NDA 19-157

S-016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-157/S-016

Medeva Pharmaceuticals
Attention: Robert B. Parker, Ph.D.
Senior Director, Regulatory Affairs
755 Jefferson Road
P.O. Box 1710
Rochester, New York 14603-1710

Dear Dr. Parker:

Please refer to your September 22, 1997, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pediapred (prednisolone sodium phosphate solution) Oral Solution.

We acknowledge receipt of your amendment dated January 5, 1998.

The supplemental application provides for the labeling for outer cartons.

We have completed the review of this supplemental application and it is approved.

This approval affects only the changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

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, please contact Sharon Schmidt, Project Manager, at 301-827-2536.

Sincerely,

1-21-98

John E. Hyde, Ph.D., M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic,
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:
NDA 19-157
HFD-550/Div. Files
DISTRICT OFFICE
HFD-92
HFD-105
HFD-550/Chem/S. Lin
HFD-550/Chem TL/H.Patel
HFD-550/Proj Mgr/S. Schmidt
HFD-830/Div Dir/C.Chen

Drafted by: Lin/January 7, 1998
File name: n:\chemists\Lin\nda19157.s16

APPROVAL (AP)

Chemistry Review	1. Division HFD-550	2. NDA Number 19-157
3. Name and Address of Applicant Medeva Pharmaceuticals 755 Jefferson Road P.O. Box 1710 Rochester, New York 14603-1710		4. Supplement Number Date SLR-016 9/22/97 Stamp Date: 9/23/97
5. Name of Drug Pediapred® Oral Solution	6. Nonproprietary Name prednisolone sodium phosphate	
7. Supplement Provides for: labeling for an outer carton		8. Amendment(s) 1/5/98
9. Pharmacological Category Glucocorticoid	10. How Dispensed ℞	11. Related Documents
12. Dosage Form Oral solution	13. Potency(ies) 6.7 mg/5 mL	

14. Chemical Name and Structure see USAN

15. Comments

In place of current shipper partitions, glass bottles of Pediapred are to be packaged in individual outer cartons. New outer cartons will provide added protection to the bottles from breakage. The text proposed in this supplement for the outer carton is the same as appears on the immediate container for the product **except** the address and the register trademark affiliation (see attached 11/18/97 fax to the sponsor). In the 1/5/98 amendment, the sponsor has made commitment to update the immediate container label to be consistent with the proposed outer carton labeling, and report the changes in the annual report.

16. Conclusions and Recommendations
Issue approval letter.

17. Name	Signature	Date
Sue-Ching Lin		1/7/98
Concurrence Hasmukh Patel, Ph.D., Team Leader		1-8-98

cc:
NDA 19-157
HFD-550/Division File
HFD-550/S Lin
HFD-550/Schmidt
HFD-830/C-w Chen

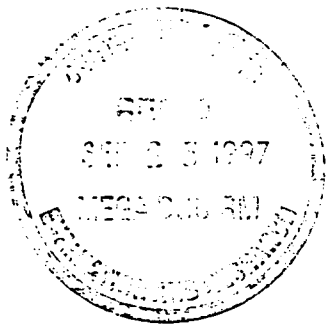
Doc ID: wordfile\nda\19157cr.S16

MEDEVA
PHARMACEUTICALS

Medeva Pharmaceuticals Mfg., Inc.
755 Jefferson Road
Post Office Box 1710
Rochester, New York 14603

Telephone: (716) 475-9000
Fax: (716) 475-1016

NDA NO. 19-157 REF. NO. 6
NDA SUPPL NO. 6



Federal Express 286/97

September 22, 1997

Wiley Chambers, M.D.
Director
Division of Analgesic, Anti-Inflammatory & Ophthalmic Drug Products, HFD-550
Attn: Document Control Room
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 19-157
Pediapred® (prednisolone sodium phosphate, USP) Oral Solution

Labeling Supplement - Expedited Review Requested

Dear Dr. Chambers:

Reference is made to the new drug application cited above approved on May 28, 1986. In accordance with CFR §314.70(b)(3), Medeva is hereby submitting a supplement, expedited review requested, to provide labeling for an outer carton to be used with Pediapred® Oral Solution.

This outer carton will be a new labeling component. Currently, glass bottles of Pediapred are not packaged in individual outer cartons. The use of a carton will provide added protection to the bottle from breakage in place of current shipper partitions. Medeva believes that by packaging each bottle in an individual outer carton, product quality and packaging efficiency will be enhanced. The text proposed on the carton is the same text as appears on the immediate container for the product.

Medeva would like to implement use of these cartons as soon as possible, and is therefore requesting expedited review of this supplement. Four copies of draft labeling (including color proofs) are enclosed.

Form FDA 356h and User Fee Form FDA 3397 are provided on the following pages.

In accordance with 21 CFR §314.71(b), a copy of this supplement is being provided under separate cover to the Buffalo District Office.

If you have any questions regarding this submission or Pediapred® Oral Solution, please contact Andrew Morgan, R.Ph., Director of Labeling and Advertising Compliance, or the undersigned.

Very truly yours,

Robert B. Parker for

Cheryl A. Rini
Manager, Regulatory Affairs

Attachments

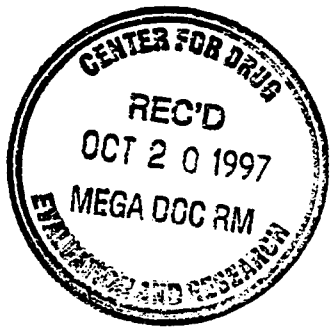
Field Copy: Ms. Cynthia Maciejewski
Acting Director, Buffalo District Office

MEDEVA
PHARMACEUTICALS

Medeva Pharmaceuticals Mfg., Inc.
755 Jefferson Road
Post Office Box 1710
Rochester, New York 14603

Telephone: (716) 475-9000
Fax: (716) 475-1016

NDA NO. 19157 REF. NO. SUPPL
NDA SUPPL FOR Labeling
ORIGINAL



Hand Delivered 331/97

October17, 1997

Wiley Chambers, M.D.
Director
Division of Analgesic, Anti-Inflammatory & Ophthalmic Drug Products, HFD-550
Attn: Document Control Room N115
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

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Very truly yours,

Cheryl Rini

Cheryl A. Rini
Manager, Regulatory Affairs

Attachments

Field Copy: Ms. Cynthia Maciejewski
Acting Director, Buffalo District Office

Desk Copy: Chin Koerner, Project Manager
Division of Analgesic, Anti-Inflammatory and Opthalmic Drug Products