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APPLICATION NUMBER:
204042Orig1s000

ENVIRONMENTAL ASSESSMENT

Janssen Research & Development, L.L.C.

Environmental Assessment

AC per CHM Rev
2/4/13

NDA Categorical Exclusion for Canagliflozin

JNJ-28431754-ZAE

Department: Chemistry, Manufacturing & Controls
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Confidentiality Statement

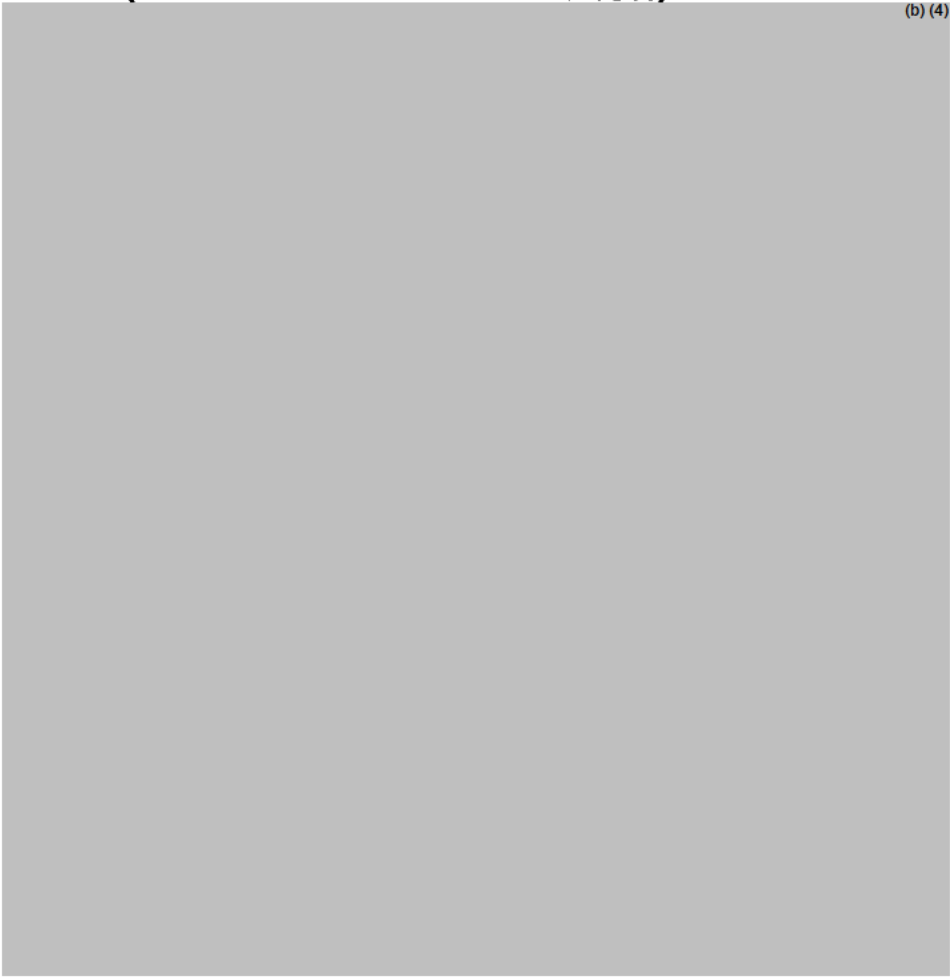
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CATEGORICAL EXCLUSION

Janssen Research & Development, L.L.C. (Janssen), 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 Janssen, no extraordinary circumstances exist. Thus, no environmental assessment needs to be performed.

APPENDIX 1 (CONFIDENTIAL INFORMATION)

(b) (4)



(b) (4)



SIGNATURES

<u>Signed by</u>	<u>Date</u>	<u>Justification</u>
KELLY QUINLAN	10Apr2012, 16:53:45 PM, UTC	Document Approval