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March 29, 2007

BY HAND DELIVERY

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COMMENTS TO CITIZEN PETITION DOCKET 2006P-0410/CP1

Sun Pharmaceutical Industries, Ltd. ("Sun"), by counsel, encloses the recent decision of the United States District Court for the District of Columbia in *Biovail Corp. v. FDA*, No. 06-1487, 2007 WL 891365 (D.D.C. Mar. 22, 2007), to supplement the record pertaining to Citizen Petition Docket 2006P-0410/CP1.

As Sun has pointed out in its previous submissions, the citizen petition filed by MedImmune Oncology, Inc. ("MedImmune") improperly assumes that health professionals who rely on Sun's proposed label for generic amifostine will misread that label and provide patients with an accidental overdose. But as Sun's submissions make clear, because there is no dispute that Sun's proposed label is safe for its labeled use, the label cannot be deemed unsafe based merely on the potential that health professionals will misread that label, or otherwise engage in medical malpractice as to non-indicated uses. Consistent with that position, the district court in *Biovail Corp.* held that the potential for physician error could not support an injunction that would preclude the FDA from approving a generic drug :

[T]he plaintiff has failed, for the second time, to allege that the generic versions of [the drug at issue] will cause health problems or that a danger to the public will result from the labeling of the generic drugs. The plaintiff merely asserts that, if the products are mislabeled, "there is a significant risk of inadvertent under-dosing,

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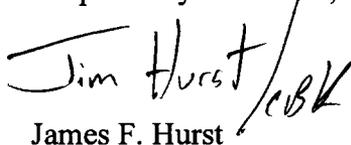
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which may increase the risk of a clinical relapse, or inadvertent over-dosing, which may significantly increase the risk of developing seizures.” . . . The court must again state that absent evidence that the generic drug pending approval will actually cause harmful health effects, these allegations fail to meet the requisite standard. . . . *The potential for physicians to err in prescribing the generic drugs and the consequent potential for harmful results is insufficient to justify the extraordinary relief of a TRO.*

Id. at *25 (emphasis added) (citations omitted).

Respectfully submitted,

Handwritten signature of Jim Hurst in black ink, with the initials 'CBK' written below the signature.

James F. Hurst

Enclosure