

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 19-304/S005

ENVIRONMENTAL ASSESSMENT AND/OR FONSI

ENVIRONMENTAL ASSESSMENT

In FDA's "Guidance for Industry Environmental Assessment of Human Drug and Biologic Applications", dated July, 1998, and under 21 CFR 25.31(b), a categorical exclusion from the filing of an environmental assessment is allowed in the case of an action on an NDA, abbreviated application, or a supplement to such applications, or action on an OTC monograph, if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion. Using the formulation from the Guidance EIC-Aquatic (ppb) = A x B x C x D where A is estimated to be _____ in the maximum production year of 2002, the calculation is as follows:

Therefore, since the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion, this supplement qualifies for a categorical exemption from an Environmental Assessment.

APPEARS THIS WAY
ON ORIGINAL