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APPLICATION NUMBER:

20-628/S-016

MEDICAL REVIEW

NDA 20,628, Invirase (saquinavir mesylate), SLR 016
Brief Review: Special Supplement, Changes Being Effected
Date Submitted: 2/1/01, 3/28/01,4/27/01
Date Review Completed: 6/6/01

This supplement contains the addition of warnings to physicians and patients in both the package insert and the patient package insert regarding co-administration of Invirase and St. John's wort or products containing St. John's wort. It also includes an alert box designed to highlight the need to learn about other important drug interactions with Invirase. These changes had been previously requested by the Division for inclusion in all protease inhibitor drug labels. There are no additional comments and these changes may proceed.

Linda L. Lewis
Medical Officer
DAVDP/ODE IV/CDER/FDA

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/s/

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6/6/01 11:23:29 AM
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7/11/01 04:40:04 PM
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