

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-976**

**ENVIRONMENTAL ASSESSMENT**

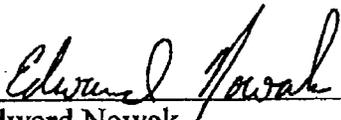
**Johnson & Johnson Pharmaceutical Research & Development, L.L.C.**  
920 ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0602

**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