021537_Original Approval_ Package.PDF

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Approval Package for:

APPLICATION NUMBER:

21-537

Trade Name: Ciprodex

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

Sponsor: Alcon Research, Ltd.

Approval Date: July 18, 2003

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 *Staphylococus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis,* and *Pseudomonas aeruginosa.*

2. Acute Otitis Externa in pediatric patients (age 6 months and older), adult and elderly patients due to *Staphylococus aureus* and *Pseudomonas aeruginosa.*

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APPLICATION NUMBER:

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Reviews / Information Included in this NDA Review.	
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Pharmacology Review(s)	X
Statistical Review(s)	X
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APPLICATION NUMBER:

21-537

APPROVAL LETTER(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-537

Alcon Research, Ltd.
Attention: Seane D. Jones, MS, RAC
Assistant Director, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Ms. Jones:

Please refer to your new drug application (NDA) dated September 23, 2002, received September 25, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for CIPRODEX®(ciprofloxacin 0.3% and dexamethasone 0.1%) Sterile Otic Suspension.

We acknowledge receipt of your submission(s) dated:

September 23, 2002	January 21, 2003	May 5, 2003	July 17, 2003
October 2, 2002	March 12, 2003	May 30, 2003	
October 31, 2002	March 28, 2003	June 24, 2003	
November 18, 2002	April 29, 2003	July 03, 2003	

This new drug application 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 (age 6 months and older), adult and elderly patients due to *Staphylococcus aureus* and *Pseudomonas aeruginosa.*

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (enclosed).

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this

submission "FPL for approved NDA 21-537." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call LT Daniel Nguyen, Regulatory Health Project Manager at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure

APPEARS THIS WAY
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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.

/s/

Janice Soreth
7/18/03 02:37:52 PM

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