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MedImmune

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BY HAND DELIVERY

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: Docket 2006P-0410/CP1
Response to Comments of Sun Pharmaceutical Industries Ltd.**

Dear Sir or Madam:

On behalf of MedImmune Oncology, Inc. (“MedImmune”), a subsidiary of MedImmune, Inc., I am writing in response to the March 29 comments of Sun Pharmaceutical Industries Ltd. (“Sun”) (2006P-0410/C5) (“Sun Comments”), in which Sun transmits and quotes from Judge Urbina’s opinion in *Biovail Corp. v. FDA*, No. 06-1487, 2007 WL 891365 (D.D.C. Mar. 22, 2007). The specific quoted language – and the decision generally – are irrelevant to the issues raised by our petition, with regard to both the law and the facts.

The *Biovail* decision involves the evidentiary standard the moving party must meet for a court to grant the “extraordinary relief” of a temporary restraining order (“TRO”). See *Biovail Corp.*, 2007 WL 891365 at *8. The excerpt quoted by Sun specifically speaks to the party’s burden to show *it* (as opposed to any patient) will suffer irreparable harm without a TRO, when the party has failed to demonstrate likelihood of success, absence of injury to other parties if a TRO is granted, or benefit to the public of issuing the TRO.¹ This is a particularly stringent standard. See *id.* at *7 (“Because the plaintiff failed to show a substantial likelihood of success

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¹ The *Biovail* court applied a “sliding scale” analysis, in which a weak showing as to one of the factors for awarding injunctive relief can be offset by a “very strong showing” as to another factor. *Biovail Corp.*, 2007 WL 891365 at *2.

on the merits, it must make a 'very strong' showing of irreparable harm to obtain a TRO."). This standard for obtaining an emergency injunction from a court simply is not relevant to either MedImmune's burden of proof as petitioner in this administrative matter or the standards governing FDA's consideration of the pending petition.

There also are important factual distinctions between the issue raised by MedImmune's petition and what is before the court in *Biovail*. The question in *Biovail* involves the appropriateness of a labeling statement about the relative bioavailability of two different drug products. *Biovail Corp.*, 2007 WL 891365 at *3 and n.7. Our petition, on the other hand, is about the fundamental risk to patients from a drug product that would lack essential information (e.g., dosing and administration) for a usual or customary use of the drug.

For these reasons, the *Biovail* opinion forwarded by Sun is inapposite to the legal standards applicable to this petition and the underlying facts.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "William C. Bertrand, Jr.", with a stylized flourish at the end.

William C. Bertrand, Jr.
Senior Vice President & General Counsel