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August 21, 2003

VIA FEDERAL EXPRESS, EMAIL & FACSIMILE

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Supplemental Submission to Citizen Petition - Docket No. 2003P-0321
Regarding the Approval of Ribavirin Capsules 200mg

The Supplemental Submission is Without Merit and the Petition Should be Denied

Dear Sir/Madam:

On behalf of Three Rivers Pharmaceuticals, LLC and its marketing partner, Par Pharmaceutical, Inc., this responds to Supplement No. 1 to the Citizen Petition filed on July 29, 2003 (the "Supplement") by ICN Pharmaceuticals, Inc. and Ribapharm Inc. (collectively "Ribapharm"). Ribapharm's Supplement argues that a license agreement between Three Rivers and Schering Corporation covering the use of ribavirin in combination with either interferon or peginterferon somehow precludes a carve-out of peginterferon from the labeling of Three Rivers' ribavirin drug product.

Ribapharm's argument is meritless. The Schering license was entered into in settlement of litigation, and was intended to resolve that litigation and all **present** and **future** disputes between the parties concerning Three Rivers' ribavirin product. The license is irrelevant to what is presently in Three Rivers' labeling, and to the availability of a carve out for peginterferon.

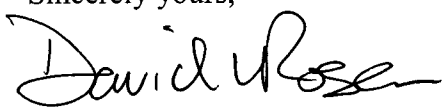
Three Rivers' ribavirin drug product will be labeled for use only in combination with interferon alpha-2b, at least until the three-year market exclusivity period for the peginterferon

combination expires. Thereafter, Three Rivers may, without further agreement **from Schering**, consider what options are available regarding any other labeled use that may be approved by the FDA at that time. Three Rivers could chose to do nothing, or to file a supplement to its ANDA seeking FDA approval for use of its ribavirin product in combination with peginterferon. The license agreement covers both situations, obviating a need to amend the Schering agreement at a future date. None of these future possibilities has any materiality whatsoever to the present availability of a carve-out.

Ribapharm's Supplement appears to be a thinly-veiled, last-ditch effort to thwart generic competition after Ribapharm lost its patent infringement action against Three Rivers. On July 14, 2003, the United States District Court for the Central District of California granted summary judgment holding that Three Rivers did not infringe any of Ribapharm's asserted patents concerning ribavirin. Schering is the NDA holder for ribavirin capsules, and the owner of several Orange-Book-listed patents relating to this drug. Ribapharm also owns patents which it listed in the Orange Book for ribavirin capsules. Three Rivers filed Paragraph IV certifications against these patents, and Schering and Ribapharm sued Three Rivers in separate actions. Three Rivers' litigation with Schering ended in conjunction with the above-referenced license agreement, and its litigation with Ribapharm ended with judgment in Three Rivers' favor. Accordingly, now that it has become clear that no patent barriers prevent FDA from approving Three Rivers' ANDA for ribavirin, Ribapharm has resorted to a strategy of raising baseless regulatory arguments to delay approval of Three Rivers' application.

For the reasons set forth herein, and in the original comments by Three Rivers and Par on the above-noted Citizen Petition, it is respectfully urged that the FDA deny the Petition in all respects.

Sincerely yours,



David L. Rosen, R.Ph., J.D.

cc: Three Rivers Pharmaceuticals, LLC
Par Pharmaceutical, Inc.