Approval Package for:

APPLICATION NUMBER:

20-778 / S-015

Trade Name: Viracept

Generic Name: (nelfinavir mesylate)

Sponsor: Pfizer Inc.

Approval Date: December 21, 2001
APPLICATION NUMBER:

20-778 / S-015

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Reviews / Information Included in this NDA Review.

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NDA 20-778/S-015

Agouron Pharmaceuticals, Inc.
Attention: Paul R. Chen, Ph.D.
10350 North Torrey Pines Road
La Jolla, CA 92037-1022

Dear Dr. Chen:

Please refer to your supplemental new drug application dated July 27, 2001, received July 30, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIRACEPT® (nelfinavir mesylate) Oral Powder, 50 mg/g.

This "Changes Being Effected in 30 days" supplemental new drug application, submitted under PAC-ATLS, provides for qualification of an additional

We have completed the review of this supplemental application, and it 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 Sean J. Belouin, R.Ph., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Stephen Paul Miller
12/21/01 05:22:07 PM
20-778 S-015 is approved
APPLICATION NUMBER:

20-778 / S-015

CHEMISTRY REVIEW(S)
3. NAME AND ADDRESS OF APPLICANT
   Agouron Pharmaceuticals, Inc.
   10350 North Torrey Pines Road
   La Jolla, CA 92037-1022
   Attn: Paul R. Chen, Ph.D.

4. TYPE OF SUPPLEMENT
   CBE-30

5. DOCUMENT(S)
   NUMBERS   DATED       RECEIVED
   SCM-015    7/27/01     7/30/01

6. NAME OF DRUG
   VIRACEPT® Oral Powder

7. NONPROPRIETARY NAME
   nelfinavir mesylate oral powder

8. SUPPLEMENT PROVIDES FOR:
   The qualification of an 2-ATLS

9. AMENDMENTS/DATES

10. PHARMACOLOGICAL CATEGORY
    Anti-HIV

11. HOW DISPENSED
    X OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(S)
    Tablets

14. POTENCY (CIES)
    50 mg/g

15. CHEMICAL NAME AND STRUCTURE
    [3S-[2(2S*,3S*,3c,4aβ,8aβ)]-N(1,1-dimethylethyl)decahydro-2-[2-hydroxy-[(3-hydroxy-2-methylbenzoyl)amino-4-(phenylthio)butyl]-3-isoquinolinecarboxamide, monomethanesulfonate (salt)

16. MEMORANDA

CH₃SO₂H

17. COMMENTS
   In this CBE-30 Supplement submitted under PAC-ATLS the four requirements set by the Guidance, i.e., the approved test methods are used, all postapproval commitments have been fulfilled, the new testing facility has the capability to perform the intended testing, and the new testing facility has had a satisfactory current good manufacturing practice (cGMP) inspection within the past 2 years, are met. In addition, an Establishment Evaluation Request was submitted and a recommendation of “acceptable” was made by the Office of Compliance.

18. CONCLUSIONS AND RECOMMENDATIONS
   This Supplement is recommended for approval.

19. REVIEWER
   NAME: George Lunn, Ph.D.
   SIGNATURE: [signed electronically in DFS]
   DATE OF DRAFT REVIEW: 9/10/01

20. CONCURRENCE: HFD-530/SMiller [signed electronically in DFS]

   DFS CC LIST
   L = Action Letter
   R = Review

   L  G Lunn  L  Med: Klaessig  PharmTox
   R  SMiller  R  PM: SBelouin  Micro
   R  ONDC3 IO (CChen)  Biopharm
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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George Lunn
9/17/01 10:50:55 AM
CHEMIST

PAC-ATLS for nelfinavir oral powder

Stephen Paul Miller
9/26/01 03:32:55 PM
CHEMIST