DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDA

Food and Drug Administration
Rockville MD 20857

APR 18 1997

TRANSMITTED VIA FACSIMILE

Connie J. Kirby
Director, Regulatory Affairs
Agouron Pharmaceuticals, Inc.
10350 North Torrey Pines Road
LaJolla, CA 92037-1020

RE: NDAs 20-778/9
Viracept (nefinavir mesylate)
MACMIS ID #5325

Dear Ms. Kirby:

As part of our routine monitoring and surveillance activities, the Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed an April 11, 1997, Agouron press release entitled "Viracept Combination Therapy Drops HIV Below Quantifiable Levels in Both Blood and Lymph Tissue."

DDMAC has determined that this press release is in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations for the following reasons:

- The press release is considered labeling for Viracept. As such, it is misleading because it lacks balance and implies that the results of this study are more representative than they really are.

  For example, Agouron has failed to provide the full indication for Viracept, including all the appropriate caveats about Viracept's use in treating HIV infection. For example, Agouron has failed to provide that Viracept's approval was based on changes in surrogate markers (e.g., CD4 cell counts and viral HIV-RNA) up to 24 weeks and that the clinical effects of the changes in viral load associated with Viracept therapy have not been established.

  Further, this study (study 509) was a pilot study and was not included in Viracept's labeling because it was very small and did not add meaningful information to the use of Viracept. Also, the description of the results are

misleading because they fail to provide the limit of quantifiable levels of HIV by the assay, i.e., 1200 copies/mL.

- The press release was not submitted to DDMAC prior to dissemination, as required by 21 CFR §314.550.

In order to address these objections, DDMAC recommends that Agouron take the following actions:

1. Immediately discontinue the distribution of any and all press releases related to Viracept, until they have been submitted to DDMAC as provided under the requirements of the accelerated approval regulations.

2. Provide to DDMAC, in writing, Agouron's intent to comply with number one above.

3. Provide to DDMAC, in writing, Agouron's intent to comply with the statute and regulations so that all promotional materials for Viracept will present a fair and balanced discussion of the product.

4. Provide to DDMAC, in writing, Agouron's intent to comply with the submission requirements of 21 CFR §314.550.

Agouron's response should be received by May 2, 1997. If Agouron has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID #5325, in addition to the NDA number.

Sincerely,

Russell Fleischer, PA-C, MPH
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

File name: nel5325.nov

Drafted: Fleischer Date: 4/17/97
Comment:
Revised: Date:
Concur: Palmer Date: 4/18/97

CC:
HFD-40/NDAs 20-778/9
HFD-40/Chron/Fleischer/Palmer
HFD-530/NDAs 20-778/9
HFD-530/Maldonado

MACMIS File ID#:

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MACMIS Action Code: VIOL
2253 ID#:
2253 Material Code:
Material ID#:
Due Date: May 2, 1997
Close Out: N

FOI STATUS: RELEASABLE