CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 21-537/S-008

Trade Name: Ciprodex

Generic Name: Ciprofloxacin 0.3% and dexamethasone 0.1% sterile otic solution

Sponsor: Alcon Pharmaceuticals Ltd.

Approval Date: May 22, 2013

Indications: Provides for the use of Ciprodex Sterile Otic Suspension for the treatment of:

1. Acute Otitis Media in pediatric patients (age 6 months and older) with tympanostomy tubes due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis,* and *Pseudomonas aeruginosa*.
2. Acute Otitis Externa in pediatric patients (age 6 months and older), adults and elderly patients due to *Staphylococcus aureus and Pseudomonas aeruginosa.*

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NDA 21-537/S-008

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APPLICATION NUMBER:

NDA 21-537/S-008

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21537/S-008

APPROVAL LETTER

Alcon Pharmaceuticals, Ltd.
Attention: Peter Parsonson
Associate Director, Regulatory Affairs
6201 South Freeway, R3-52
Fort Worth, TX 76134-2099

Dear Mr. Parsonson:

Please refer to your Supplemental New Drug Application (sNDA) dated November 21, 2012, received November 23, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ciprodex® (ciprofloxacin 0.3% and dexamethasone 0.1%) Suspension.

This "Changes Being Effected in 30 days" supplemental new drug provides for: 1) change in the expiry for the drug product from (b) (4) to 18 months in order to comply with ICH and USP "controlled room temperature" storage conditions and 2) the storage condition is being updated to the current USP defined "controlled room temperature" to now read, "Store at 20°-25 °C (68-77 °F); excursions permitted to 15-30 ° C (59-86 °F) [see USP Controlled Room Temperature]. Avoid freezing. Protect from light."

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Althea Cuff, Regulatory Health Project Manager, at (301) 796-4061.

Sincerely,

{See appended electronic signature page}

Thomas F. Oliver, Ph.D.
Branch Chief, Branch VI
Division of New Drug Quality Assessment II
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

THOMAS F OLIVER
05/22/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-537/S-008

CHEMISTRY REVIEW(S)

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER
	ONDQA Div II, Branch VI HFD-530	**21-537 / S-008**

3. NAME AND ADDRESS OF APPLICANT		4. COMMUNICATION, DATE	
Applicant name:	Alcon Research, Ltd.	**CBE-30**	
Address:	6201,South Freeway Fort Worth, TX 76134-2099	Letter date: Stamp date: Received by reviewer: PDUFA due date:	21 November 2012 23 November 2012 7 December 2012 23 May 2013

5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE
CIPRODEX®	Ciprofloxacin and Dexamethasone	

8. SUPPLEMENT PROVIDES FOR:

1) a change in the expiry dating for the product from [redacted] (b) (4) to 18 months in order to comply with ICH and USP "controlled room temperature" storage conditions and 2) the storage condition is being updated to the current USP defined "controlled room temperature" to now read, "Store at 20°-25 °C (68-77 °F); excursions permitted to 15-30 ° C (59-86° F) [see USP Controlled Room Temperature]. Avoid freezing. Protect from light."

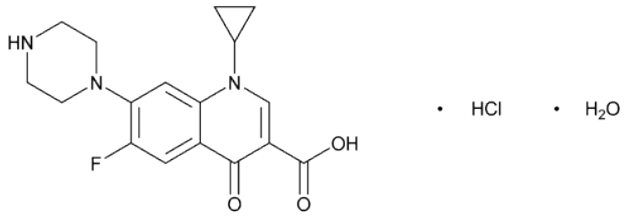
9. PHARMACOLOGICAL CATEGORY:	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
Antibacterial/ Anti-inflammatory	Rx	
12. DOSAGE FORM	**13. POTENCY**	
Sterile Otic Suspension	Ciprofloxacin 0.3% Dexamethasone 0.1%	

14. CHEMICAL NAME AND STRUCTURE

Chemical name: 1-Cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid, monohydrochloride, monohydrate

Formula: $C_{17}H_{18}FN_3O_3 \cdot HCl \cdot H_2O$

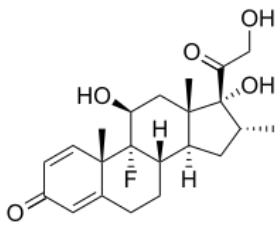
M.W: 385.82



Chemical name: 9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione

Formula: $C_{22}H_{29}FO_5$

MW: 392.47



15. COMMENTS		
During routine stability testing of CIPRODEX Lot 183106F, [redacted] (b) (4) Therefore, the applicant proposed for a change in the expiry dating for the product from [redacted] (b) (4) to 18 months. The proposed change of the expiry to 18 months is acceptable. Additionally, the applicant proposed a change from "Store at controlled room temperature, 15°C to 30°C (59°F to 86°F)" to the current USP defined "controlled room temperature", "Store at 20°-25°C (68-77°F); excursions permitted to 15-30°C (59- 86°F) [see USP Controlled Room Temperature] to the current USP, Avoid freezing. Protect from light." The proposed update of the storage condition to the current USP defined controlled room temperature is acceptable. The proposed update of storage condition is captured in the carton and container labels. Hence, this supplement is recommended for approval.		
16. CONCLUSION AND RECOMMENDATION		
Approval		
17. NAME	**18. REVIEWERS SIGNATURE**	**19. DATE COMPLETED**
Yong Wang	See appended electronic signature sheet	05-20-2013
DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE		

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/s/

YONG WANG
05/20/2013

THOMAS F OLIVER
05/20/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-537/S-008

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21537/S-008

CBE-30 SUPPLEMENT

Alcon Pharmaceuticals, Ltd.
Attention: Peter Parsonson
Associate Director, Regulatory Affairs
6201 South Freeway, R3-52
Fort Worth, TX 76134-2099

Dear Mr. Parsonson:

We have received your November 21, 2012, Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER: 21537

SUPPLEMENT NUMBER: 008

PRODUCT NAME: Citrodex® (ciprofloxacin 0.3% and dexamethasone 0.1%) Suspension

DATE OF SUBMISSION: NOVEMBER 21, 2013

DATE OF RECEIPT: NOVEMBER 23, 2013

This supplemental application, submitted as a "Changes Being Effected in 30 days" supplement, proposes the following change(s): : 1) change in the expiry for the drug product from (b) (4) to 18 months in order to comply with ICH and USP "controlled room temperature" storage conditions and 2) the storage condition is being updated to the current USP defined "controlled room temperature" to now read, "Store at 20o-25oC (68-77oF); excursions permitted to 15-30oC (59-86oF) [see USP Controlled Room Temperature]. Avoid freezing. Protect from light."

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 January 22, 2013, in accordance with 21 CFR 314.101(a).

If the application is filed, the user fee goal date will be May 23, 2013.

Cite the application 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 Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

If you have any questions, call me at (301) 796-4061.

Sincerely,

{See appended electronic signature page}

Althea Cuff, MS
Regulatory Health Project Manager
Branch V, Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

ALTHEA CUFF
12/19/2012