CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022556Orig1s000

ENVIRONMENTAL ASSESSMENT

1.12.14 Environmental Assessment or Claim for Exclusion

Tris Pharma Inc. (Tris) claims an exclusion to the preparation and submission of an Environmental Assessment under 21 CFR § 25.31(a). This section specifies that for human drugs and biologics, preparation of an Environmental Assessment or Environmental Impact Statement is not required under a categorical exclusion for, as in this case, action on an NDA, if the action does not increase the use of the active moiety. This is a 505(b)(2) application for a novel clonidine formulation. The reference listed drug is Carbinoxamine Maleate Oral Solution, which has been approved since 2003. The introduction of Tris' product would be another form of the already marketed drug carbinoxamine maleate, and so its use would not increase the overall use of the active moiety. Tris also states that, no extraordinary circumstances, as defined under 21 CFR § 25.21, exist which would preclude the categorical exclusion.

W. Scott Groner
Director, Regulatory Affairs and Compliance
Tris Pharma Inc.

10/30/08
Date