

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-976

ENVIRONMENTAL ASSESSMENT

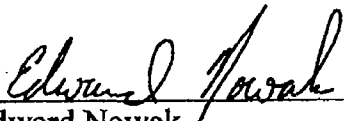
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
920 ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0602

ENVIRONMENTAL ASSESSMENT

CATEGORICAL EXCLUSION

- TMC 114 Enthanolate Tablets (300 mg) -

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) of Raritan, New Jersey, certifies that the above referenced action meets the criteria for categorical exclusion defined in the regulations [21 CFR 25.31(b)], and that to the knowledge of J&JPRD, no extraordinary circumstances exist. Thus, no environmental assessment needs to be performed.



Edward Nowak
Director, Global Environmental, Health and Safety

23, September 2006
Date



2 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

Withheld Track Number: Administrative-1
Environmental Assessment