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March 30, 2006

VIA HAND DELIVERY
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2006P-0124

PETITION FOR STAY OF ACTION
(Amended)

ViroPharma Incorporated respectfully submits this petition pursuant to 21 CFR 10.35 requesting the Food and Drug Administration immediately stay the effective date of the following matter:

DECISION INVOLVED

For the reasons described below, ViroPharma requests a stay of any Agency action that would result in the approval of an Abbreviated New Drug Application (ANDA) or an application filed under section 505(b)(2) that references Vancocin® (vancomycin capsules). ViroPharma requests such stay of action in the absence of evidence that the Agency has established and applied appropriate standards for approving vancomycin capsule ANDAs or 505(b)(2) applications.

ACTION REQUESTED

ViroPharma will shortly submit scientific evidence to present to the FDA formally requesting that the Agency:

(a) Require using the most rigorous scientific method that will demonstrate a rate and extent of drug release to the site of action consistent with good medicine and science;
(b) Require a demonstration that the stability of a vancomycin capsule ANDA or 505(b)(2) product is at least as good as Vancocin;

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(c) Require any applicant relying on Vancocin to provide evidence that its product is bioequivalent to Vancocin along the entire gastrointestinal tract;
(d) Convene a joint meeting of the Advisory Committee for Pharmaceutical Science and the Advisory Committee for Anti-infective Drug Products, with industry participation, to examine the relevant data and information relating to vancomycin delivery to the GI tract for the purpose of developing appropriate and consistent standards for the approval of new vancomycin capsule products;
(e) Validate with both the FDA Medical Policy Coordinating Committee and the FDA Biopharmaceutics Coordinating Committee the scientific and medical appropriateness of the approval standards for a new locally acting vancomycin capsule product;
(f) Provide an opportunity for public review and comment on the appropriate approval standards for a new locally acting vancomycin capsule product.

STATEMENT OF GROUNDS

The agency should grant ViroPharma's Petition for Stay of Action because it satisfies the criteria set forth in 21 CFR 10.35(e).

The public interest would be served by the Agency establishing standards for the approval of a new locally acting vancomycin capsule product, a product that is used for treating serious, life threatening infections. For safety and reliability purposes, FDA should not apply unsubstantiated and potentially inadequate bioequivalence standards for such a serious drug.

Approving a new vancomycin capsule product relying on Vancocin without an adequate demonstration of bioequivalence has the potential of causing ViroPharma irreparable harm. If the composition of a new vancomycin capsule raises safety issues or its local release cannot be effectively measured to show therapeutic equivalence, the reputation and goodwill that ViroPharma has established in this field may be destroyed.

ViroPharma respectfully requests that the Agency stay approval of new vancomycin capsule products in good faith and for non-frivolous reasons. ViroPharma believes the FDA must define a bioequivalence standard in order to ensure the approval of safe and efficacious new products. Standing alone, matching *in vitro* release cannot demonstrate bioequivalence for non-systemically absorbed products like Vancocin. For a drug used for life threatening infections, this is particularly inappropriate.

Sound public policy supports a stay in this case. In addition to medical and scientific arguments for establishing bioequivalence standards, the public has an interest in requiring an agency such as FDA to act lawfully, to fulfill obligations under its governing statutes and implementing regulations and to treat regulated parties fairly and equally.

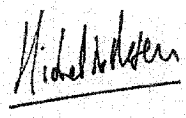
Vancocin, the drug that a new vancomycin capsule product would reference in its application, is safe and efficacious for patients. The approval process for new vancomycin capsule products, however, must be in a manner in which the public can

place their confidence. Thus, any delay resulting from a stay would not be outweighed by other interests. Although there is a public interest in lawful competition, there is a greater interest in ensuring that ANDA and 505(b)(2) drug products meet the fundamental statutory and regulatory requirements for approval, i.e., are truly the same as the drug to which they claim to be equivalent.

CONCLUSION

For the foregoing reasons this Petition for Stay of Action should be granted.

Respectfully submitted,



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