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Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

January 26, 2006

To Whom It May Concern:

Suitability Petition

Macleod Pharmaceuticals Inc, the Petitioner, is asking by this letter for CVM to consider its suitability petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act.

We request the approval of a suitability petition to change the dosage form of Schering Plough' s Phenylzone Paste, NADA # 116-087 from a paste to granules to be administered in a small amount of palatable feed.

The pioneer product is manufactured as an oral paste that contains 12 g of phenylbutazone per 60 g of paste (i.e., 200 mg of phenylbutazone per g of paste).

Macleod wishes to file an ANADA for Unibute Granules that contains 200 mg of phenylbutazone per g of granules. This product will be administered orally in a small amount of palatable feed.

An *in vivo* bioequivalence protocol will be submitted to the agency prior to initiating the study.

Under 21 CFR 25.24(a)(8) we request a categorical exclusion from the Environmental Impact assessment.

We certify that we have included all information that is available to this petition.

Sincerely,

Giovanni Parrinello, Ph.D.

Vice President of Pharmaceutical Operations

2006 P-0060

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