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CLINICAL PHARMACOLOGY
REVIEW(S)

Office of Clinical Pharmacology Review

NDA or BLA Number	213051
Link to EDR	\\Cdsub1\evsprod\NDA213051\213051.enx
Submission Date	20 Mar 2019
Submission Type	505 (b)(1)
Brand Name	Rybelsus (Proposed)
Generic Name	Semaglutide
Dosage Form and Strength	Tablet; 3 mg, 7 mg and 14 mg
Route of Administration	Oral
Proposed Indication	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
Applicant	Novo Nordisk
Associated IND	IND-114464
OCP Review Team	<i>Suryanarayana Sista, PhD; Mohammad (Abir) Absar, PhD; Justin Penzenstadler, PharmD, MS; Justin Earp, PhD; Manoj Khurana, PhD</i>

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