

ENCLOSURE C

ANDA 75-117

December 14, 2000

Ascent Pediatrics
Attention: William E. Brochu, Ph.D.
187 Ballardvale Street, Suite B125
Wilmington, MA 01887

Dear Sir:

This is in reference to your abbreviated new drug application dated April 21, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Orapred (Prednisolone Sodium Phosphate Oral Solution), 15 mg (base)/5 mL).

Reference is also made to your amendments dated February 3, September 18, November 19, December 11, and December 14, 1998; and February 11, March 10, July 14, September 21, September 29, October 16, October 23, and December 11, 2000. Reference is also made to the suitability petition submitted under Section 505(j)(2)(C) of the Act and approved on November 4, 1987, permitting you to file this ANDA for a drug product that differs in strength from the reference listed drug product (RLD).

The RLD referenced in your application, PEDIAPRED Oral Solution of Medeva Pharmaceuticals, Inc., is subject to a period of patent protection which expires on December 22, 2002 (U.S. Patent No. 4,448,774, the '774 patent). Your application contains a patent certification to the '774 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on the patent. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Ascent Pediatrics (Ascent) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Ascent within the statutory forty-five day period.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The drug product, Orapred, can be expected to have the same therapeutic effect as that of an equivalent dose of the reference listed drug product upon which the Agency relied as the basis of safety and effectiveness.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies which may be identified.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

certified 196. 37

FISONS

Fisons Corporation
Two Preston Court
Bedford, Massachusetts 01730
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July 1, 1987

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 4-62
5600 Fishers Lane
Rockville, MD 20857

CITIZENS PETITION

Fisons Corporation submits this petition in accordance with 21 CFR §10.30 to request that the Commissioner of Food and Drugs issue a regulation amending the list of drug products for which the FDA has found that abbreviated new drug applications (ANDA's) are acceptable [21 CFR §314.55(b)(c)(d)].

A. Action Requested

Fisons Corporation requests that the Food and Drug Administration issue a determination of the suitability for submitting an abbreviated new drug application (ANDA) for a prednisolone sodium phosphate solution containing prednisolone sodium phosphate 15 mg prednisolone base/5 mL. This action can be found specified in 21 CFR §314.55 (b)(c), and (d).

B. Statement of Grounds

The seventh edition of Approved Drug Products with Therapeutic Equivalency Evaluations contains several oral prednisolone or prednisolone sodium phosphate products, which are compared with the product being proposed for ANDA suitability in the following table .

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Fisons Corporation

TABLE I

Product Proposed for ANDA Suitability	Other Prednisolone Sodium Phosphate Product	Related Drug Products Approved for ANDA Suitability
Prednisolone Sodium Phosphate Oral Solution 15 mg prednisolone base/5 mL.	Prednisolone Sodium Phosphate Oral Solution 5 mg prednisolone base/5 mL.	Prednisolone Oral Syrup 15 mg/5 mL Prelone syrup Muro (NDA 89-081)
	PEDIAPRED® Oral Liquid (Fisons Corporation NDA 19-157)	Prednisolone Oral Syrup 5 mg/5 mL LIQUID PRED Muro (NDA 87-611)0
		Prednisolone Oral Solution 5 mg/5 mL Prednisolone Roxane Labs (NDA 88-703)
		Prednisone Oral Syrup 5 mg/mL PREDNISONO INTERSOL Rexene Labs (NDA 88-810)

The proposed product is intended as an alternative dosage strength to our existing approved product (prednisolone sodium phosphate 5 mg prednisolone base/5 mL) PEDIAPRED® Oral Liquid. This petition requesting ANDA eligibility for a new strength of an existing prednisolone oral product is similar to that approved on December 8, 1986 for Muro Pharmaceuticals' 5 mg/5 mL prednisolone syrup (Docket No. 86 P-0399/CP).

The proposed product will allow greater flexibility in prescribing, producing better patient compliance in an area where acceptance of other forms, such as tablet or suspension, is difficult.

All packaging items of the proposed drug would be equivalent to the approved product (prednisolone sodium phosphate 5 mg prednisolone base/5 mL - PEDIAPRED Oral Liquid) and Labeling would be identical save in those aspects needing adjustment in view of the concentration change.

Certified 196/87

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July 1, 1987

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Fisons Corporation

C. Environmental Impact

Prednisolone sodium phosphate is a well-known and well used compound with a known structure, pharmacological profile, and indications comparable with drug products already marketed by many manufacturers. The introduction of the 15 mg prednisolone base/5 mL product will not change the overall pattern of use of prednisolone or prednisolone sodium phosphate containing products. No impact on the environment, as defined in 21 CFR §25, should thus follow from introduction after ANDA eligibility determination and ANDA approval is obtained.

D. Economic Impact

Information on the economic impact of this product, as covered in 21 CFR §10.30, is not applicable to the subject of this petition.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



John Glasby
Director, Regulatory Compliance
Fisons Corporation
2 Preston Court
Bedford, MA 01730

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Enclosures: Approved Drug Products with Therapeutic Equivalency
7th Edition, pages 3-199 to 3-203, 3-294



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

1500 F
Fisons Corporation
Attention: Mr. John Glasby
Two Preston Court
Bedford, MA 01730

NOV 4 1987

Docket 87P-0235/CP

Dear Mr. Glasby:

Reference is made to your petition filed July 14, 1987 requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Prednisolone Sodium Phosphate Oral Solution, eq to 15 mg base/5 mL. The listed drug product to which you refer in your petition is Prednisolone Sodium Phosphate Oral Solution eq to 5 mg base/5 mL manufactured by your firm.

We have reviewed your petition under Section 505(j)(2)(C) of Federal Food, Drug, and Cosmetic Act (Act), and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced product.

Your request involves a change in strength from the listed reference drug product (i.e., from 5 mg/5 mL to 15 mg/5 mL). The type of change you request is the type of change authorized under Section 505(j)(2)(C) of the Act.

Under Section 505(j)(2)(C)(i) of the Act the Agency will approve a petition seeking a strength which differs from the strength of the listed reference drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The Agency has determined that the change in strength for this specific product does not pose questions of safety or effectiveness. The basis for this determination is that although you propose a change in concentration from 5 mg/5 mL to 15 mg/5 mL, the doses, uses and administration of the proposed product are the same as those of the listed product. The labeling of the listed drug product indicates that doses may vary from 5 mL-60 mL (5 mg-60 mg) per day. In addition, for certain disease states doses of up to 200 mL (200 mg) daily may be required. Your proposed product is merely offered as an alternative dosage strength designed for patients who, because of their individual dosage requirements, would require volumes of 15 mL or larger of the listed drug product. Thus, there are no investigations that would be required to demonstrate safety or effectiveness of the proposed product and therefore, an ANDA may be submitted.

The approval of this petition to allow an ANDA to be submitted for the above referenced product does not mean that the Agency has determined that the ANDA will be approved for the product. The determination that an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

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To permit review of your ANDA submission you must submit all information required under Section 505(j)(2)(A) and (B) of the Act. To be approved the product will, among other things, be required to meet current bioequivalence requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you contact the Director, Division of Bioequivalence at (301) 443-0181 to determine the specific requirements for this product. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the petition docket number above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, HFA-305, Room 4-62.

Sincerely yours,



Peter H. Rheinstein, M.D., J.D., M.S.
Director, Office of Drug Standards
Center for Drugs and Biologics