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Re: Docket No. 98P-0145; Response to Andrx's Petition for Reconsideration and Stay of Action, and Petition to Modify Decision

Biovail Corporation International ("Biovail") supports FDA's decision of October 22, 1999, which denied Andrx's challenge to the Agency's diltiazem bioequivalence criteria. In its latest filings (dated November 5, 1999), Andrx advances repetitive arguments that continue to misinterpret the Federal Food, Drug, and Cosmetic Act (the Act) and FDA's bioequivalence regulation. Andrx insists on ignoring the discretion that Congress granted FDA in section 505(j)(8)(B)(i) of the Act, which clearly authorizes FDA's bioequivalence determinations to include an assessment of whether "a significant difference" exists between the rate and extent of absorption of two drugs. The Agency's October 22 decision in this matter makes clear that FDA has exercised this discretion in a manner that fully protects the public health. Because Andrx's latest filings advance only repetitive or irrelevant arguments, Biovail encourages FDA to deny immediately Andrx's Petition for Reconsideration and Stay of Action and Petition to Modify FDA's October 22, 1999 decision.

Respectfully submitted,

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