

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-830/S008

ENVIRONMENTAL ASSESSMENT AND/OR FONSI

Hilfiker

MEMO TO THE FILE

NDA: 20-830/S-008
Drug: Singulair (montelukast sodium) 4 mg Chewable Tablets
Applicant: Merck and Co.

From: David Hilfiker
Regulatory Project Manager */S/ 2/7/00*

Subject: Environmental Assessment

The statement of environmental assessment can be found on page 3 of the cover letter to the application, dated May 6, 1999. The applicant has requested a categorical exclusion as per 21 CFR 25.31(b). The request reads as follows:

Merck is requesting a categorical exclusion from the requirements to prepare an Environmental Assessment under 21 CFR § 25.31(b). The production of montelukast sodium meets the requirements of a categorical exclusion under 21 CFR § 25.31(b) because the estimated concentration of drug substance, montelukast sodium, at the point of entry, referred to as the Expected Introduction Concentration (EIC), into the aquatic environment will be below 1 part per billion (ppb). To the best of Merck's knowledge no extraordinary circumstances exist in regards to this action.

Cc: Orig NDA 20-830/S-008
HFD-570/Div File
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APPEARS THIS WAY
ON ORIGINAL