

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0338  
Expiration Date: September 30, 2008  
See OMB Statement on page 2.

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC,  
OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT

Alimera Sciences, Inc.

DATE OF SUBMISSION

06/02/2006

TELEPHONE NO. (Include Area Code)

678-527-1330

FACSIMILE (FAX) Number (Include Area Code)

678-990-5743

APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):

6120 Windward Parkway, Suite 290  
Alpharetta GA 30005

AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 21-996

ESTABLISHED NAME (e.g., Proper name, USP/USAN name)

ketotifen fumarate ophthalmic solution 0.025%

PROPRIETARY NAME (trade name) IF ANY

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any)

CODE NAME (If any)

DOSAGE FORM:

ophthalmic solution

STRENGTHS:

0.025%

ROUTE OF ADMINISTRATION:

ophthalmic topical

(PROPOSED) INDICATION(S) FOR USE:

APPLICATION INFORMATION

APPLICATION TYPE

(check one)



NEW DRUG APPLICATION (NDA, 21 CFR 314.50)



ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)



BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE



505 (b)(1)



505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug

Zaditor

Holder of Approved Application

Novartis Pharmaceuticals, Inc.

TYPE OF SUBMISSION (check one)



ORIGINAL APPLICATION



AMENDMENT TO A PENDING APPLICATION



RESUBMISSION



PRESUBMISSION



ANNUAL REPORT



ESTABLISHMENT DESCRIPTION SUPPLEMENT



EFFICACY SUPPLEMENT



LABELING SUPPLEMENT



CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT



OTHER

General Correspondence

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY



CBE



CBE-30



Prior Approval (PA)

REASON FOR SUBMISSION

Response to request for carton mock-up

PROPOSED MARKETING STATUS (check one)



PRESCRIPTION PRODUCT (Rx)



OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED

1

THIS APPLICATION IS



PAPER



PAPER AND ELECTRONIC



ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the application.)

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: (Check all that apply)

<input type="checkbox"/>	1. Index
<input type="checkbox"/>	2. Labeling (check one) <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling
<input type="checkbox"/>	3. Summary (21 CFR 314.50 (c))
<input type="checkbox"/>	4. Chemistry section
<input type="checkbox"/>	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
<input type="checkbox"/>	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
<input type="checkbox"/>	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
<input type="checkbox"/>	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
<input type="checkbox"/>	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
<input type="checkbox"/>	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
<input type="checkbox"/>	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
<input type="checkbox"/>	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
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<input type="checkbox"/>	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
<input type="checkbox"/>	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
<input type="checkbox"/>	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
<input type="checkbox"/>	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
<input type="checkbox"/>	15. Establishment description (21 CFR Part 600, if applicable)
<input type="checkbox"/>	16. Debarment certification (FD&C Act 306 (k)(1))
<input type="checkbox"/>	17. Field copy certification (21 CFR 314.50 (l)(3))
<input type="checkbox"/>	18. User Fee Cover Sheet (Form FDA 3397)
<input type="checkbox"/>	19. Financial Information (21 CFR Part 54)
<input checked="" type="checkbox"/>	20. OTHER (Specify) <u>Carton Mock-up</u>

**CERTIFICATION**

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

**Warning:** A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT <i>Barbara H. Bauschka</i>	TYPED NAME AND TITLE Barbara H. Bauschka, Manager Regulatory Affairs	DATE 06/02/2006
ADDRESS (Street, City, State, and ZIP Code) 6120 Windward Parkway, Suite 290, Alpharetta GA 30005		Telephone Number 678-527-1330

**Public reporting burden for this collection of information** is estimated to average 24 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:

Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research Central Document Room 5901-B Ammendale Road Beltsville, MD 20705-1266	Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research (HFM-99) 1401 Rockville Pike Rockville, MD 20852-1448	An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.
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## Office of Surveillance and Epidemiology

### Memo

**To:** Janice Soreth, MD  
Director, Division of Anti-Infective and Ophthalmology Products  
HFD-520

**Through:** Linda Kim-Jung, PharmD., Team Leader  
Denise Toyer, PharmD., Deputy Director  
Carol Holquist, R.Ph., Director  
Division of Medication Errors and Technical Support (HFD-420)  
Office of Surveillance and Epidemiology

**From:** Linda Wisniewski, RN, Safety Evaluator  
Division of Medication Errors and Technical Support (HFD-420)  
Office of Surveillance and Epidemiology

**Date:** March 22, 2006

**Re:** ODS Consult 06-0096, — (Ketotifen Fumarate Ophthalmic Solution), NDA# 21-996

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This memorandum is in response to a request from the Division of Anti-Infective and Ophthalmology Products (HFD-520), for an assessment of the proprietary name, —

Upon review of the name, DMETS learned that the name “ — ” already exists in the market. The currently marketed product, —

— However, the name — still appears in commonly used reference texts such as the Orange Book and Micromedex. These references are routinely used by healthcare practitioners. Although the branded product is not available, this does not prevent practitioners from prescribing “ — ”. The pharmacist may look up the name, —, in a reference source and find that the brand — is not available and dispense the generic product

— instead, without contacting the prescriber for further clarification. Therefore, DMETS believes that Ketotifen Fumarate Ophthalmic Solution and — should not co-exist in the marketplace with the same proprietary name.

In discussion with the review division, the division concurs with DMETS safety concerns regarding the proprietary name, —. Therefore, DMETS will not proceed with the safety review of the proposed proprietary name, — since the Division supports DMETS' objection of the name based on safety concerns. We recommend the sponsor be notified immediately of the decision to object to the name based on safety concerns. Additionally, DMETS recommends that the sponsor is requested to submit an alternative proprietary name for NDA # 21-996. Please forward the alternate name for DMETS review upon submission.

If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-796-0538.

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

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Linda Wisniewski  
5/31/2006 03:13:06 PM  
DRUG SAFETY OFFICE REVIEWER

Linda Kim-Jung  
5/31/2006 03:18:17 PM  
DRUG SAFETY OFFICE REVIEWER

Denise Toyer  
5/31/2006 03:47:11 PM  
DRUG SAFETY OFFICE REVIEWER

Carol Holquist  
5/31/2006 03:56:18 PM  
DRUG SAFETY OFFICE REVIEWER

**LIMERA**  
SCIENCES

May 24, 2006

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

Re: NDA 21-996  
Ketotifen Fumarate Ophthalmic Solution, 0.025%  
General Correspondence: Product Name

Dear Sir or Madam:

Alimera Sciences, Inc. is proposing the following two names for the drug product submitted in NDA 21-996 **Ketotifen Fumarate Ophthalmic Solution, 0.025%**.

**Alaway**

These names are alternatives to the submitted name of — . Alimera is currently in discussions with the application holder of the product — but would like to continue to move forward with these possible names in case an alternative name is required.

Once Alimera receives notification that this name is not already being used, graphics and associated artwork will commence. If additional information is required or there are questions about this request, please contact me at 678-527-1330, by fax at 678-527-1335 or by email.

Sincerely,

*Barbara H. Bauschka*

Barbara H. Bauschka  
Manager, Regulatory Affairs

Cc: Alison Rodgers, Project Manager

**CDER/CDR**

MAY 26 2006

**RECEIVED**

N-000000

**NEW CORRESP**

**RECEIVED**

MAY 30 2006

**CDER White Oak DR1**

**ORIGINAL**

**ALIMERA**  
SCIENCE

April 12, 2006

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

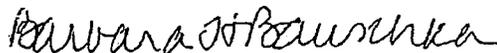
Re: **NDA 21-996**  
**Ketotifen Fumarate Ophthalmic Solution, 0.025%**  
**Amendment: Receipt of Notification of Patent Certification**

Dear Sir or Madam:

Alimera Sciences, Inc. is providing Return Receipts, as required by 21 CFR §314.52 (e), documenting that the patent holder, as required by 21 CFR §314.52 (a), has been notified of the filing of NDA 21-996.

If you have any questions or need additional information please contact me at 678-527-1330.

Sincerely,



Barbara H. Bauschka  
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

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(Title 21, Code of Federal Regulations, Parts 314 & 601)

FOR FDA USE ONLY

APPLICATION NUMBER

**APPLICANT INFORMATION**

NAME OF APPLICANT Allimera Sciences, Inc.	DATE OF SUBMISSION 04/12/2006
TELEPHONE NO. (Include Area Code) 678-527-1830	FACSIMILE (FAX) Number (Include Area Code) 678-990-5743
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued): 6120 Windward Parkway, Suite 290 Alpharetta, GA 30005	AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE

**PRODUCT DESCRIPTION**

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (if previously issued) 21-996		
ESTABLISHED NAME (s.o., Proper name, USP/USAN name) Ketotifen fumarate ophthalmic solution 0.025%	PROPRIETARY NAME (trade name) IF ANY	
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (if any)	CODE NAME (if any)	
DOSAGE FORM: Ophthalmic solution	STRENGTHS: 0.025%	ROUTE OF ADMINISTRATION: Ophthalmic/ocular
(PROPOSED) INDICATION(S) FOR USE: J		

**APPLICATION INFORMATION**

APPLICATION TYPE (check one)	<input checked="" type="checkbox"/> NEW DRUG APPLICATION (NDA, 21 CFR 314.50)	<input type="checkbox"/> ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
	<input checked="" type="checkbox"/> BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)	
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE	<input checked="" type="checkbox"/> 505 (b)(1)	<input checked="" type="checkbox"/> 505 (b)(2)
IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION	Holder of Approved Application Novartis Pharmaceuticals, Inc.	
TYPE OF SUBMISSION (check one)	<input checked="" type="checkbox"/> ORIGINAL APPLICATION	<input type="checkbox"/> AMENDMENT TO A PENDING APPLICATION
	<input type="checkbox"/> PRESUBMISSION	<input type="checkbox"/> RESUBMISSION
	<input type="checkbox"/> ANNUAL REPORT	<input type="checkbox"/> EFFICACY SUPPLEMENT
	<input type="checkbox"/> ESTABLISHMENT DESCRIPTION SUPPLEMENT	<input type="checkbox"/> LABELING SUPPLEMENT
	<input type="checkbox"/> CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT	<input type="checkbox"/> OTHER
IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:		
IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY	<input type="checkbox"/> CBE	<input type="checkbox"/> CBE-30
	<input type="checkbox"/> Prior Approval (PA)	
REASON FOR SUBMISSION	Documentation of Receipt of Notice	
PROPOSED MARKETING STATUS (check one)	<input type="checkbox"/> PRESCRIPTION PRODUCT (Rx)	<input checked="" type="checkbox"/> OVER THE COUNTER PRODUCT (OTC)
NUMBER OF VOLUMES SUBMITTED	THIS APPLICATION IS <input checked="" type="checkbox"/> PAPER <input type="checkbox"/> PAPER AND ELECTRONIC <input type="checkbox"/> ELECTRONIC	

**ESTABLISHMENT INFORMATION** (Full establishment information should be provided in the body of the application.)  
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

\_\_\_\_\_

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\_\_\_\_\_

DMF \_\_\_\_\_

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<input checked="" type="checkbox"/>	19. Financial Information (21 CFR Part 54)
<input checked="" type="checkbox"/>	20. OTHER (Specify) Documentation of Recall of Notices

**CERTIFICATION**

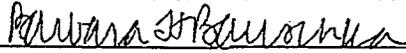
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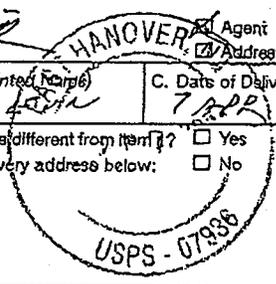
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SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT 	TYPED NAME AND TITLE Barbara J. Bauschka, Manager Regulatory Affairs	DATE 04/12/2006
ADDRESS (Street, City, State, and ZIP Code) 6120 Windward Parkway, Suite 290, Alpharetta, GA 30005	Telephone Number 678-527-1390	

**Public reporting burden for this collection of information is estimated to average 24 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:**

Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research Central Document Room 5901-B Amundale Road Beltsville, MD 20705-1266	Department of Health and Human Services Food and Drug Administration Center for Biologicals Evaluation and Research (HFM-99) 1401 Rockville Pike Rockville, MD 20852-1448	An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.
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SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY
<ul style="list-style-type: none"> <li>Complete Items 1, 2, and 3. Also complete Item 4 if Restricted Delivery is desired.</li> <li>Print your name and address on the reverse so that we can return the card to you.</li> <li>Attach this card to the back of the mailpiece, or on the front if space permits.</li> </ul>	<p>A. Signature  <input checked="" type="checkbox"/> <i>[Signature]</i> <input type="checkbox"/> Agent <input checked="" type="checkbox"/> Addressee</p> <p>B. Received by (Printed Name)  <i>W. B. L. 2/18/00</i></p> <p>C. Date of Delivery  <i>7/18/00</i></p>
<p>1. Article Addressed to:</p> <p>Thomas Hoxie          Corporate IP          Novartis Pharmaceuticals          One Health Plaza, Bldg. 430          East Hanover, NJ 07936-1080</p>	<p>D. Is delivery address different from item 1? <input type="checkbox"/> Yes          If YES, enter delivery address below: <input type="checkbox"/> No</p> <p>3. Service Type  <input checked="" type="checkbox"/> Certified Mail <input type="checkbox"/> Express Mail  <input type="checkbox"/> Registered <input type="checkbox"/> Return Receipt for Merchandise  <input type="checkbox"/> Insured Mail <input type="checkbox"/> C.O.D.</p> <p>4. Restricted Delivery? (Extra Fee) <input type="checkbox"/> Yes</p>
<p>2. Article Number (Transfer from service label) <u>7005 3110 0002 5201 1343</u></p>	



SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY	
<ul style="list-style-type: none"> <li>Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.</li> <li>Print your name and address on the reverse so that we can return the card to you.</li> <li>Attach this card to the back of the mailpiece, or on the front if space permits.</li> </ul>	<p>A. Signature  <input checked="" type="checkbox"/> Agent  <input type="checkbox"/> Addressee</p>	
<p>1. Article Addressed to:</p> <p>Alex Gorsky  Head of Pharma N.A.  Novartis Pharmaceutical  One Health Plaza  East Hanover, NJ 07936-1080</p>	<p>B. Received by (Printed Name)  ROBERT L. GORSKY</p>	<p>C. Date of Delivery  7 APR 02</p>
<p>2. Article Number  (Transfer from service label)</p>	<p>D. Is delivery address different from item 1? <input type="checkbox"/> Yes  <input checked="" type="checkbox"/> No  If YES, enter delivery address below:</p> <p>USPS - 07936</p>	
<p>7005 3110 0002 5201 1312</p>	<p>3. Service Type  <input checked="" type="checkbox"/> Certified Mail <input type="checkbox"/> Express Mail  <input type="checkbox"/> Registered <input type="checkbox"/> Return Receipt for Merchandise  <input type="checkbox"/> Insured Mail <input type="checkbox"/> C.O.D.</p>	
<p>PS Form 3811, February 2004</p>	<p>4. Restricted Delivery? (Extra Fee) <input type="checkbox"/> Yes</p> <p>Domestic Return Receipt</p> <p>102595-02-M-1640</p>	

**ALIMERA**  
**SCIENCES**

April 10, 2006

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

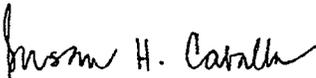
**Re: NDA 21-996**  
**Ketotifen Fumarate Ophthalmic Solution, 0.025%**  
**Amendment: Notification of Patent Certification**

Dear Sir or Madam:

Alimera Sciences, Inc. certifies that the patent holder, as required by 21 CFR §314.52 (a), has been notified of the filing of NDA 21-996. Furthermore, Alimera Sciences, Inc. certifies that the notice contains all content as required by 21 CFR §314.52 (c).

If you have any questions or need additional information please contact me at 678-527-1328.

Sincerely,

  
Susan H. Caballa  
Vice-President, Regulatory and Medical Affairs

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0538  
Expiration Date: September 30, 2008  
See OMB Statement on page 2.

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC,  
OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT

Allimera Sciences, Inc.

DATE OF SUBMISSION

04/10/2006

TELEPHONE NO. (Include Area Code)

678-527-1330

FACSIMILE (FAX) Number (Include Area Code)

678-990-5743

APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):

6120 Windward Parkway, Suite 290  
Alpharetta GA 30005

AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (if previously issued)

21996

ESTABLISHED NAME (e.g., Proper name, USP/USAN name)

Ketotifen fumarate ophthalmic solution; 0.025%

PROPRIETARY NAME (trade name) IF ANY

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (if any)

CODE NAME (if any)

DOSEAGE FORM:

ophthalmic solution

STRENGTHS:

0.025%

ROUTE OF ADMINISTRATION:

ophthalmic topical

(PROPOSED) INDICATION(S) FOR USE:

APPLICATION INFORMATION

APPLICATION TYPE

(check one)

NEW DRUG APPLICATION (NDA, 21 CFR 314.60)

ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)

BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE

605 (b)(1)

505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug

Zaditor

Holder of Approved Application

Inovative Pharmaceuticals Inc.

TYPE OF SUBMISSION (check one)

ORIGINAL APPLICATION

AMENDMENT TO A PENDING APPLICATION

RESUBMISSION

PRESUBMISSION

ANNUAL REPORT

ESTABLISHMENT DESCRIPTION SUPPLEMENT

EFFICACY SUPPLEMENT

LABELING SUPPLEMENT

CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT

OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY

OBE

OBE-90

Prior Approval (PA)

REASON FOR SUBMISSION

Notification of Patent Certification

PROPOSED MARKETING STATUS (check one)

PRESCRIPTION PRODUCT (Rx)

OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED

THIS APPLICATION IS

PAPER

PAPER AND ELECTRONIC

ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the application.)

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (List related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: *(Check all that apply)*

<input checked="" type="checkbox"/>	1. Index
<input checked="" type="checkbox"/>	2. Labeling <i>(check one)</i> <input checked="" type="checkbox"/> Draft Labeling <input checked="" type="checkbox"/> Final Printed Labeling
<input checked="" type="checkbox"/>	3. Summary (21 CFR 314.50 (c))
<input checked="" type="checkbox"/>	4. Chemistry section
<input checked="" type="checkbox"/>	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
<input checked="" type="checkbox"/>	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
<input checked="" type="checkbox"/>	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(f); 21 CFR 601.2)
<input checked="" type="checkbox"/>	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
<input checked="" type="checkbox"/>	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
<input checked="" type="checkbox"/>	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
<input checked="" type="checkbox"/>	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
<input checked="" type="checkbox"/>	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
<input checked="" type="checkbox"/>	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
<input checked="" type="checkbox"/>	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
<input checked="" type="checkbox"/>	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
<input checked="" type="checkbox"/>	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
<input checked="" type="checkbox"/>	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
<input checked="" type="checkbox"/>	15. Establishment description (21 CFR Part 600, if applicable)
<input checked="" type="checkbox"/>	16. Debarment certification (FD&C Act 306 (k)(1))
<input checked="" type="checkbox"/>	17. Field copy certification (21 CFR 314.50 (l)(3))
<input checked="" type="checkbox"/>	18. User Fee Cover Sheet (Form FDA 3997)
<input checked="" type="checkbox"/>	19. Financial Information (21 CFR Part 54)
<input checked="" type="checkbox"/>	20. OTHER <i>(Specify)</i> Notification of Patent Certification

**CERTIFICATION**

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT <i>Barbara H. Bauschka</i>	TYPED NAME AND TITLE Barbara H. Bauschka, Manager, Regulatory Affairs	DATE 04/10/2006
ADDRESS (Street, City, State, and ZIP Code) 6120 Windward Parkway, Suite 290, Alpharetta, GA 30005	Telephone Number 678-527-1390	

Public reporting burden for this collection of information is estimated to average 24 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:

Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
5901-B Ammendsle Road  
Beltsville, MD 20705-1286

Department of Health and Human Services  
Food and Drug Administration  
Center for Biological Evaluation and Research (HFM-99)  
1401 Rockville Pike  
Rockville, MD 20852-1448

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

**FILING COMMUNICATION**

NDA 21-996

Alimera Sciences, Inc.  
Attention: Barbara H. Bauschka  
Manager, Regulatory Affairs  
6120 Windward Parkway, Suite 290  
Alpharetta, GA 30005

Dear Ms. Bauschka:

Please refer to your January 31, 2006, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for — (ketotifen fumarate ophthalmic solution) 0.025%.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, this application was filed under section 505(b) of the Act on April 2, 2006, in accordance with 21 CFR 314.101(a).

At this time, we have not identified any potential filing 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.

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

*{See appended electronic signature page}*

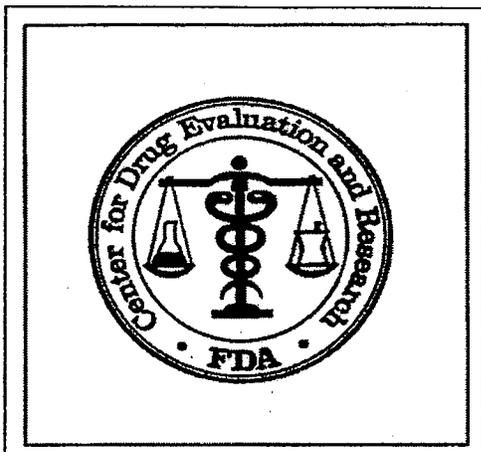
Maureen P. Dillon-Parker  
Chief, Project Management Staff  
Division of Anti-Infective and  
Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

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

-----  
Maureen Dillon-Parker  
4/14/2006 02:19:18 PM  
NDA 21-996/Filing Letter - no issues identified

FACSIMILE TRANSMISSION  
RECORD



From: Lin Qi, Ph.D.

Office of New Drug Quality Assessment

Phone 301-796-1438

Fax 301-796-9850

Date: 4/3/06

To: Name Ms. Barbara H. Bauschka  
Company Alimera Sciences, Inc.  
City Alpharetta State GA  
Phone # 678-527-1330  
FAX # 678-990-5743

Number of Pages (INCLUDING COVER PAGE) ` 2 `

Please telephone (301) 796-1438 IMMEDIATELY if re-transmission is necessary.

**THIS DOCUMENT IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.**

If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any view, disclosure, copying, or other action based on the content of this communication is NOT authorized. If you have received this document in error, please notify us immediately by telephone and return it to us at the above address by mail. Thank you.

**NDA 21-996**

**— (ketotifen hydrogen fumarate ophthalmic solution) 0.025%**

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.

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 and a copy via facsimile to the reviewer.

**CMC COMMENTS**

1. Please submit the missing Letter of Authorization (LOA) for the DMFs that were requested as stated in the NDA
2. According to ICH Q6A, either one specific or two non-specific identification tests should be proposed. Please revise the drug product specification accordingly.
3. Actual values, where appropriate, should be reported for stability data instead of "conform".
4. A system suitability test to include a standard at the quantitation limit should be incorporated in the impurity test to ensure the detectability of impurities down to that level during analysis.
5. Clarify how the RSD at NMT  $\frac{1}{2}$  % for the ketotifen fumarate peak is obtained. Discuss as appropriate the number of injections, how the standard(s) is distributed during analysis.
6. Provide the  $\frac{1}{2}$  residual testing data to support the validation of the container closure — sterilization process.
7. Updated stability data should be submitted.
8. Include the reference to  $\frac{1}{2}$  in the stability protocol commitment.
9. Provide the comparative viscosity value of the drug product with the referenced product.

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

-----  
Lin Qi  
4/3/2006 01:57:50 PM  
CHEMIST

Norman Schmuff  
4/3/2006 03:49:00 PM  
CHEMIST

# ALIMERA SCIENCES

March 20, 2006

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

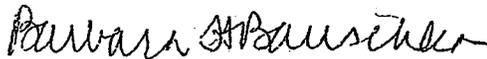
**Re: NDA 21-996**  
**Ketotifen Fumarate Ophthalmic Solution, 0.025%**  
**Amendment: Form 3542a, Form 3455 and Drug Facts font specifications**

Dear Sir or Madam:

Alimera Sciences, Inc. is providing as requested by Ms. Alison Rodgers, Project Manager, an amendment to NDA 21-996 containing Form 3542a, Form 3455 and font specifications for Drug Facts.

If you have any questions or need additional information please contact me at 678-527-1330.

Sincerely,



Barbara H. Bauschka  
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0338  
Expiration Date: September 30, 2008  
See OMB Statement on page 2.

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC,  
OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT Alimera Sciences, Inc.	DATE OF SUBMISSION 03/30/2006
TELEPHONE NO. (Include Area Code) 678-527-1330	FACSIMILE (FAX) Number (Include Area Code) 678-990-5743
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued): 6120 Windward Parkway, Suite 290 Alpharetta GA 30005	AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 21-996		
ESTABLISHED NAME (e.g., Proper name, USP/USAN name) ketotifen fumarate ophthalmic solution, 0.025%	PROPRIETARY NAME (trade name) IF ANY	
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any)	CODE NAME (If any)	
DOSE FORM: Ophthalmic solution	STRENGTHS: 0.025%	ROUTE OF ADMINISTRATION: Ophthalmic/Topical
(PROPOSED) INDICATION(S) FOR USE:		

APPLICATION INFORMATION

APPLICATION TYPE (check one) <input checked="" type="checkbox"/> NEW DRUG APPLICATION (NDA, 21 CFR 314.50) <input type="checkbox"/> ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) <input type="checkbox"/> BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE <input type="checkbox"/> 505 (b)(1) <input checked="" type="checkbox"/> 505 (b)(2)
IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION Name of Drug: Zaditor Holder of Approved Application: Novartis Pharmaceuticals Inc.
TYPE OF SUBMISSION (check one) <input type="checkbox"/> ORIGINAL APPLICATION <input checked="" type="checkbox"/> AMENDMENT TO A PENDING APPLICATION <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> PRESUBMISSION <input type="checkbox"/> ANNUAL REPORT <input type="checkbox"/> ESTABLISHMENT DESCRIPTION SUPPLEMENT <input type="checkbox"/> EFFICACY SUPPLEMENT <input type="checkbox"/> LABELING SUPPLEMENT <input type="checkbox"/> CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT <input type="checkbox"/> OTHER
IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:
IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY <input type="checkbox"/> CBE <input type="checkbox"/> CBE-30 <input type="checkbox"/> Prior Approval (PA)
REASON FOR SUBMISSION: Amendment Form 3542a, Form 3455, font specifications for Drug Facts
PROPOSED MARKETING STATUS (check one) <input type="checkbox"/> PRESCRIPTION PRODUCT (Rx) <input checked="" type="checkbox"/> OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED:	THIS APPLICATION IS <input checked="" type="checkbox"/> PAPER <input type="checkbox"/> PAPER AND ELECTRONIC <input type="checkbox"/> ELECTRONIC
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ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the application.)  
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)
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This application contains the following items: (Check all that apply)

<input checked="" type="checkbox"/>	1. Index
<input checked="" type="checkbox"/>	2. Labeling (check one) <input checked="" type="checkbox"/> Draft Labeling <input checked="" type="checkbox"/> Final Printed Labeling
<input checked="" type="checkbox"/>	3. Summary (21 CFR 314.50 (c))
<input checked="" type="checkbox"/>	4. Chemistry section
<input checked="" type="checkbox"/>	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
<input checked="" type="checkbox"/>	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
<input checked="" type="checkbox"/>	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
<input checked="" type="checkbox"/>	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
<input checked="" type="checkbox"/>	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
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<input checked="" type="checkbox"/>	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
<input checked="" type="checkbox"/>	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
<input checked="" type="checkbox"/>	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
<input checked="" type="checkbox"/>	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
<input checked="" type="checkbox"/>	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
<input checked="" type="checkbox"/>	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
<input checked="" type="checkbox"/>	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
<input checked="" type="checkbox"/>	15. Establishment description (21 CFR Part 600, if applicable)
<input checked="" type="checkbox"/>	16. Debarment certification (FD&C Act 306 (k)(1))
<input checked="" type="checkbox"/>	17. Field copy certification (21 CFR 314.50 (l)(3))
<input checked="" type="checkbox"/>	18. User Fee Cover Sheet (Form FDA 3397)
<input checked="" type="checkbox"/>	19. Financial Information (21 CFR Part 54)
<input checked="" type="checkbox"/>	20. OTHER (Specify) Form 3542a, Form 3455, font specifications for Drug Facts

**CERTIFICATION**

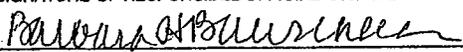
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT 	TYPED NAME AND TITLE Barbara H. Bauschka, Manager, Regulatory Affairs	DATE 03/30/2006
ADDRESS (Street, City, State, and ZIP Code) 6120 Windward Parkway, Suite 290, Alpharetta, GA 30005	Telephone Number 678-527-1330	

Public reporting burden for this collection of information is estimated to average 24 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:

Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Department of Health and Human Services  
Food and Drug Administration  
Center for Biologics Evaluation and Research (HFM-99)  
1401 Rockville Pike  
Rockville, MD 20852-1448

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**ALIMERA**  
SCIENTIFICS

DUPLICATE

**RECEIVED**

MAR 21 2006

**CDER CDR**

March 20, 2006

**RECEIVED**

MAR 22 2006

**CDER White Oak DR1**

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

NEW CORRESPONDENCE

*NOOOC*

**Re: NDA 21-996**  
**Ketotifen Fumarate Ophthalmic Solution, 0.025%**  
**Amended Patent Paragraph IV Certification**

Dear Sir or Madam:

Alimera Sciences, Inc. is providing as requested by Ms. Alison Rodgers, Project Manager, an amendment to NDA 21-996 for Patent Paragraph IV certifications. The amended certification lists all patents that are presently listed in the Orange Book.

If you have any questions or need additional information please contact me at 678-527-1330.

Sincerely,

*Barbara H. Bauschka*

Barbara H. Bauschka  
Manager, Regulatory Affairs

DUPLICATE

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0338  
Expiration Date: September 30, 2008  
See OMB Statement on page 2.

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC,  
OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT

Allimera Sciences, Inc.

DATE OF SUBMISSION

03/20/2006

TELEPHONE NO. (Include Area Code)

678-527-1330

FACSIMILE (FAX) Number (Include Area Code)

678-990-5743

APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):

6120 Windward Parkway, Suite 290  
Alpharetta GA 30005

AUTHORIZED U.S. AGENT NAME AND ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE

MAR 21 2006

NEW CORRESPONDENCE

NOUUC

RECEIVED

CDER CDR

PRODUCT DESCRIPTION

MAR 22 2006

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued)

21-996

ESTABLISHED NAME (e.g., Proper name, USP/USAN name)

ketotifen fumarate ophthalmic solution, 0.025%

CDER White Oak DR1

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any)

CODE NAME (If any)

DOSAGE FORM:

ophthalmic solution

STRENGTHS:

0.025%

ROUTE OF ADMINISTRATION:

ophthalmic topical

(PROPOSED) INDICATION(S) FOR USE:

[ ]

APPLICATION INFORMATION

APPLICATION TYPE

(check one)



NEW DRUG APPLICATION (NDA, 21 CFR 314.50)



ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)



BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE



505 (b)(1)



505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug

Zaditor

Holder of Approved Application

Novartis Pharmaceuticals, Inc.

TYPE OF SUBMISSION (check one)



ORIGINAL APPLICATION



AMENDMENT TO A PENDING APPLICATION



RESUBMISSION



PRESUBMISSION



ANNUAL REPORT



ESTABLISHMENT DESCRIPTION SUPPLEMENT



EFFICACY SUPPLEMENT



LABELING SUPPLEMENT



CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT



OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY



CBE



CBE-30



Prior Approval (PA)

REASON FOR SUBMISSION

Amended Patent Paragraph IV Certification

PROPOSED MARKETING STATUS (check one)



PRESCRIPTION PRODUCT (Rx)



OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED

1

THIS APPLICATION IS



PAPER



PAPER AND ELECTRONIC



ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the application.)

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

[ ]

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

[ ]

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<input type="checkbox"/>	4. Chemistry section
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<input type="checkbox"/>	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
<input type="checkbox"/>	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
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<input type="checkbox"/>	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
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<input type="checkbox"/>	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
<input type="checkbox"/>	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
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<input type="checkbox"/>	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
<input type="checkbox"/>	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
<input checked="" type="checkbox"/>	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
<input type="checkbox"/>	15. Establishment description (21 CFR Part 600, if applicable)
<input type="checkbox"/>	16. Debarment certification (FD&C Act 306 (k)(1))
<input type="checkbox"/>	17. Field copy certification (21 CFR 314.50 (l)(3))
<input type="checkbox"/>	18. User Fee Cover Sheet (Form FDA 3397)
<input type="checkbox"/>	19. Financial Information (21 CFR Part 54)
<input type="checkbox"/>	20. OTHER (Specify) _____

**CERTIFICATION**

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

**Warning:** A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT <i>Barbara H. Bauschka</i>	TYPED NAME AND TITLE Barbara H. Bauschka, Manager Regulatory Affairs	DATE 03/20/2006
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ADDRESS (Street, City, State, and ZIP Code) 6120 Windward Parkway, Suite 290, Alpharetta GA 30005	Telephone Number 678-527-4330
--	----------------------------------

**Public reporting burden for this collection of information** is estimated to average 24 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:

Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Department of Health and Human Services  
Food and Drug Administration  
Center for Biologics Evaluation and Research (HFM-99)  
1401 Rockville Pike  
Rockville, MD 20852-1448

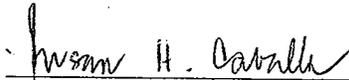
An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Amended Patent Paragraph IV Certification

Applicant hereby certifies that, in its opinion and to the best of its knowledge:

I, Susan Caballa, Vice President of Regulatory and Medical Affairs for Alimera Sciences, certify that U.S. Patent Nos. 6,774,137, 6,776,982, and 6,777,429 are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of eye drops containing Ketotifen Fumarate for which this application is submitted.

Applicant will comply with the requirements under 21 C.F.R. § 314.52(a) with respect to providing a notice to each owner of the patents or their representatives and to the holder of the approved application for the drug product which is claimed by the patents or a use of which is claimed by the patents and with the requirements under 21 C.F.R. § 314.52(c) with respect to the content of the notice.



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Susan Caballa

Vice President Regulatory & Medical Affairs



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-996

**NDA ACKNOWLEDGMENT**

Alimera Sciences, Inc.  
Attention: Barbara H. Bauschka  
Manager  
6120 Windward Parkway, Suite 290  
Alpharetta, GA 30005

Dear Ms. Bauschka:

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

Name of Drug Product: (ketotifen fumarate ophthalmic solution) 0.025%

Date of Application: January 31, 2006

Date of Receipt: February 1, 2006

Review Priority Classification: Standard

Our Reference Number: NDA 21-996

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 April 2, 2006, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be December 1, 2006.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have not fulfilled the requirements. We acknowledge receipt of your request for a waiver of pediatric studies for this application. Once the application has been filed we will notify you whether we have waived the pediatric study requirement for this application.

NDA 21-996

Page 2

Please cite the NDA number listed above 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

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

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

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

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Maureen Dillon-Parker  
3/1/2006 03:15:36 PM  
NDA 21-996 - New NDA Ack Ltr

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0338  
Expiration Date: August 31, 2005  
See OMB Statement on page 2.

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC,  
OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

RECEIVED  
APPLICATION NUMBER

FEB - 3 2006

APPLICANT INFORMATION

NAME OF APPLICANT Allimera Sciences, Inc.	DATE OF SUBMISSION 01/31/2006
TELEPHONE NO. (Include Area Code) 678-527-1330	FACSIMILE (FAX) Number (Include Area Code) 678-990-5743
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued): 6120 Windward Parkway, Suite 290 Alpharetta GA 30005	AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE RECEIVED FEB 01 2006

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued)	CDER/CDER	
ESTABLISHED NAME (e.g., Proper name, USP/USAN name) ketotifen fumarate ophthalmic solution 0.025%	PROPRIETARY NAME (trade name) IF ANY	
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any)	CODE NAME (If any)	
DOSAGE FORM: ophthalmic solution	STRENGTHS: 0.025%	ROUTE OF ADMINISTRATION: ophthalmic topical
(PROPOSED) INDICATION(S) FOR USE:		

APPLICATION INFORMATION

APPLICATION TYPE (check one) <input checked="" type="checkbox"/> NEW DRUG APPLICATION (NDA, 21 CFR 314.50) <input type="checkbox"/> ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) <input type="checkbox"/> BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE <input type="checkbox"/> 505 (b)(1) <input checked="" type="checkbox"/> 505 (b)(2)
IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION Name of Drug: Zaditor Holder of Approved Application: Novartis Pharmaceuticals, Inc.
TYPE OF SUBMISSION (check one) <input checked="" type="checkbox"/> ORIGINAL APPLICATION <input type="checkbox"/> AMENDMENT TO A PENDING APPLICATION <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> PRESUBMISSION <input type="checkbox"/> ANNUAL REPORT <input type="checkbox"/> ESTABLISHMENT DESCRIPTION SUPPLEMENT <input type="checkbox"/> EFFICACY SUPPLEMENT <input type="checkbox"/> LABELING SUPPLEMENT <input type="checkbox"/> CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT <input type="checkbox"/> OTHER
IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:
IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY <input type="checkbox"/> CBE <input type="checkbox"/> CBE-30 <input type="checkbox"/> Prior Approval (PA)
REASON FOR SUBMISSION
PROPOSED MARKETING STATUS (check one) <input type="checkbox"/> PRESCRIPTION PRODUCT (Rx) <input checked="" type="checkbox"/> OVER THE COUNTER PRODUCT (OTC)
NUMBER OF VOLUMES SUBMITTED: 8 THIS APPLICATION IS <input checked="" type="checkbox"/> PAPER <input type="checkbox"/> PAPER AND ELECTRONIC <input type="checkbox"/> ELECTRONIC

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Please see attached sheet for additional information.

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**CERTIFICATION**

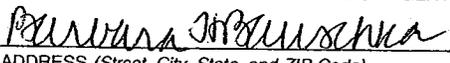
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1401 Rockville Pike  
Rockville, MD 20852-1448

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1 Page(s) Withheld

X § 552(b)(4) Trade Secret / Confidential

       § 552(b)(4) Draft Labeling

       § 552(b)(5) Deliberative Process