PEDIATRIC PAGE

Complete for all original applications and an efficacy supplements

NDA # **NDA 20-809** Applicant: **Alcon Laboratories**
Supplement #
Therapeutic Class **4S**
Circle one: SE1 SE2 SE3 SE4 SE5 SE6
Action: (AP) AE NA
HFD-550

Trade (generic) name/dosage form: Diclofenac Sodium Ophthalmic Solution, 0.1%
Applicant Indication(s) previously approved: **N/A**
Pediatric labeling of approved indication(s) is adequate____ inadequate_____
Indication in this application: for the treatment of postoperative inflammation in patients who have undergone cataract extraction
(For supplements, answer the following questions in relation to the proposed indication.)

_____ 1. **PEDIATRIC LABELING IS ADEQUATE.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for all pediatric subgroups. Further information is not required.

_____ 2. **PEDIATRIC STUDIES ARE NEEDED.** There is potential for use in children, and further information is required to permit adequate labeling for this use.

_____ a. A new dosing formation is needed, and applicant has agreed to provide the appropriate formulation.

_____ b. The applicant has committed to doing such studies as will be required.
____ (1) Studies are ongoing,
____ (2) Protocols were submitted and approved.
____ (3) Protocols were submitted and are under review.
____ (4) If no protocol has been submitted, explain the status on the back of this form.

____ c. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

__X__ 3. **PEDIATRIC STUDIES ARE NOT NEEDED.** The drug/biologic product has little potential for use in children. Explain why pediatric studies are not needed.: The indication is not common in children.

____ 4. EXPLAIN. If none of the above apply, explain, as necessary, on the back of this form.

EXPLAIN, AS NECESSARY, ANY OF THE FOREGOING ITEMS ON THE BACK OF THIS FORM.

/S/ CSO
Signature of Preparer and Title (PM, CSO, MO, other)

April 8, 1998
Date

cc: Original **NDA 20-809**
HFD-550/DIV File
NDA Action Package
HFD-510 G.Troendle (plus, for CDER APs and AEs, copy of action letter and labeling)

NOTE: A new Pediatric Page must be completed at the time of each action even though one was prepared at the time of the last action.
5/95

PART 15. **DEBARMENT STATEMENT**

Pursuant to section 306(k)(1) of the Federal, Food, Drug and Cosmetic Act, Alcon Laboratories, Inc., certifies that, to the best of its knowledge and belief, the applicant did not and will not use in any capacity in connection with this application, the services of any person listed pursuant to section 306(e) as debarred under subsections 306(a) or (b) of the Act.

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

March 6, 1998

Dr. Wiley Chambers
Deputy Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809 Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending NDA

Dear Dr. Chambers:

In response to our discussions with both Ms. Charlote Yaciw and Dr. Hasmukh Patel, please find a revised response to Issue 3 and a revised stability protocol commitment. We have included weight loss as a specification to samples stored in an inverted position.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs

398.fda

FEDERAL EXPRESS AIRBILL 3623413323

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

January 17, 1997

Ms. Joanne Holmes
Project Manager
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%

Dear Joanne:

Per your request, please find 6 additional copies of Summary Volume 1.1.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs

DUPLICATE

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

February 5, 1997

NEW CORRESPONDENCE

Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
12229 Wilkins Avenue
Rockville, Maryland 20852

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%

Dear Sir/Madam:

Pursuant to the provisions of 21 CFR § 314.52(b), Alcon is amending its application to certify that a notice has been been provided to Ciba Geigy Corporation [identified under paragraph (a) of this section] on February 5, 1997. Alcon further certifies that the notice met the content requirement under paragraph (c) of this section.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

ORIGINAL

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

bm
NDA ORIG AMENDMENT

February 6, 1997

Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
12229 Wilkins Avenue
Rockville, Maryland 20852

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending Application

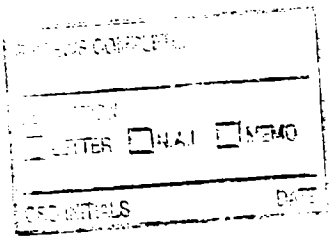
Dear Sir/Madam:

Per Ms. Holmes' request of January 22, 1997, please find attached the formats for SAS variables from the two Diclofenac studies: C-95-16 and C-95-07. The Case Report Forms with annotated SAS variables are also included.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs



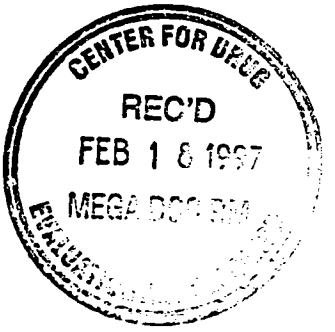
252.fda

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

CERTIFIED MAIL Z 047 936 531
RETURN RECEIPT REQUESTED

February 10, 1997 NEW CORRESPONDENCE



Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products
CDER, HFD-550
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

RE: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%

Dear Madam or Sir:

Per Ms. Holmes' request of February 7, 1997, please find attached a table showing the establishment registration numbers for the facilities cited in the NDA.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa

Susan H. Caballa
Associate Director
Regulatory Affairs

SHC/ple

Attachment

REVIEWS COMPLETED

DATE

DUPLICATE

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

February 21, 1997

NC
NEW CORRESP

Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending Application

Dear Sir/Madam:

Pursuant to the provisions of 21 CFR § 314.52(e), Alcon is amending its application to provide documentation of receipt of the notice of certification of noninfringement of a patent sent to the Ciba Geigy Corporation [identified under paragraph (a) of this section] on February 5, 1997. Ciba Geigy acknowledged receipt of said notice on February 12, 1997. Copy of the certified mail receipt is appended.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Susan H. Caballa
Assoc. Director
Regulatory Affairs

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
FEB 25 1997
MEGA DOC RM

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DUPLICATE

Certified Mail Z 047 936 564
Return Receipt Requested

Alcon LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

NC
NEW CORRESP

March 4, 1997

Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending Application

Dear Sir/Madam:

Pursuant to the provisions of 21 CFR § 314.53(c)(2)(i) and (ii), Alcon is amending its application to provide additional patent information. Patent 5,603,929 was assigned to Alcon Laboratories on February 18, 1997 with an expiration date of November 16, 2014. An original declaration and a copy of the patent are appended.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Susan H. Caballa
Assoc. Director
Regulatory Affairs

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

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DUPLICATE

noted 4/28/97

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

Certified Mail Z047936608
Return Receipt Requested

N C

NEW CORRESP

April 15, 1997

CSO INITIALS DATE
CSO ACTION: ☐ LETTER ☐ N.A.I. ☐ MEMO
REVIEWS COMPLETED

Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products
CDER, HFD-550
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

RE: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%

Dear Madam or Sir:

Per Ms. Holmes' request, please find attached a signature page regarding the above referenced NDA.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Susan H. Caballa
Associate Director
Regulatory Affairs

4/28 [5] orig to Yaeum copy c consult to Sue

SHC/ple

Attachment

REC APR 21 1997 HFD- EVALUATION AND RESEA

ORIGINAL

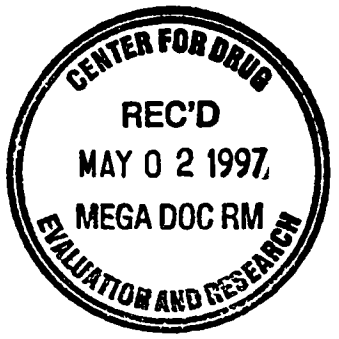
Certified Mail Z 047 936 622
Return Receipt Requested

Alcon LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

SU
NDA ORIG AMENDMENT

April 28, 1997



Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Part 9 - Safety Update Report

Dear Sir/Madam:

Please find enclosed three (3) copies (one Archival, one Clinical review copy and one Pharmacology review copy) of Part 9, four month Safety Update Report for the above referenced NDA which was submitted on December 20, 1996.

I may be reached at (817) 568-6296 should you require further information.

Sincerely,

Susan H. Caballa
Susan H. Caballa
Assoc. Director
Regulatory Affairs

284.fda

REVIEWS COMPLETED
CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO
CSO INITIALS DATE

ORIGINAL

NC

NEW CORRESP

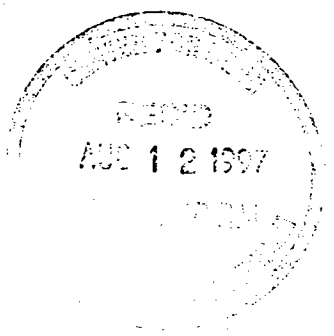
Certified Mail Z 047 939 723
Return Receipt Requested

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

August 6, 1997

Michael Weintraub, M.D.
Acting Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850



Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Intent to Amend

Dear Dr. Weintraub:

Reference is made to your non-approvable letter dated July 29, 1997 for Diclofenac Sodium Ophthalmic Solution, 0.1%. Pursuant to the conditions outlined under 21 CFR 314.120(a)(1), please be advised that Alcon intends to file an amendment to the NDA. This constitutes an agreement on Alcon's part to extend the review period under 21 CFR 314.60. In addition, pursuant to the provisions of 21 CFR 314.102(d), Alcon will be requesting a formal meeting with Agency officials to discuss what further steps need to be taken by Alcon before the application can be approved. The request for a formal meeting with the agenda and meeting participants will be sent under separate cover.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa

Susan H. Caballa
Assoc. Director
Regulatory Affairs

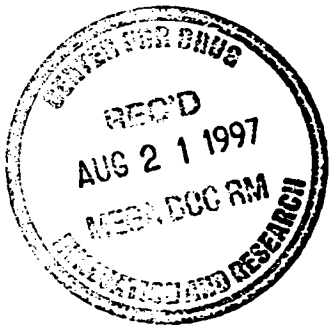
306.fda

ORIGINAL

Certified Mail Z 047 939 726
Return Receipt Requested

Alcon LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450



August 15, 1997

Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending Application

Dear Sir/Madam:

Pursuant to the provisions of 21 CFR § 314.53(c)(2)(i) and (ii), Alcon is amending its application to provide additional patent information. Patent 5,653,972 was assigned to Alcon Laboratories on August 5, 1997 with an expiration date of November 16, 2014. An original declaration and a copy of Patent 5,653,972 are appended.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs

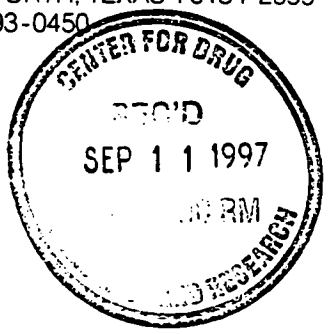
312..fda

AirBorne Express 2204148262

ORIGINAL

Alcon LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450



September 10, 1997

Michael Weintraub, M.D.
Acting Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending Application

Dear Dr. Weintraub:

On behalf of Alcon, I would like to start by expressing our appreciation to you and your staff for taking the time to meet with us to review your non-approvable letter of July 29, 1997 and the comments/suggestions by Dr. Chambers in our telephone conversation of August 29, 1997. It was a very productive meeting which I believe resolved all the clinical issues. A copy of the minutes is enclosed as Attachment 1. I would like to request a copy of your minutes for our files.

As agreed at the meeting, the materials presented are being submitted as a formal amendment to the NDA (Attachment 2). Under separate cover, an electronic version of the Alcon presentation in Word 6.0 is being forwarded to Ms. Lissante C. LoBianco, Acting Supervisory Project Manager.

Our response to your request for additional CMC information is provided in Attachment 3. We have already responsed to issue number 15 on August 20, 1997.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa

Susan H. Caballa
Assoc. Director
Regulatory Affairs

cc: Dr. W. Chambers
Dr. E. Ludwig
Ms. L. LoBanco

316.fda

ORIGINAL

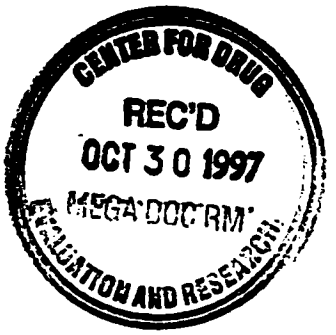
Certified Mail Z 047 939 773
Return Receipt Requested

6L
ORIG AMENDMENT

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

October 24, 1997



Ms. Lissante C. LoBianco
Regulatory Health Project Manager
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending Application

Dear Lissante:

In response to your telephone request on October 21, 1997, please find your desk copy of the mock labeling (carton and primary container label) for the 2.5 mL and 5.0 mL sizes. This product will be marketed by Falcon Ophthalmics, Alcon's generic marketing arm. Falcon is located in Alcon's corporate headquarters in Fort Worth.

If you need additional information, please do not hesitate to contact me at (817) 568-6296.

Sincerely,

Susan H. Caballa
Susan H. Caballa
Assoc. Director
Regulatory Affairs

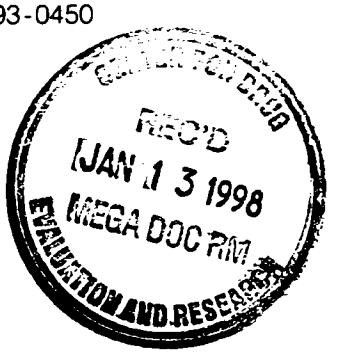
332.fda

Certified Mail Z 047 937 899
Return Receipt Requested

NC
NEW CORRESP

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450



January 6, 1998

Wiley A. Chambers, M.D.
Deputy Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Intent to Amend

Dear Dr. Chambers:

Reference is made to your approvable letter dated January 5, 1998. Pursuant to the conditions outlined under 21 CFR 314.120(a)(1), please be advised that Alcon intends to file an amendment to the NDA. This constitutes an agreement on Alcon's part to extend the review period under 21 CFR 314.60.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs

354.fda

Airborne Express 9768768656

Courtesy Copy

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

ORIGINAL

AZ

ORIG AMENDMENT

January 30, 1998

Wiley A. Chambers, M.D.
Deputy Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%

Dear Dr. Chambers:

Attached please find our response to the approvable letter dated January 5, 1998. Included are: revised labeling (package insert, carton and label), an updated stability report which supports expiry dating of 18 and 24 months for the 2.5 and 5 mL fill sizes, respectively, a revised post approval stability protocol which addresses the stability of the product when stored in both the upright and inverted positions, and a revised "Paragraph IV Certification" which addresses United States Patent No. 4,960,799.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Susan H. Caballa
Assoc. Director
Regulatory Affairs

Airborne Express 9768768752

363.fda

BZ

ORIG AMENDMENT

ORIGINAL

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

February 24
ruary 24 1998

ey A. Chambers, M.D.
puty Director
ision of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
nter for Drug Evaluation and Research
od and Drug Administration
cument Control Room
01 Corporate Boulevard
ckville, Maryland 20850

: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%

ear Dr. Chambers:

er Ms. Lori Gorsky's request of February 20, 1998, please find four copies of the Methods alidation Package: one archival copy, one review copy and two field copies. I have included ie latest draft labeling (container, carton and package insert) submitted in our January 30, 1998 mendment.

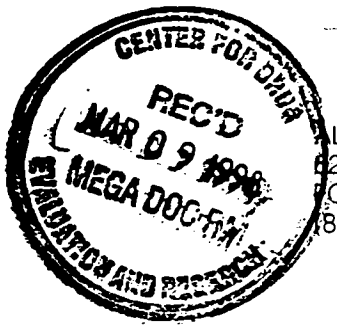
may be reached at (817) 568-6296 should you require additional information.

iincerely,

Susan H. Caballa
Susan H. Caballa
Assoc. Director
Regulatory Affairs

382.fda
AirBorne Express 9768766254

ORIGINAL



ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

February 27, 1998

Dr. Wiley Chambers
Deputy Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809 Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending NDA

Dear Dr. Chambers:

In response to Ms. Charlotte Yaciw's telephone request of February 26, 1998, please find a revised response to Issue 3 and a revised stability protocol commitment. We have included a diclofenac assay to samples stored in an inverted position.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa

Susan H. Caballa
Assoc. Director
Regulatory Affairs

385.fda

NEW CORRESP

DUPLICATE

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

March 3, 1998

Ms. Lori Gorski
Project Manager
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
General Correspondence

Dear Lori:

Per my conversation with Ms. Charlotte Yaciw yesterday, please find better art copies of the carton and container label for the professional sample size. I have been assured by our Art Department that the final printed labeling will be more readable because of the color contrast that will be used.

If these are acceptable, we can go ahead and order final printed labeling and will forward them to you once they become available.

Thank you for forwarding these to Ms. Yaciw.

I may be reached at (817) 568-6296 should you require further information.

Sincerely,

Susan H. Caballa
Susan H. Caballa
Assoc. Director
Regulatory Affairs

391.fda

March 4, 1998

NEW CORRESPONDENCE

ORIGINAL

Hasmukh B. Patel, Ph.D.
Chemistry Team Leader
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to Pending NDA

Dear Dr. Patel,

Reference is made to the revised stability protocol commitment submitted to the FDA February 27, 1998. As discussed today with Mr. Scott Krueger, Alcon agrees to revise its stability protocol to monitor weight loss for samples stored in an inverted position for the first three production batches.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Associate Director
Regulatory Affairs

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

March 6, 1998

Dr. Wiley Chambers
Deputy Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809 Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending NDA

Dear Dr. Chambers:

In response to our discussions with both Ms. Charlote Yaciw and Dr. Hasmukh Patel, please find a revised response to Issue 3 and a revised stability protocol commitment. We have included weight loss as a specification to samples stored in an inverted position.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs

398.fda

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

March 13, 1998

Dr. Wiley Chambers
Deputy Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809 Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending NDA

Dear Dr. Chambers:

Per my conversation with Ms. Lori Gorski today, Alcon agrees to revise the Rx legend in the container label, carton and package insert to state "Rx Only" in accordance with the FDA Modernization Act.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs

409.fda

NC
DUPLICATE

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

April 21, 1998

Dr. Wiley Chambers
Deputy Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809 Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending NDA

Dear Dr. Chambers:

Per your telephone request of April 13, 1998, please find additional information on the three cases of endolphthalmitis cited in the Safety Update Report submitted on April 6, 1998. In each of these three cases, the investigators deemed the infection to be not related or unlikely to be related to the study medication.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs

438.fda

BM

NC

NEW CORRESP

DUPLICATE

Alcon LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

April 22, 1998

Dr. Wiley Chambers
Deputy Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809 Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending NDA

Dear Dr. Chambers:

Per your telephone request today, we broke the code for the 3 reported cases of endophthalmitis.

Patient Number	Country	Study Drug
816	France	Voltaren (CIBA)
616	Germany	Diclofenac (Alcon)
110	Mexico	Diclofenac (Alcon)

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs

440.fda

Airborne Airbill
#5278770125

BL
ORIG AMENDMENT
DUPLICATE

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

April 27, 1998

Dr. Wiley Chambers
Deputy Director
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809 Diclofenac Sodium Ophthalmic Solution 0.1%
Amendment to a Pending NDA

Dear Dr. Chambers:

Please find attached a true art copy of the package insert for Diclofenac Sodium Ophthalmic Solution, 0.1%. This is identical to the draft labeling submitted on January 30, 1998, except for changing the prescription legend to read "Rx Only" as per the new regulations and using all capital letters for VOLTAREN OPHTHALMIC® and CIBA VISION OPHTHALMICS®.

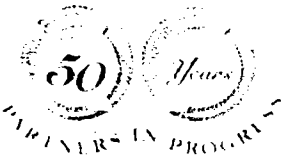
I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa

Susan H. Caballa
Assoc. Director
Regulatory Affairs

441.fda



550 HOLMES

NDA 20-809

JAN - 9 1997

Alcon Laboratories, Inc.
Attention: Susan H. Caballa
Associate Director, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Caballa:

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: Diclofenac sodium ophthalmic solution, 0.1%

Therapeutic Classification: Standard

Date of Application: December 20, 1996

Date of Receipt: December 23, 1996

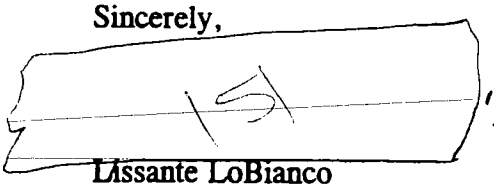
Our Reference Number: 20-809

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on February 21, 1997, in accordance with 21 CFR 314.101(a).

If you have any questions, please contact Joanne M. Holmes, M.B.A., Project Manager, at (301) 827-2090.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

Sincerely,



1/9/97

Lissante LoBianco
Acting Supervisory Project Manager
Division of Anti-Inflammatory, Analgesic, and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:
Original NDA 20-809
HFD-550/Div. Files
HFD-550/Clin Rev/Holmes
HFD-550/SPMS/LoBianco
HFD-550/Acting Div Dir/Chambers
DISTRICT OFFICE

1/8/97

Drafted by: jh/January 8, 1997/20809ack.dic
Final:

ACKNOWLEDGEMENT (AC)

APPEARS THIS WAY
ON ORIGINAL

DUPLICATE
NEW CORRESP

NC

FEDERAL EXPRESS WAYBILL 3623413290

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

January 6, 1997

Ms. Joanne Holmes
Project Manager
Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%

Dear Joanne:

Please find the CANDA for the above named NDA submitted on December 20, 1996. The entire dossier is in Wordperfect 5.1/5.2 on 3.5 inch micro-diskettes. Additionally, the Case Report Tabulations are provided in Lotus 1-2-3 spreadsheets on the same media. The clinical biostatistics SAS data sets are also provided electronically on 3.5 inch micro-diskettes. The electronic version is a true copy of the hard copy. Please note one exception: in the appendix to Part 3.B.7, Tab. 26, the hard copy indicates version 0 (handwritten); the electronic version will indicate version 1. The text however is identical to the electronic version.

I may be reached at (817) 568-6296 should you require additional information.

Sincerely,

Susan H. Caballa

Susan H. Caballa
Assoc. Director
Regulatory Affairs

Alcon
LABORATORIES

December 20, 1996

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

Division of Analgesic, Anti-Inflammatory and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
12229 Wilkins Avenue
Rockville, Maryland 20852

Re: NDA 20-809
Diclofenac Sodium Ophthalmic Solution 0.1%
Original New Drug Application

Dear Sir/Madam:

Pursuant to the provisions of Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, and 21 CFR 314.54, a New Drug Application (NDA) for Diclofenac Sodium Ophthalmic Solution 0.1% is hereby submitted. The drug product is an ophthalmic solution indicated for the treatment of postoperative inflammation in patients who have undergone cataract extraction.

Majority of the preclinical and clinical information in support of the safety and efficacy of this drug product are based on published literature and studies conducted by Geigy in support of Voltaren® tablets (NDA-19-201) and studies conducted by Ciba Vision Ophthalmics in support of Voltaren Ophthalmic Solution (NDA 20-037). The applicant is submitting the application under Section 505(b)(2) since the studies relied upon by the applicant were not conducted by or for the applicant and the applicant has not obtained a right of reference or use from the persons who conducted the investigations.

The Prescription Drug User Fee Act of 1992 does not require an applicant to pay a fee for an application filed under Section 505(b)(2) unless the application is for a new molecular entity which is an active ingredient or an indication for a use that has not been approved under a Section 505(b) application. This 505(b)(2) application therefore does not require a user fee because diclofenac sodium, the active ingredient, is not a new molecular entity (approved in NDAs cited above). The indication for treatment of postoperative inflammation after cataract surgery has been approved under NDA 20-037.

The application consists of an Archival and Technical Review copy. The Archival copy consists of 14 volumes and an overall index is located in Volume 1.1. The Technical Review copy consists of volumes for:

Chemistry
Pharmacology
Human Pharmacokinetics
Microbiology (Aseptic Manufacturing Processes)
Clinical
Statistics

We are holding three copies of the Methods Validation Package and will send them upon FDA request.

A copy of the Chemistry and Microbiology sections have been sent to the District Office in Dallas, Texas.

Pagination: The document is consecutively paginated in the lower right hand corner. The page number is made up of two parts. An example is page "3-0012". The "3" represents the item number corresponding to Part 3, Chemistry, Manufacturing and Controls Section (Form 356h) and "0012" is the consecutive page number within the CMC section.

CANDA: A desk copy will be provided under separate cover which consists of the entire dossier in Wordperfect 5.1/5.2 on 3.5 inch micro-diskettes. Additionally, the Case Report Tabulations will be provided in Lotus 1-2-3 spreadsheets on the same media. The clinical biostatistics SAS data sets are also provided electronically on 3.5 inch micro-diskettes. These diskettes will be sent to the attention of Ms. Joanne Holmes, Project Manager. The electronic version is a true copy of the hard copy. Please note one exception: in the appendix to Part 3.B.7, Tab. 26, the hard copy indicates version 0 (handwritten); the electronic version will indicate version 1. The text however is identical to the electronic version.

GLP Compliance Statements: In Part 2.E., Summary of Nonclinical Pharmacology & Toxicology, copies of the GLP Compliance Statements, which can be found in Part 5, are reproduced.

If there are any questions regarding the content or format of this application or CANDA, please contact me at (817) 568-6296. If I am not available and you need a response to your inquiry, please contact Cheryl Anderson at (817) 551-4325.

Sincerely,

Susan H. Caballa
Assoc. Director
Regulatory Affairs

cc: Ms. Joanne Holmes, Project Manager, HFD-550