p>(5) Did the patent owner, its representative, or the exclusive patent licensee bring suit against the (b)(2) applicant for patent infringement within 45 days of the patent owner's receipt of the applicant's notice of certification?</p> <p>(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)). If no written notice appears in the NDA file, confirm with the applicant whether a lawsuit was commenced within the 45-day period).</p> <p><i>If "No," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (Summary Reviews).</i></p> <p><i>If "Yes," a stay of approval may be in effect. To determine if a 30-month stay is in effect, consult with the OND ADRA and attach a summary of the response.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
---	--

CONTENTS OF ACTION PACKAGE

❖ Copy of this Action Package Checklist ³	05/18/2010
Officer/Employee List	
❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list (<i>approvals only</i>)	<input checked="" type="checkbox"/> Included
Documentation of consent/non-consent by officers/employees	<input checked="" type="checkbox"/> Included
Action Letters	
❖ Copies of all action letters (<i>including approval letter with final labeling</i>)	Action(s) and date(s) AP 05/18/2010
Labeling	
❖ Package Insert (<i>write submission/communication date at upper right of first page of PI</i>)	
<ul style="list-style-type: none"> • Most recent draft labeling. If it is division-proposed labeling, it should be in track-changes format. 	Enclosed dated 04/20/2010
<ul style="list-style-type: none"> • Original applicant-proposed labeling 	Enclosed dated 07/30/2009
<ul style="list-style-type: none"> • Example of class labeling, if applicable 	N/A

³ Fill in blanks with dates of reviews, letters, etc.
Version: 5/14/10

<ul style="list-style-type: none"> ❖ Medication Guide/Patient Package Insert/Instructions for Use (<i>write submission/communication date at upper right of first page of each piece</i>) 	<input type="checkbox"/> Medication Guide <input type="checkbox"/> Patient Package Insert <input type="checkbox"/> Instructions for Use <input checked="" type="checkbox"/> None
<ul style="list-style-type: none"> • Most-recent draft labeling. If it is division-proposed labeling, it should be in ttrack-changes format. 	
<ul style="list-style-type: none"> • Original applicant-proposed labeling 	
<ul style="list-style-type: none"> • Example of class labeling, if applicable 	
<ul style="list-style-type: none"> ❖ Labels (full color carton and immediate-container labels) (<i>write submission/communication date on upper right of first page of each submission</i>) 	
<ul style="list-style-type: none"> • Most-recent draft labeling 	Enclosed dated 04/20/2010
<ul style="list-style-type: none"> ❖ Proprietary Name <ul style="list-style-type: none"> • Acceptability/non-acceptability letter(s) (<i>indicate date(s)</i>) • Review(s) (<i>indicate date(s)</i>) 	11/17/2009 11/13/2009, 04/13/2010
<ul style="list-style-type: none"> ❖ Labeling reviews (<i>indicate dates of reviews and meetings</i>) 	<input type="checkbox"/> RPM <input checked="" type="checkbox"/> DMEPA 01/27/2010 <input type="checkbox"/> DRISK <input checked="" type="checkbox"/> DDMAC 04/20/2010 <input type="checkbox"/> CSS <input type="checkbox"/> Other reviews
Administrative / Regulatory Documents	
<ul style="list-style-type: none"> ❖ Administrative Reviews (<i>e.g., RPM Filing Review⁴/Memo of Filing Meeting</i>) (<i>indicate date of each review</i>) 	04/09/2010
<ul style="list-style-type: none"> ❖ 505(b)(2) Assessment (<i>indicate date</i>) 	<input checked="" type="checkbox"/> Not a (b)(2)
<ul style="list-style-type: none"> ❖ NDAs only: Exclusivity Summary (<i>signed by Division Director</i>) 	<input checked="" type="checkbox"/> Included
<ul style="list-style-type: none"> ❖ Application Integrity Policy (AIP) Status and Related Documents http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm 	
<ul style="list-style-type: none"> • Applicant is on the AIP 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> • This application is on the AIP <ul style="list-style-type: none"> ○ If yes, Center Director’s Exception for Review memo (<i>indicate date</i>) ○ If yes, OC clearance for approval (<i>indicate date of clearance communication</i>) 	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not an AP action
<ul style="list-style-type: none"> ❖ Pediatrics (<i>approvals only</i>) <ul style="list-style-type: none"> • Date reviewed by PeRC <u>03/03/2010</u> If PeRC review not necessary, explain: _____ • Pediatric Page (<i>approvals only, must be reviewed by PERC before finalized</i>) 	<input checked="" type="checkbox"/> Included
<ul style="list-style-type: none"> ❖ Debarment certification (original applications only): verified that qualifying language was not used in certification and that certifications from foreign applicants are cosigned by U.S. agent (<i>include certification</i>) 	<input checked="" type="checkbox"/> Verified, statement is acceptable
<ul style="list-style-type: none"> ❖ Outgoing communications (<i>letters (except action letters), emails, faxes, telecons</i>) 	Included
<ul style="list-style-type: none"> ❖ Internal memoranda, telecons, etc. 	N/A

⁴ Filing reviews for scientific disciplines should be filed behind the respective discipline tab.
Version: 5/14/10

❖ Minutes of Meetings		
• Regulatory Briefing (<i>indicate date of mtg</i>)		<input checked="" type="checkbox"/> No mtg
• If not the first review cycle, any end-of-review meeting (<i>indicate date of mtg</i>)		<input checked="" type="checkbox"/> N/A or no mtg
• Pre-NDA/BLA meeting (<i>indicate date of mtg</i>)		<input type="checkbox"/> No mtg 11/26/2001, 03/17/2009
• EOP2 meeting (<i>indicate date of mtg</i>)		<input type="checkbox"/> No mtg
• Other milestone meetings (e.g., EOP2a, CMC pilots) (<i>indicate dates of mtgs</i>)		
❖ Advisory Committee Meeting(s)		<input checked="" type="checkbox"/> No AC meeting
• Date(s) of Meeting(s)		
• 48-hour alert or minutes, if available (<i>do not include transcript</i>)		
Decisional and Summary Memos		
❖ Office Director Decisional Memo (<i>indicate date for each review</i>)		<input checked="" type="checkbox"/> None
Division Director Summary Review (<i>indicate date for each review</i>)		<input type="checkbox"/> None 05/17/2010
Cross-Discipline Team Leader Review (<i>indicate date for each review</i>)		<input type="checkbox"/> None 05/17/2010
PMR/PMC Development Templates (<i>indicate total number</i>)		<input checked="" type="checkbox"/> None
Clinical Information⁵		
❖ Clinical Reviews		
• Clinical Team Leader Review(s) (<i>indicate date for each review</i>)		05/17/2010
• Clinical review(s) (<i>indicate date for each review</i>)		05/14/2010
• Social scientist review(s) (if OTC drug) (<i>indicate date for each review</i>)		<input checked="" type="checkbox"/> None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here <input type="checkbox"/> and include a review/memo explaining why not (<i>indicate date of review/memo</i>)		CDTL Review pg. 25 Clinical Review pg. 9
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers (<i>indicate date of each review</i>)		<input checked="" type="checkbox"/> None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation (<i>indicate date of each review</i>)		<input checked="" type="checkbox"/> Not applicable
❖ Risk Management		
• REMS Documents and Supporting Statement (<i>indicate date(s) of submission(s)</i>)		
• REMS Memo(s) and letter(s) (<i>indicate date(s)</i>)		
• Risk management review(s) and recommendations (including those by OSE and CSS) (<i>indicate date of each review and indicate location/date if incorporated into another review</i>)		<input checked="" type="checkbox"/> None
❖ DSI Clinical Inspection Review Summary(ies) (<i>include copies of DSI letters to investigators</i>)		<input type="checkbox"/> None requested Enclosed

⁵ Filing reviews should be filed with the discipline reviews.
Version: 5/14/10

Clinical Microbiology <input type="checkbox"/> None	
❖ Clinical Microbiology Team Leader Review(s) <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
Clinical Microbiology Review(s) <i>(indicate date for each review)</i>	<input type="checkbox"/> None 02/25/2010
Biostatistics <input type="checkbox"/> None	
❖ Statistical Division Director Review(s) <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
Statistical Team Leader Review(s) <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
Statistical Review(s) <i>(indicate date for each review)</i>	<input type="checkbox"/> None 03/26/2010
Clinical Pharmacology <input type="checkbox"/> None	
❖ Clinical Pharmacology Division Director Review(s) <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
Clinical Pharmacology Team Leader Review(s) <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
Clinical Pharmacology review(s) <i>(indicate date for each review)</i>	<input type="checkbox"/> None 03/15/2010
❖ DSI Clinical Pharmacology Inspection Review Summary <i>(include copies of DSI letters)</i>	<input checked="" type="checkbox"/> None
Nonclinical <input type="checkbox"/> None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
• Supervisory Review(s) <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
• Pharm/tox review(s), including referenced IND reviews <i>(indicate date for each review)</i>	<input type="checkbox"/> None 12/14/2009
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
❖ Statistical review(s) of carcinogenicity studies <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> No carc
❖ ECAC/CAC report/memo of meeting	<input checked="" type="checkbox"/> None Included in P/T review, page
❖ DSI Nonclinical Inspection Review Summary <i>(include copies of DSI letters)</i>	<input checked="" type="checkbox"/> None requested
Product Quality <input type="checkbox"/> None	
❖ Product Quality Discipline Reviews	
• ONDQA/OBP Division Director Review(s) <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
• Branch Chief/Team Leader Review(s) <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
• Product quality review(s) including ONDQA biopharmaceutics reviews <i>(indicate date for each review)</i>	<input type="checkbox"/> None 04/01/2010, 04/26/2010
❖ Microbiology Reviews <input checked="" type="checkbox"/> NDAs: Microbiology reviews (sterility & pyrogenicity) (OPS/NDMS) <i>(indicate date of each review)</i> <input type="checkbox"/> BLAs: Sterility assurance, microbiology, facilities reviews (DMPQ/MAPCB/BMT) <i>(indicate date of each review)</i>	<input type="checkbox"/> Not needed 04/16/2010
❖ Reviews by other disciplines/divisions/Centers requested by CMC/quality reviewer <i>(indicate date of each review)</i>	<input checked="" type="checkbox"/> None

❖ Environmental Assessment (check one) (original and supplemental applications)	
<input checked="" type="checkbox"/> Categorical Exclusion (<i>indicate review date</i>)(<i>all original applications and all efficacy supplements that could increase the patient population</i>)	04/01/2010 CMC Review pg. 59
<input type="checkbox"/> Review & FONSI (<i>indicate date of review</i>)	
<input type="checkbox"/> Review & Environmental Impact Statement (<i>indicate date of each review</i>)	
❖ Facilities Review/Inspection	
<input checked="" type="checkbox"/> NDAs: Facilities inspections (include EER printout) (<i>date completed must be within 2 years of action date</i>)	Date completed: <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation
<input type="checkbox"/> BLAs: TB-EER (<i>date of most recent TB-EER must be within 30 days of action date</i>)	Date completed: <input type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation
❖ NDAs: Methods Validation (<i>check box only, do not include documents</i>)	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Requested <input type="checkbox"/> Not yet requested <input type="checkbox"/> Not needed

Appendix to Action Package Checklist

An NDA or NDA supplemental application is likely to be a 505(b)(2) application if:

- (1) It relies on published literature to meet any of the approval requirements, and the applicant does not have a written right of reference to the underlying data. If published literature is cited in the NDA but is not necessary for approval, the inclusion of such literature will not, in itself, make the application a 505(b)(2) application.
- (2) **Or** it relies for approval on the Agency's previous findings of safety and efficacy for a listed drug product and the applicant does not own or have right to reference the data supporting that approval.
- (3) **Or** it relies on what is "generally known" or "scientifically accepted" about a class of products to support the safety or effectiveness of the particular drug for which the applicant is seeking approval. (Note, however, that this does not mean *any* reference to general information or knowledge (e.g., about disease etiology, support for particular endpoints, methods of analysis) causes the application to be a 505(b)(2) application.)

Types of products for which 505(b)(2) applications are likely to be submitted include: fixed-dose combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations); OTC monograph deviations (see 21 CFR 330.11); new dosage forms; new indications; and, new salts.

An efficacy supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2).

An efficacy supplement is a 505(b)(1) supplement if the supplement contains all of the information needed to support the approval of the change proposed in the supplement. For example, if the supplemental application is for a new indication, the supplement is a 505(b)(1) if:

- (1) The applicant has conducted its own studies to support the new indication (or otherwise owns or has right of reference to the data/studies).
- (2) **And** no additional information beyond what is included in the supplement or was embodied in the finding of safety and effectiveness for the original application or previously approved supplements is needed to support the change. For example, this would likely be the case with respect to safety considerations if the dose(s) was/were the same as (or lower than) the original application.
- (3) **And** all other "criteria" are met (e.g., the applicant owns or has right of reference to the data relied upon for approval of the supplement, the application does not rely for approval on published literature based on data to which the applicant does not have a right of reference).

An efficacy supplement is a 505(b)(2) supplement if:

- (1) Approval of the change proposed in the supplemental application would require data beyond that needed to support our previous finding of safety and efficacy in the approval of the original application (or earlier supplement), and the applicant has not conducted all of its own studies for approval of the change, or obtained a right to reference studies it does not own. For example, if the change were for a new indication AND a higher dose, we would likely require clinical efficacy data and preclinical safety data to approve the higher dose. If the applicant provided the effectiveness data, but had to rely on a different listed drug, or a new aspect of a previously cited listed drug, to support the safety of the new dose, the supplement would be a 505(b)(2).
- (2) **Or** the applicant relies for approval of the supplement on published literature that is based on data that the applicant does not own or have a right to reference. If published literature is cited in the supplement but is not necessary for approval, the inclusion of such literature will not, in itself, make the supplement a 505(b)(2) supplement.
- (3) **Or** the applicant is relying upon any data they do not own or to which they do not have right of reference.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, consult with your ODE's ADRA.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22548	ORIG-1	ALLERGAN	GATIFLOXACIN OPHTHALMIC SOLUTION 0.5%

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/s/

CONSTANTINE J MARKOS
05/19/2010

Markos, Constantine

From: Markos, Constantine
Sent: Wednesday, May 19, 2010 11:23 AM
To: 'Lemmo_Joanne'
Cc: 'Gryziewicz_Lewis@Allergan.com'
Subject: FW: NDA 022548 - ZYMAXID (gatifloxacin ophthalmic solution) 0.5% - Allergan, Inc.

Importance: High

Attachments: ViewDocument.pdf

From: Markos, Constantine
Sent: Tuesday, May 18, 2010 7:28 PM
To: 'Lemmo_Joanne'
Subject: FW: NDA 022548 - ZYMAXID (gatifloxacin ophthalmic solution) 0.5% - Allergan, Inc.
Importance: High

From: Markos, Constantine
Sent: Tuesday, May 18, 2010 7:18 PM
To: 'Lemmo_Joanne'
Subject: NDA 022548 - ZYMAXID (gatifloxacin ophthalmic solution) 0.5% - Allergan, Inc.

Hello Joanne,

Please find attached below your APPROVAL letter, with the approved labeling.



ViewDocument.pdf
(519 KB)

Please respond to this e-mail so that I know that you received it. Thank you. I will also follow-up this e-mail with a phone call to you as well.

Kind Regards,

Constantine

Constantine J. Markos, Pharm.D., R.Ph.
Regulatory Health Project Manager
FDA/CDER/OND/OAP/DAIOP
P--301-796-3871
F--301-796-9881
Constantine.Markos@FDA.HHS.GOV

NOTE: Approval Letter and Label are for attachment purposes only. Please refer to original NDA Approval and Label at beginning of package.

NDA 022548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

From: Lemmo_Joanne [Lemmo_Joanne@Allergan.com]

Sent: Wednesday, March 03, 2010 12:51 PM

To: Markos, Constantine

Subject: RE: NDA 022548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Attachments: emfinfo.txt

Hi Constantine,

Yes, I ve received the email. Thank you.

Joanne

From: Markos, Constantine [mailto:Constantine.Markos@fda.hhs.gov]

Sent: Wednesday, March 03, 2010 9:32 AM

To: Lemmo_Joanne

Subject: NDA 022548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Good Morning Joanne,

Please find below, Clinical comments from our Division in regards to NDA 022548:

Please provide the demographics and a subgroup analysis of the primary endpoint by age. Include the following categories: age < 18, age >= 18, and by age in 5 year blocks from age 0 -18 yrs (i.e., age 1-5, age 6-10, etc.)

Please respond to this e-mail so that I know that you received it. Thank you for your time. I hope all is well.

Regards,

Constantine

Constantine J. Markos, Pharm.D., R.Ph.

Regulatory Health Project Manager

FDA/CDER/OND/OAP/DAIOP

P--301-796-3871

F--301-796-9881

Constantine.Markos@FDA.HHS.GOV

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22548	ORIG-1	ALLERGAN	GATIFLOXACIN OPHTHALMIC SOLUTION 0.5%

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/s/

CONSTANTINE J MARKOS
03/03/2010

NDA 022548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc. From: Lemmo_Joanne [Lemmo_Joanne@Allergan.com]

Sent: Wednesday, February 24, 2010 5:54 PM

To: Markos, Constantine

Subject: RE: NDA 022548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Attachments: emfinfo.txt

Hi Constantine, Hope all is well, I heard you got a lot of snow!

I ve received the email.

Kind regards,

Joanne

From: Markos, Constantine [mailto:Constantine.Markos@fda.hhs.gov]

Sent: Wednesday, February 24, 2010 2:37 PM

To: Lemmo_Joanne

Subject: NDA 022548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Good Afternoon Joanne,

Please find below, Microbiology (sterility) comments from our Division in regards to NDA 022548:

* Provide the routine production (b) (4)

* Provide the Validation protocol and summary final report supporting the (b) (4)

* Provide the most recent re-validation/re-qualification reports supporting the continued use of the (b) (4)

* Provide the (b) (4)

* Provide the Validation protocol and summary final report supporting the (b) (4)

* Provide the most recent re-validation/re-qualification reports supporting the continued use of the (b) (4).

The validation reports should address the following issues:

* What are the actual (b) (4) being used for the Allergan NDA22-548 caps during commercial production?

* What method was used to determine that sterilizing dose?

* What validation data supports these parameters and how recent is it (how often is it re-confirmed/re-validated)?

* Verification dose studies

* Component bioburden studies

* Number and identification of lots used

* Calculated verification dose

* Minimum actual dose used

* Results of the Sterility tests of units exposed to the verification dose

* Final summary report

* Provide load diagrams/descriptions used in the validation and how they r

elate to commercial production procedures

* What is the [REDACTED] (b) (4)

* During [REDACTED] (b) (4)

* Is [REDACTED] (b) (4) permitted and if so, under what conditions is this p
ermitted?

Please respond to this e-mail so that I know that you received it. Thank you fo
r your time.

Constantine

Constantine J. Markos, Pharm.D., R.Ph.

Regulatory Health Project Manager

FDA/CDER/OND/OAP/DAIOP

P--301-796-3871

F--301-796-9881

Constantine.Markos@FDA.HHS.GOV

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22548	ORIG-1	ALLERGAN	GATIFLOXACIN OPHTHALMIC SOLUTION 0.5%

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/s/

CONSTANTINE J MARKOS
02/24/2010

From: Lemmo_Joanne [Lemmo_Joanne@Allergan.com]

Sent: Tuesday, January 12, 2010 3:09 PM

To: Markos, Constantine

Subject: RE: NDA 022548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Attachments: emfinfo.txt

Hello Constantine,

I received your email message.

Kind regards,

Joanne

From: Markos, Constantine [mailto:Constantine.Markos@fda.hhs.gov]

Sent: Tuesday, January 12, 2010 11:56 AM

To: Lemmo_Joanne

Subject: NDA 022548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Good Afternoon Joanne,

Please find below, CMC comments from our Division in regards to NDA 022548:

It is observed that the solubility of gatifloxacin decreases from (b) (4) (b) (4) and the strength of the drug product is (b) (4). It is recommended that the upper limit of pH for shelf-life be lowered to (b) (4) for drug product to avoid (b) (4). Otherwise, please provide justification.

If your response can be found in the contents of your submission, just cite those sections of the submission that are relevant to the issue under consideration. Otherwise, provide the appropriate information. Your response should be submitted as an amendment to the submission.

Please respond to this e-mail so that I know that you received it. Thank you for your time.

Constantine

Constantine J. Markos, Pharm.D., R.Ph.

Regulatory Health Project Manager

FDA/CDER/OND/OAP/DAIOP

P--301-796-3871

F--301-796-9881

Constantine.Markos@FDA.HHS.GOV

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22548	ORIG-1	ALLERGAN	GATIFLOXACIN OPHTHALMIC SOLUTION 0.5%

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/s/

CONSTANTINE J MARKOS
01/12/2010

From: Lemmo_Joanne [Lemmo_Joanne@Allergan.com]

Sent: Thursday, December 17, 2009 6:32 PM

To: Markos, Constantine

Subject: RE: NDA 022548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Attachments: emfinfo.txt

Hi Constantine,

Yes, I have received your email. Thanks.

Joanne

From: Markos, Constantine [mailto:Constantine.Markos@fda.hhs.gov]

Sent: Thursday, December 17, 2009 3:03 PM

To: Lemmo_Joanne

Subject: NDA 022548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Good Afternoon Joanne,

Per our phone conversation earlier today, please find below, further comments from our Division in regards to NDA 022548:

Tabular data included in the application contains conflicting information regarding the numbers of specific bacterial pathogens seen in Studies 004 (US) and 005 (India). As an example, Table 2.5.4-5 lists 134 isolates of Streptococcus pneumoniae recovered in Study 004 and none in Study 005, while Table 2.7.3.3-23 lists 127 isolates of S. pneumoniae recovered in Study 004 and 7 recovered in Study 005. Similar discrepancies exist for other bacterial species (including Haemophilus influenzae). Please clarify all such discrepancies, and submit a tabulated summary of all principle ocular pathogens, with correct data listing pathogen recovered by trial.

Please respond to this e-mail so that I know that you received it. Thank you for your time.

Constantine

Constantine J. Markos, Pharm.D., R.Ph.

Regulatory Health Project Manager

FDA/CDER/OND/OAP/DAIOP

P--301-796-3871

F--301-796-9881

Constantine.Markos@FDA.HHS.GOV

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22548	ORIG-1	ALLERGAN	GATIFLOXACIN OPHTHALMIC SOLUTION 0.5%

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/s/

CONSTANTINE J MARKOS
12/17/2009



NDA 022548

**PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE**

Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612

ATTENTION: Joanne Lemmo
Senior Manager, Regulatory Affairs

Dear Ms. Lemmo:

Please refer to your New Drug Application (NDA) dated July 30, 2009, received July 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gatifloxacin Ophthalmic Solution 0.5%.

We also refer to your August 20, 2009, correspondence, received August 21, 2009, requesting review of your proposed proprietary name, Zymaxid. We have completed our review of the proposed proprietary name, Zymaxid and have concluded that it is acceptable.

The proposed proprietary name, Zymaxid, will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If **any** of the proposed product characteristics as stated in your August 20, 2009, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Brantley Dorch, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-0150. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, Constantine Markos, at (301) 796-3871.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22548

ORIG-1

ALLERGAN

GATIFLOXACIN OPHTHALMIC
SOLUTION 0.5%

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/s/

CAROL A HOLQUIST
11/17/2009

From: Lemmo_Joanne [Lemmo_Joanne@Allergan.com]

Sent: Friday, October 30, 2009 4:43 PM

To: Markos, Constantine

Subject: RE: NDA 22548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Attachments: emfinfo.txt

Hello Constantine,

Thanks for the email, I did receive it. I will probably call you back on Monday regarding the cross referencing question for the IND.

Have a good weekend,

Joanne

From: Markos, Constantine [mailto:Constantine.Markos@fda.hhs.gov]

Sent: Friday, October 30, 2009 12:57 PM

To: Lemmo_Joanne

Subject: NDA 22548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Good Afternoon Joanne,

Please find below, follow-up clarification comments from our Division in regards to NDA 22548:

It is unclear why you are using different criteria for the "second" in vitro list for the Zymaxid application than was used for the Zymar application. The Agency expects the following criteria to be utilized in the selection of organisms for the "second" list in the label:

- 1) organism must be associated with the disease (indication), i.e. bacterial conjunctivitis

- 2) over 100 isolates must have been tested in at least two separate studies
- 3) MIC 90 value for the organism must be at or below the systemic susceptible breakpoint

Please respond to this e-mail so that I know that you received it. Thank you for your time.

Constantine

Constantine J. Markos, Pharm.D., R.Ph.

Regulatory Health Project Manager

FDA/CDER/OND/OAP/DAIOP

P--301-796-3871

F--301-796-9881

Constantine.Markos@FDA.HHS.GOV

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22548

ORIG-1

ALLERGAN

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SOLUTION 0.5%

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/s/

CONSTANTINE J MARKOS

10/30/2009



NDA 022548

FILING COMMUNICATION

Allergan, Inc.
Attention: Joanne Lemmo, RAC
Senior Manager, Global Regulatory Affairs
2525 Dupont Drive
Irvine, CA 92612

Dear Ms. Lemmo:

Please refer to your new drug application (NDA) dated July 30, 2009, received July 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, for gatifloxacin ophthalmic solution 0.5%.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application was considered filed 60 days after the date we received your application. The review classification for this application is **Standard**. Therefore, the user fee goal date is May 30, 2010.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If the potential review issue identified below is resolved during our review and no new deficiencies are identified during our review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by March 23, 2010.

During our filing review of your application, we identified the following potential review issue:

In Studies 198782-004 and 198782-005, the protocol-defined primary efficacy endpoints of clinical success did not achieve statistical significance of $p \leq 0.05$ using the specified modified intent-to-treat populations.

We are providing the above comments to give you preliminary notice of potential review issues. Our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review. Issues may be added, deleted, expanded upon, or modified as we review the application.

We do not expect a response to this letter, and we may not review any such response during the current review cycle.

If you have not already done so, you must submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>. The content of labeling must be in the Prescribing Information (physician labeling rule) format.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have submitted pediatric studies with this application for pediatric patients above the age of 1 year. We acknowledge receipt of your request for a partial waiver of pediatric studies for this application. Once the review of this application is complete, we will notify you whether the partial waiver has been granted and whether you have fulfilled all of the pediatric study requirements.

If you have any questions, call Constantine J. Markos, Pharm.D., R.Ph., Regulatory Health Project Manager, at (301) 796-3871.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22548

ORIG-1

ALLERGAN

GATIFLOXACIN OPHTHALMIC
SOLUTION 0.5%

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/s/

WILEY A CHAMBERS

10/08/2009

Markos, Constantine

From: Rodriguez, Raphael R
Sent: Thursday, September 24, 2009 2:53 PM
To: 'lemmo_joanne@allergan.com'
Cc: Markos, Constantine; Dillon Parker, Maureen P
Subject: NDA 22548 Information Request

Attachments: NDA 22548 Review comments to sponsor (2).doc



NDA 22548 Review
comments to s...

Good afternoon Ms. Lemmo: (see attached) please respond to the following request for information as soon as possible. A response by October 3, 2009 would be greatly appreciated. Please let me know if this deadline cannot be met. I apologize for the lateness of this requests. Any questions, please give me a call at 301.796.0798, or simply reply back to this email.

Raphael Rodriguez
RPM (covering for Constantine)

NDA 22-548 Gatifloxacin Ophthalmic Solution 0.5%
ATTN: Joanne Lemmo
Senior Manager, Global Regulatory Affairs

These comments are being provided to you prior to completion of our review of the application to give you preliminary notice of issues that have been identified. Per the user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and are subject to change as the review of your application is finalized. In addition, we may identify other information that must be provided prior to approval of this application. Depending on the timing of your response, as per user fee reauthorization agreements, we may or may not be able to consider your response prior to taking an action on your application during this review cycle.

Your response should be submitted as an amendment to the submission and a copy via email (if available) to the project manager at raphael.rodriguez@fda.hhs.gov.

Chemistry

1. Please provide evidence of compliance with USP <467> "Residual Solvents."
2. Provide available updated stability data.

Statistical

3. It is not clear to us which variables from which dataset recorded the primary endpoint evaluation date and the corresponding duration from randomization date. Please clarify.

Microbiologist

4. The list of bacteria included in "second list" of indicated organisms in the proposed label for Zymaxid (b) (4) differs substantially from the "second list" in the approved label for Zymar (NDA 21493). Please provide a rationale for the new list and provide recent in vitro data to support any and all bacteria proposed for inclusion in that list.

Markos, Constantine

From: Markos, Constantine
Sent: Tuesday, September 29, 2009 1:29 PM
To: Snow, Kerry
Cc: Rodriguez, Raphael R; Chambers, Wiley A; Dillon Parker, Maureen P; Marsik, Frederic J; Boyd, William M; Lloyd, Rhea
Subject: FW: Request for clarification of question received regarding NDA 22-548
Attachments: emfinfo.txt

Hello Kerry,

Please find below an e-mail I just received from Allergan in regards to our Microbiology question sent to them by Raphael a few days ago (Thanks Raphael!!). This was sent along with some other comments from other disciplines (Thank you to all involved, including Kerry, Raphael, Maureen, Bill and Wiley for putting this document together while I was out with a sick family last week).

It looks like they need some clarification.

Please advise.

Thanks again to everyone for your help with this application so far!!

C

From: Lemmo_Joanne [mailto:Lemmo_Joanne@Allergan.com]
Sent: Tuesday, September 29, 2009 1:15 PM
To: Markos, Constantine
Cc: Rodriguez, Raphael R; Chambers, Wiley A
Subject: Request for clarification of question received regarding NDA 22-548

Dear Constantine,

Allergan would like to get clarification on Question 4 received on 9/24/09 from Raphael Rodriguez regarding NDA 22-548 (copy of question provided below).

Question 4:

The list of bacteria included in the "second list" of indicated organisms in the proposed label for Zymaxid (b) (4) differs substantially from the "second list" in the approved label for Zymar (NDA 21493). Please provide a rationale for the new list and provide recent in vitro data to support any and all bacteria proposed for inclusion in that list.

10/7/2009

A justification for inclusion of organisms in the 'second' in-vitro list was provided in the original NDA 22-548 in Module 2.5.4.4.3, Table 2.5.4-5 and Module 2.7.3.3.8.5, Table 2.7.3.3-38. This list included organisms collected from the 2 clinical studies (198782-004 and 198782-005) if:

- 1) there were at least 5 patients with a given organism in the qualified eye at baseline; and
- 2) the MIC₉₀ to gatifloxacin for that organism was (b) (4) in the pooled data.

However, if FDA believes that it would be more appropriate to include the list of organisms from the 'second list' for Zymar (gatifloxacin ophthalmic solution) 0.3% Allergan would propose to revise the proposed labeling. Please clarify if the appropriate method to determine the organisms for inclusion on the second list could be based on the data obtained with Zymar and from in-vitro analysis of organisms obtained during these recent clinical studies.

Kind regards,

Joanne

Joanne Lemmo, RAC
Global Regulatory Affairs
Allergan, Inc.
office: 714-246-5844
fax: 714-246-4051
lemmo_joanne@allergan.com

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22548	ORIG-1	ALLERGAN	GATIFLOXACIN OPHTHALMIC SOLUTION 0.5%

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/s/

CONSTANTINE J MARKOS
10/07/2009

NDA FILEABILITY CHECKLIST

NDA Number: 22-548
Applicant: Allergan
Letter Date: July 30, 2009
Stamp Date: July 30, 2009
Drug Name: Gantifloxacin Ophthalmic Solution 0.5%

IS THE CMC SECTION OF THE APPLICATION FILEABLE? (Yes or No) Yes

The following parameters are necessary in order to initiate a full review, i.e., complete enough to review but may have deficiencies.

	Parameter	Yes	No	Comment
1	On its face, is the section organized adequately?	Y		
2	Is the section indexed and paginated adequately?	Y		This is an eCTD NDA
3	On its face, is the section legible?	Y		
4	Are ALL of the facilities (including contract facilities and test laboratories) identified with full <u>street</u> addresses and CFNs?	Y		Firm was asked to confirm list by ONDQA PM
5	Is a statement provided that all facilities are ready for GMP inspection?			Not able to locate
6	Has an environmental assessment report or categorical exclusion been provided?	Y		Claims categorical exclusion 1.12.14
7	Does the section contain controls for the drug substance?	Y		Gantifloxacin supplied by Kyorin Pharmaceuticals. DMF 15597
8	Does the section contain controls for the drug product?	Y		
9	Has stability data and analysis been provided to support the requested expiration date?	Y		One strength with (b) (4) 1 mL, 2.5 mL (b) (4) Total of 6 batches 6 months stability RT, 30°C and accelerated to cover all the fill sizes, horizontal and upright. 1 mL physician claims 12 expiry; others 24 months expiry. Supportive longer stability data submitted.
10	Has all information requested during the IND phase, and at the pre-NDA meetings been included?	Y		This is similar formulation as the approved product except for strength. Referenced IND 59,408 and NDA 21-493.
11	Have draft container labels been provided?	Y		
12	Has the draft package insert been provided?	Y		
13	Has an investigational formulations section been provided?	Y		
14	Is there a Methods Validation package?	Y		
15	Is a separate microbiological section included?			No separate section; information incorporated in CMC section

NDA 22-548

Chemistry Reviewer:
Pharmaceutical Assessment Lead:
Branch Chief:
Prepared by: LN 9/31/09

Lin Qi, Ph.D.
Linda Ng, Ph.D.
Norman Schmuff, Ph.D.

DMF Number	Holder	Description	LOA Included	Status
15,597	Kyorin Pharmaceutical	Gantifloxacon	August 31, 2009	
2461	Allergan	USP qualification for bottle, tip and cap	May 15, 2009	
(b) (4)	(b) (4)	(b) (4)	January 17, 2000	

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/s/

LINDA L NG
09/02/2009

NORMAN R SCHMUFF
09/02/2009

From: Lemmo_Joanne [Lemmo_Joanne@Allergan.com]
Sent: Monday, August 31, 2009 6:36 PM
To: Markos, Constantine
Subject: RE: NDA 22548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Attachments: emfinfo.txt
[Hello Constantine,](#)

I can confirm that I have received your email. I will respond to you as soon as possible.

Kind regards,

Joanne

From: Markos, Constantine [mailto:Constantine.Markos@fda.hhs.gov]
Sent: Monday, August 31, 2009 3:05 PM
To: Lemmo_Joanne
Subject: NDA 22548 - Gatifloxacin Ophthalmic Solution 0.5% - Allergan, Inc.

Good Afternoon Joanne,

Please find below, comments from our Division in regards to NDA 22548:

Clinical

Section 11.1.1.1.5 of the CSR for 198782-005 reports a data integrity problem with investigator 13020. Please provide additional information regarding the specific problems noted at this site. If this information is located within the NDA submission, please identify its location.

Please respond to this e-mail so that I know that you received it. Thank you for your time.

Constantine

Constantine J. Markos, Pharm.D., R.Ph.
Regulatory Health Project Manager
FDA/CDER/OND/OAP/DAIOP
P--301-796-3871
F--301-796-9881
Constantine.Markos@FDA.HHS.GOV

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/s/

CONSTANTINE J MARKOS
08/31/2009

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		REQUEST FOR CONSULTATION		
TO (Division/Office): Director, DDMAC Attn: Paul Loebach, RPM		FROM: Wiley Chambers, MD, Acting Director, DAIOP Constantine Markos, RPM ext #6-3871		
DATE 8/27/09	IND NO.	NDA NO. 22-548	TYPE OF DOCUMENT Original NDA	DATE OF DOCUMENT July 30 & Aug 20, 2009
NAME OF DRUG ZYMAXID (gatifloxacin ophthalmic sol) 0.5%		PRIORITY CONSIDERATION Standard Review	CLASSIFICATION OF DRUG Antibacterial	DESIRED COMPLETION DATE Jan 30, 2010
NAME OF FIRM: Allergan, Inc.				
REASON FOR REQUEST				
I. GENERAL				
<input type="checkbox"/> NEW PROTOCOL <input type="checkbox"/> PROGRESS REPORT <input type="checkbox"/> NEW CORRESPONDENCE <input type="checkbox"/> DRUG ADVERTISING <input type="checkbox"/> ADVERSE REACTION REPORT <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION <input type="checkbox"/> MEETING PLANNED BY <input type="checkbox"/> PRE--NDA MEETING <input type="checkbox"/> END OF PHASE 2 <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> SAFETY/EFFICACY <input type="checkbox"/> CONTROL SUPPLEMENT <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER <input type="checkbox"/> FINAL PRINTED LABELING <input type="checkbox"/> LABELING REVISION <input checked="" type="checkbox"/> ORIGINAL NEW CORRESPONDENCE <input type="checkbox"/> FORMULATIVE REVIEW <input type="checkbox"/> OTHER (SPECIFY BELOW):				
II. BIOMETRICS				
STATISTICAL EVALUATION BRANCH		STATISTICAL APPLICATION BRANCH		
<input type="checkbox"/> TYPE A OR B NDA REVIEW <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW <input type="checkbox"/> OTHER (SPECIFY BELOW):		<input type="checkbox"/> CHEMISTRY REVIEW <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER (SPECIFY BELOW):		
III. BIOPHARMACEUTICS				
<input type="checkbox"/> DISSOLUTION <input type="checkbox"/> BIOAVAILABILITY STUDIES <input type="checkbox"/> PHASE IV STUDIES		<input type="checkbox"/> DEFICIENCY LETTER RESPONSE <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS <input type="checkbox"/> IN-VIVO WAIVER REQUEST		
V. SCIENTIFIC INVESTIGATIONS				
<input type="checkbox"/> CLINICAL		<input type="checkbox"/> PRECLINICAL		
COMMENTS: Please provide a labeling reviews for the ZYMAXID (gatifloxacin ophthalmic sol) 0.5%. This entire submission was sent via Electronic Submissions Gateway (ESG), eCTD which means there are NO jackets to distribute. ATTACHMENT link: Launch GSReview for viewing eCTD documents. \\cdsesub1\evsprod\NDA022548 PDUFA DATE: 5/27/2010 Please let me know if you need any additional information to complete the labeling reviews. Thanks in advance.				
SIGNATURE OF REQUESTER Raphael Rodriguez ext 6-0798		METHOD OF DELIVERY (Check one) Via: Interoffice Mail		
SIGNATURE OF RECEIVER		SIGNATURE OF DELIVERER		

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/s/

RAPHAEL R RODRIGUEZ
08/27/2009

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		REQUEST FOR CONSULTATION		
TO (Division/Office): CDER OSE CONSULTS		FROM: Wiley Chambers, M.D., Acting Dir, DAIOP Constantine Markos, RPM, ext# 6-3871		
DATE 8/26/09	IND NO.	NDA NO. 22-548	TYPE OF DOCUMENT Original NDA	DATE OF DOCUMENT July 30, & Aug 20, 2009
NAME OF DRUG ZYMAXID (gatifloxacin ophthalmic sol) 0.5%		PRIORITY CONSIDERATION Standard review	CLASSIFICATION OF DRUG Antibacterial	DESIRED COMPLETION DATE Jan 30, 2010
NAME OF FIRM: Allergan, Inc.				
REASON FOR REQUEST				
I. GENERAL				
<input type="checkbox"/> NEW PROTOCOL <input type="checkbox"/> PROGRESS REPORT <input type="checkbox"/> NEW CORRESPONDENCE <input type="checkbox"/> DRUG ADVERTISING <input type="checkbox"/> ADVERSE REACTION REPORT <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION <input type="checkbox"/> MEETING PLANNED BY <input type="checkbox"/> PRE--NDA MEETING <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> SAFETY/EFFICACY <input type="checkbox"/> PAPER NDA <input type="checkbox"/> CONTROL SUPPLEMENT <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER <input type="checkbox"/> FINAL PRINTED LABELING <input type="checkbox"/> LABELING REVISION <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE <input type="checkbox"/> FORMULATIVE REVIEW <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW): Trade name review				
II. BIOMETRICS				
STATISTICAL EVALUATION BRANCH		STATISTICAL APPLICATION BRANCH		
<input type="checkbox"/> TYPE A OR B NDA REVIEW <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW <input type="checkbox"/> OTHER (SPECIFY BELOW):		<input type="checkbox"/> CHEMISTRY REVIEW <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER (SPECIFY BELOW):		
III. BIOPHARMACEUTICS				
<input type="checkbox"/> DISSOLUTION <input type="checkbox"/> BIOAVAILABILTY STUDIES <input type="checkbox"/> PHASE IV STUDIES		<input type="checkbox"/> DEFICIENCY LETTER RESPONSE <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS <input type="checkbox"/> IN-VIVO WAIVER REQUEST		
IV. DRUG EXPERIENCE				
<input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP		<input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE <input type="checkbox"/> POISON RISK ANALYSIS		
V. SCIENTIFIC INVESTIGATIONS				
<input type="checkbox"/> CLINICAL		<input type="checkbox"/> PRECLINICAL		
COMMENTS/SPECIAL INSTRUCTIONS: Please provide tradename reviews for ZYMAIXD (gatifloxacin ophthalmic sol) 0.5% This entire submission was sent via Electronic Submissions Gateway (ESG), eCTD which means there are NO jackets to distribute. ATTACHMENT link: Launch GSReview for viewing eCTD documents. \\cdsesub1\evsprod\NDA022548 PDUFA DATE: 5/27/2010 Please let me know if you need any additional information to complete the labeling reviews. Thanks in advance.				
NAME AND PHONE NUMBER OF REQUESTER Raphael Rodriguez ext#6-0798		METHOD OF DELIVERY (Check one) <input type="checkbox"/> DFS ONLY <input type="checkbox"/> MAIL <input type="checkbox"/> HAND		
SIGNATURE OF RECEIVER		SIGNATURE OF DELIVERER		

Linked Applications	Submission Type/Number	Sponsor Name	Drug Name / Subject
----- NDA 22548	----- ORIG 1	----- ALLERGAN	----- GATIFLOXACIN OPHTHALMIC SOLUTION 0.5%

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/s/

RAPHAEL R RODRIGUEZ
08/27/2009



NDA 22548

NDA ACKNOWLEDGMENT

Allergan, Inc.
Attention: Joanne Lemmo
Senior Manager, Global Regulatory Affairs
2525 Dupont Drive
Irvine, CA 92612

Dear Ms. Lemmo:

We have received your new drug application (NDA) submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: gatifloxacin ophthalmic solution 0.5%

Date of Application: July 30, 2009

Date of Receipt: July 30, 2009

Our Reference Number: NDA 22548

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on September 28, 2009 in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

The NDA number provided above should be cited at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective and Ophthalmology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see <http://www.fda.gov/cder/ddms/binders.htm>.

If you have any questions, call Constantine J. Markos, Pharm.D., R.Ph., Regulatory Health Project Manager, at (301) 796-3871.

Sincerely,

{See appended electronic signature page}

Maureen P. Dillon-Parker
Chief, Project Management Staff
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

MAUREEN P DILLON PARKER
08/26/2009

David, Jeannie C

From: David, Jeannie C
Sent: Friday, August 21, 2009 5:42 PM
To: 'Lemmo_Joanne'
Cc: Markos, Constantine
Subject: RE: NDA 22-548 CMC Establishment Information Requests

Dear Joanne,

As discussed, on behalf of the CMC review team for NDA 22-548, we have the following requests and recommendation regarding the establishment information provided in the NDA:

1. All listed sites should have name of firm, street address, Central File Number (CFN) or Federal Establishment Identifier (FEI) number, name of contact person, phone and facsimile numbers. The purpose for each, i.e., manufacturing, packaging, labeling, sterilization, release or stability testing should be stated. Please update or confirm the accuracy of the submitted information.
2. It would be helpful to provide a table like Table 3.2.P.3.1-1 in the Continuation Sheet to Form 356h, to outline Operations Performed for all of the drug substance and drug product establishments for NDA 22-548, including additional columns for site contact persons with fax and phone numbers, CFN and FEI numbers, DMF and NDA numbers relevant to each site, and whether or not each site is ready for inspection.

As you had requested, I am providing the following written details on the specific issues to address:

- If possible, please provide a contact person located at each establishment where each manufacturing or testing occurs. If this is not available, please confirm that the contact provided is the most appropriate to effectively coordinate a site inspection for that establishment. Provide, at minimum, a name and fax number for each contact provided.
- Please provide a Central File Number (CFN) or Federal Establishment Identifier (FEI) number for the establishments for drug substance manufacturing and analysis, and drug product quality control and sterilization.
- Please confirm that the FEI number provided in the NDA for Allergan Westport is 3002806348. We have another number on file.
- Please list what type of analysis(es) is(are) performed on the drug substance by Allergan Waco and Allergan Westport.
- Please resolve a discrepancy in the drug product functions listed for Allergan Westport, found between the Continuation Sheet to Form 356h and Table 3.2.P.3.1-1. The Continuation Sheet lists this site under the Manufacturing, Packaging, and Control responsibilities for the drug product, whereas Table 3.2.P.3.1-1 does not list these in the column for Operations Performed.

Please submit the final updated information as an amendment to the NDA, addressed to the Division Director of the Division of Anti-Infective and Ophthalmology Products.

Contact me immediately if you have any further questions on these CMC requests. Please cc: the lead Regulatory Project Manager for this NDA, Constantine Markos, in the Division of Anti-Infective and Ophthalmology Products, in all of your email communications with me.

Thank you,

Jeannie

Jeannie David, M.S.
Regulatory Project Manager

8/21/2009

Food and Drug Administration
Center for Drug Evaluation and Research
Office of New Drug Quality Assessment
10903 New Hampshire Avenue
Building 22, Mail Room 1491
Silver Spring, MD 20993
Phone: (301) 796-4247

From: Lemmo_Joanne [mailto:Lemmo_Joanne@Allergan.com]
Sent: Friday, August 21, 2009 5:20 PM
To: David, Jeannie C
Cc: Markos, Constantine
Subject: NDA 22-548 CMC Establishment Information Requests

Dear Jeannie,

Per our conversation this afternoon I am emailing you regarding your request for additional site establishment information. Please send me the list of clarifications and I will provide you the information you request.

Kind regards,

Joanne

Joanne Lemmo, RAC
Global Regulatory Development
Allergan, Inc.
office: 714-246-5844
cell: 949-294-7923
fax: 714-246-4051
lemmo_joanne@allergan.com

8/21/2009

Linked Applications	Submission Type/Number	Sponsor Name	Drug Name / Subject
----- NDA 22548	----- ORIG 1	----- ALLERGAN	----- GATIFLOXACIN OPHTHALMIC SOLUTION 0.05%

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/s/

JEANNIE C DAVID
08/21/2009