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March 17, 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

PETITION FOR STAY OF ACTION

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) referencing Vancocin® (vancomycin capsules) as its reference listed drug (RLD). ViroPharma requests such stay of action in the absence of evidence that the Agency has established and applied appropriate standards for approving a generic vancomycin capsule product.

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 generic vancomycin product is at least as good as the RLD;

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(c) Require the ANDA 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 products by generic applicants;
(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 generic locally acting vancomycin capsule product.
(f) Provide an opportunity for public review and comment on the appropriate approval standards for a generic 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 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 generic vancomycin capsule product relying on Vancocin as the RLD based on inadequate demonstration of bioequivalence, has the potential of causing ViroPharma irreparable harm. If the composition of a generic 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 a generic vancomycin capsule 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.

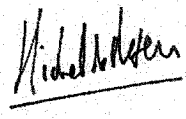
Sound public policy supports a stay in this case. In addition to medical and scientific arguments for establishing bioequivalence standards, the public has an interest in requiring an agency such as FDA to act lawfully, to fulfill obligations under its governing statutes and implementing regulations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

Vancocin, the RLD that a generic vancomycin capsule would rely on in its ANDA, is safe and efficacious for patients. The approval process for an ANDA, 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 generic competition, there is a greater interest in ensuring that generic drugs meet the fundamental statutory and regulatory requirements for approval, i.e., are truly the same as the reference listed drugs 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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