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APPLICATION NUMBER:
202439Orig1s000

ENVIRONMENTAL ASSESSMENT

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Environmental Assessment

NDA Categorical Exclusion for Rivaroxaban

JNJ-39039039

Department: Chemistry, Manufacturing & Controls
Document No.: EDMS-ERI-18310777:2.0
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CATEGORICAL EXCLUSION

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), Raritan, NJ, certifies that the above referenced action meets the criteria for a 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.

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SIGNATURES

| <u>Signed by</u> | <u>Date</u> | <u>Justification</u> |
|------------------|-----------------------------|----------------------|
| KELLY QUINLAN | 04Nov2010, 19:01:47 PM, UTC | Document Approval |

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