APPLICATION NUMBER for: 020778, S011

CHEMISTRY REVIEW(S)
## BEST POSSIBLE COPY

### SUPPLEMENTAL NDA CHEMIST'S REVIEW

<table>
<thead>
<tr>
<th>3. NAME AND ADDRESS OF APPLICANT (City and State)</th>
<th>4. AF NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agouron Pharmaceuticals, Inc.</td>
<td></td>
</tr>
<tr>
<td>10350 North Torrey Pines Road</td>
<td></td>
</tr>
<tr>
<td>La Jolla, CA 92037-1022</td>
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</tbody>
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<tr>
<th>5. SUPPLEMENT(S)</th>
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<tbody>
<tr>
<td>NUMBER(S)</td>
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<tr>
<td>SE2-022</td>
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<thead>
<tr>
<th>6. NAME OF DRUG</th>
<th>7. NONPROPRIETARY NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIRACEPT® Tablets</td>
<td>nelfinavir mesylate tablets</td>
</tr>
</tbody>
</table>

8. SUPPLEMENT(S) PROVIDES FOR:
- BID dosing of Viracept (nelfinavir mesylate) tablets.

9. AMENDMENTS / REPORTS
   Amendment of 11/22/99

10. PHARMACOLOGICAL CATEGORY
    Anti-HIV

11. HOW DISPENSED
    [X] Rx  |   [ ] OTC

12. RELATED IND/NDA/DMF(S)

13. DOSAGE FORM(S)
    Tablets
    250 mg

14. POTENCY(IES)

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

![Chemical Structure Image]

16. MEMORANDA

17. COMMENTS
    None

18. CONCLUSIONS AND RECOMMENDATIONS
    This Supplement provides for BID dosing of Viracept (nelfinavir mesylate) tablets. All CMC information has been previously submitted and approved. The package insert notes that the bottles now contain 300 tablets (as discussed during the review of 20-779/SCS-023), the tablets are film coated (reviewed in 20-779/SCF-027), the container should be kept tightly closed, and the tablets should be dispensed in the original container. In addition, the container label now contains the statements "Keep container tightly closed" and "Dispense in original container". This Supplement is therefore recommended for approval from a CMC perspective.

19. REVIEWER
    George Lunn, Ph.D.

20. CONCURRENCE: HFD-530/SMiller
    DISTRIBUTION
    X Original Jacket  X GLunn  X SLynne
    X Division File  X SMiller  X Med
    X HFD-830/CChen  X Micro  X PharmTox
    DATE COMPLETED: 1/24/99