

021503\_ Original Approval - Package . PDF

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

**APPLICATION NUMBER:**

**21-503**

***Trade Name:*** Viracept

***Generic Name:*** Nelfinavir mesylate 625 mg tablets

***Sponsor:*** Agouron Pharmaceuticals, Inc, A Pfizer Company

***Approval Date:*** April 30, 2003

***Indications:*** Provides for the use of Viracept (nelfinavir mesylate) 625 mg tablets for the treatment of HIV.

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*APPLICATION NUMBER:*

**21-503**

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### Reviews / Information Included in this NDA Review.

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<b>Final Printed Labeling</b>	<b>X</b>
<b>Medical Review(s)</b>	<b>X</b>
<b>Chemistry Review(s)</b>	<b>X</b>
<b>EA/FONSI</b>	
<b>Pharmacology Review(s)</b>	<b>X</b>
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*APPLICATION NUMBER:*

**21-503**

**APPROVAL LETTER(S)**



Food and Drug Administration  
Rockville MD 20857

NDA 21-503

Agouron Pharmaceuticals, Inc., A Pfizer Company  
Attn: Marie-Do Mompas, Pharm.D., Director, Regulatory Strategy  
10777 Science Center Drive  
San Diego, CA 92121

Dear Dr. Mompas:

Please refer to your New Drug Application (NDA) dated June 28, 2002, received July 1, 2002, submitted under section 505(b) (1) of the Federal Food, Drug, and Cosmetic Act for Viracept® (nelfinavir mesylate) 625 mg tablets.

We acknowledge receipt of your submissions dated:

25 July 2002	9 September 2002
27 September 2002	25 October 2002
29 October 2002	4 December 2002
16 December 2002	20 December 2002
14 February 2003	27 February 2003
1 April 2003	4 April 2003
10 April 2003	11 April 2003
14 April 2003	

This new drug application provides for the use of Viracept® (nelfinavir mesylate) 625 mg tablets for the treatment of HIV.

We 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.

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 an FPL that is not identical to the approved labeling text 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 ten of the copies on heavy-weight paper or similar

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material. For administrative purposes, designate this submission "FPL for approved NDA 21-503." Approval of this submission by FDA is not required before the labeling is used.

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling regarding the Pediatric Rule. Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). Please refer to the FDA's Written Request for pediatric studies dated March 29, 1999 and the amendment to the Written Request dated June 18, 2001, for Viracept.

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

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 Jeff D. O'Neill, ACRN, Regulatory Project Manager, at (301) 827-2362.

Sincerely,

(See appended electronic signature page)

**APPEARS THIS WAY  
ON ORIGINAL**

Debra Birnkrant, M.D.  
Director  
Division of Antiviral Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

Enclosures

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