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WHITE & CASE
LIMITED LIABILITY PARTNERSHIP

1155 AVENUE OF THE AMERICAS
NEW YORK, NEW YORK 10036-2787

TELEPHONE: (1-212) 819-8200
FACSIMILE: (1-212) 354-8113

DIRECT DIAL: (212) 819-8936
E-MAIL: joelke@whitecase.com

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August 26, 2003

VIA FACSIMILE AND FEDERAL EXPRESS

Docket Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Docket No. CP1 2003P-0321 (Petition of ICN Pharmaceuticals, Inc. And Ribapharm Inc. Regarding Approval Of Generic Ribavirin)

On behalf of Geneva Pharmaceuticals, Inc. ("Geneva"), we submit the following comments to Supplement No. 1 to the Citizen Petition submitted by ICN Pharmaceuticals, Inc. and Ribapharm Inc. (collectively "ICN"). Specifically, we are submitting this Response to refute statements made by ICN about the license agreement between Schering and Geneva concerning ribavirin ("License Agreement").

ICN's supplemental submission presents a misleading version of the facts concerning the License Agreement between Schering and Geneva concerning ribavirin, in order to support ICN's argument that "intended uses of ribavirin, as set forth in the labeling for PEG-Intron, also must be regarded as intended uses of the proposed generic products." (ICN Citizen Petition Supplement No. 1 at 3). Instead, the facts concerning the License Agreement demonstrate that the combination of ribavirin and PEG-Intron cannot be an intended use of Geneva's generic ribavirin product.

First, ICN's argument ignores the timing of the License Agreement in relation to the resolution of ICN's patent infringement suit against Geneva. Schering and Geneva entered into the License Agreement on March 26, 2003, as a result of settling Schering's patent infringement suit against Geneva in the District of New Jersey. As of March 26, 2003, in ICN's patent infringement suit against Geneva, the Court in the Central District of California had not yet ruled on infringement or any other issue. As of the time Geneva entered into the License Agreement with Schering, therefore, Geneva did not know how the California Court would rule on Geneva's proposed use of ribavirin. Accordingly, the License Agreement's grant is not a reflection of the

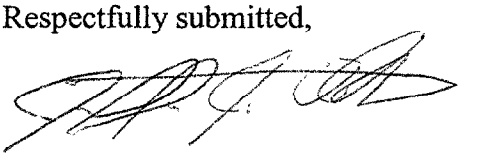
intended use of Geneva's generic ribavirin product because as of the time Geneva entered into the License Agreement, it did not know how the California Court would rule on Geneva's rights to market and label its product.

On July 14, 2003, the California Court held that Geneva did not infringe with respect to Geneva's proposed ribavirin labeling, which was for use in combination with Intron-A, and not for use in combination with PEG-Intron. Specifically, the California Court limited its noninfringement holding to ribavirin treatment dosages in combination with Intron A (at ribavirin treatment dosages of 1000 or 1200 mg/day) and not for ribavirin treatment dosages in combination with PEG-Intron (at a ribavirin treatment dosage of 800 mg/day). Geneva's proposed labeling for its generic ribavirin product, therefore, did not include administration with PEG-Intron as an intended use and it was this proposed labeling, limited to ribavirin in combination with Intron A, that the California Court determined to be noninfringing.

Second, ICN's argument fails to mention the labeling exclusivity on the combination of ribavirin and PEG-Intron. The License Agreement does not grant Geneva rights to any labeling exclusivity that Schering might obtain with respect to the combination use of ribavarin and PEG-Intron. At the time the License Agreement was executed, Geneva was aware of the possibility that Schering would receive labeling exclusivity for the supplemental indication of ribavirin in combination with PEG-Intron, but such exclusivity had not yet been granted. After the execution of the License Agreement, the FDA granted Schering labeling exclusivity, until March 6, 2005, on the combination of ribavirin and PEG-Intron. Because the License Agreement does not grant Geneva rights to Schering's labeling exclusivity on the combination of ribavirin and PEG-Intron, it is clear that the License Agreement fails to show that the combination of ribavirin and PEG-Intron was an intended use of Geneva's ribavirin product.

In summary, the License Agreement in no way supports ICN's assertion that the use of ribavirin in combination with PEG-Intron is an intended use of Geneva's ribavirin product. ICN's arguments in its Supplement No. 1 to its Citizen Petition should therefore be rejected, and for the reasons set forth herein, as well as our letter of July 30, 2003, the FDA should promptly approve Geneva's ribavirin ANDA as submitted.

Respectfully submitted,



Jeffrey J. Oelke

JJO:cg

Enclosures