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NYCRR 300.13(b)(2)(iv) and (3) for

this Application for

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in the manner described in Section

2 below. I certify that service of this

Application for Reconsideration/Full

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was completed within 30 calendar days from the filing of the decision that is the subject of this

Application. INSTRUCTIONS FOR COMPLETING RB-89 REVIEWER:

JOHN COLERANGLE NDA No. 21-919 1 EXECUTIVE SUMMARY I.

Recommendations A.

Recommendation on approvability:

Approval (AP). B. Recommendation

for nonclinical studies: The non-clinical studies reviewed is

sufficient to support the safety of subcutaneous administration of

exenatide to Type II diabetic patients at PHARMACOLOGY

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Nov. 2011 by Richard J. Fruncillo MD

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