Exhibit B

[PMA's "alternate"] — BIOEQUIVALENCY/BIOAVAILABILITY BATTLE

Given the large number of mfrs. and products and FDA's limited resources, the agency is simply not in the position to assure the quality and eq uivalency of all products on the market. The number of annual inspections FDA can make is, by its own account, descreasing; indeed, FDA no longer reports publicly the number of plants it inspects. Similarly, the number of drug recalls for safety, potency and other quality problems is persistently high.

Another factor of importance is the experience under the Dept. of Defense (DoD) drug procurement program. It is reported that the Dept. rejects 42% of drug product samples submitted to it. Forty-five percent of mfrs.' facilities inspected fail to meet DoD standards. Furthermore, the scientific literature contains many reports showing a lack of therapeutic equivalency among Rx drugs.

The issue is not one of brandname versus generic drugs, as some would like to describe it. The issue is quality of drugs from different mfrs. Unless and until FDA is in a position to assure the therapeutic equivalence of all drugs on the market, the necessary underpinnings for limiting costs in the way the Secty. suggested simply do not exist.

Furthermore, the problem of quality of drugs cannot be solved simply by having FDA satisfy itself as to the quality of one particular mfr.'s product selected as being "generally available" at the lowest price because drugs from other sources available at similar prices but of unknown quality may be selected by the physician or the pharmacist.

> Most physicians and pharmacists, it should be added, do not agree with the premise that price *alone* should determine whether or not the drug prescribed and dispensed should be fully reimbursed. They reject the notion that there is no need for professional judgment in choosing a particular drug product and identifying a preferred source.

In the last analysis, only the prescribing physician is in a position to know which drug products have performed satisfactorily for his patient. Under the Dec. 19 proposal, in cases where the physician or the pharmacist determine that the patient will be better served by a product which costs more than the lowest priced product on the market, the patient would have to bear the additional cost.

This result is neither equitable nor consistent with the principles of the Medicare and Medicaid programs. Escape clauses, that would permit reimbursement of a higher priced product only if the doctor details his bases for selection and some govt. official or advisory cmte. accepts them, would only serve to discourage physicians from exercising their own professional judgment. Such procedures would also lead to expenditures that would dissipate the expected savings from the program.

Finally, the effect of the Dec. 19 proposal may well be to discourage competition in drug quality that has benefited patients by leading to improvements in product quality. It is exceptionally important to stress the relationship between quality pharmaceuticals and source identification, in our view, and to recognize that the need to preserve meaningful incentives toward excellence in all aspects of pharmaceutical manufacture, control and distribution is absolute.

The reputation of American medicines for excellence is unexcelled throughout the world, and is quite independent of the diverse regulatory environments in which these firms manufacture and market their products. Decades of effort to regulate quality into pharmaceutical manufacturing have not mitigated the significance, in the minds of the health professions, of the reputation of the maker of the product.