CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
21-976

ENVIRONMENTAL ASSESSMENT
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CATEGORICAL EXCLUSION

- TMC 114 Enhanolate 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  
Date  23, September 2006
Director, Global Environmental, Health and Safety
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