

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206510Orig1s000

ENVIRONMENTAL ASSESSMENT

B. Environmental Assessment Or Claim Of Categorical Exclusion

“Merck is requesting a categorical exclusion from the requirements to prepare an Environmental Assessment under 21 CFR §25.31(a). The filing meets the requirements of a categorical exclusion under 21 CFR §25.31(a) since the predicted environmental concentrations of the products are not expected to increase due to this action, as patients will be prescribed the combined therapy in place of the existing single-component therapies. To the best of the company’s knowledge, no extraordinary circumstances exist in regards to this action.”

Comments: The request for a categorical exclusion from the preparation of an environmental assessment (EA) is granted based the understanding that the proposed action will not increase the use of the drugs.

III. List Of Deficiencies To Be Communicated

There are no deficiencies to be communicated to the applicant at this time.

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/s/

MARY GRACE LUBAO
02/19/2015