CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209637Orig1s000

<u>ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS</u>

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION[1]	
NDA # 209637 BLA #	NDA Supplement # BLA Supplement #

If NDA, Efficacy Supplement Type: N/A *(an action package is not required for SE8 or SE9 supplements)*

Proprietary Name: Ozempic Established/Proper Name: semaglutide Dosage Form: injection	Applicant: Novo Nordisk Inc. Agent for Applicant (if applicable): N/A
RPM: Peter Franks	Division: DMEP

NDA Application Type: ☒ 505(b)(1) ☐ 505(b)(2) Efficacy Supplement: ☐ 505(b)(1) ☐ 505(b)(2) BLA Application Type: ☐ 351(k) ☐ 351(a) Efficacy Supplement: ☐ 351(k) ☐ 351(a)	**For ALL 505(b)(2) applications, two months prior to EVERY action:** • **Review the information in the 505(b)(2) Assessment and submit the draft[2] to CDER OND IO for clearance.** • **Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)** ☐ No changes ☐ New patent/exclusivity *(notify CDER OND IO)* Date of check: *Note: If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.*

❖ Actions	
• Proposed action • User Fee Goal Date is <u>December 5, 2017</u>	☒ AP ☐ TA ☐CR
• Previous actions *(specify type and date for each action taken)*	☒ None
❖ If accelerated approval or approval based on efficacy studies in animals, were promotional materials received? Note: Promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf). If not submitted, explain _____	☐ Received
❖ Application Characteristics [3]	

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[1] The **Application Information** Section is (only) a checklist. The **Contents of Action Package** Section (beginning on page 2) lists the documents to be included in the Action Package.

[2] For resubmissions, 505(b)(2) applications must be cleared before the action, but it is not necessary to resubmit the draft 505(b)(2) Assessment to CDER OND IO unless the Assessment has been substantively revised (e.g., new listed drug, patent certification revised).

[3] Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA

Review priority: ☒ Standard   ☐ Priority

Chemical classification (new NDAs only):   Type 1 (New Molecular Entity)

(confirm chemical classification at time of approval)

☐ Fast Track   ☐ Rx-to-OTC full switch
☐ Rolling Review   ☐ Rx-to-OTC partial switch
☐ Orphan drug designation   ☐ Direct-to-OTC
☐ Breakthrough Therapy designation

*(**NOTE:** Set the submission property in DARRTS and notify the CDER Breakthrough Therapy Program Manager;*
*Refer to the "RPM BT Checklist for Considerations after Designation Granted" for other required actions: **CST SharePoint**)*

NDAs: Subpart H   BLAs: Subpart E
    ☐ Accelerated approval (21 CFR 314.510)   ☐ Accelerated approval (21 CFR 601.41)
    ☐ Restricted distribution (21 CFR 314.520)   ☐ Restricted distribution (21 CFR 601.42)
    Subpart I   Subpart H
    ☐ Approval based on animal studies   ☐ Approval based on animal studies

☐ Submitted in response to a PMR   REMS: ☐ MedGuide
☐ Submitted in response to a PMC   ☐ Communication Plan
☐ Submitted in response to a Pediatric Written Request   ☐ ETASU
                                                               ☒ MedGuide w/o REMS
                                                              ☒ REMS not required

Comments:

❖	BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 *(approvals only)*	☐ Yes ☐ No
❖	Public communications *(approvals only)*	
	• Office of Executive Programs (OEP) liaison has been notified of action	☐ Yes ☒ No
	• Indicate what types (if any) of information were issued	☒ None ☐ FDA Press Release ☐ FDA Talk Paper ☐ CDER Q&As ☐ Other
❖	Exclusivity	
	• Is approval of this application blocked by any type of exclusivity (orphan, 5-year NCE, 3-year, pediatric exclusivity)? • If so, specify the type	☒ No ☐ Yes
❖	Patent Information (NDAs only)	
	• Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought.	☒ Verified ☐ Not applicable because drug is an old antibiotic.

CONTENTS OF ACTION PACKAGE

Officer/Employee List

❖	List of officers/employees who participated in the decision to approve this application and consented to be identified on this list *(approvals only)* (link)	☒ Included
	Documentation of consent/non-consent by officers/employees (link)	☒ Included

Action Letters	
❖ Copies of all action letters *(including approval letter with final labeling)*	Action(s) and date(s) Approval 12/5/2017
Labeling	
❖ Package Insert *(write submission/communication date at upper right of first page of PI)*	
• Most recent draft labeling *(if it is division-proposed labeling, it should be in track-changes format)*	☒ Included See labeling attached to approval letter
• Original applicant-proposed labeling	☒ Included
❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling *(write submission/communication date at upper right of first page of each piece)*	☒ Medication Guide ☐ Patient Package Insert ☒ Instructions for Use ☐ Device Labeling ☐ None
• Most-recent draft labeling *(if it is division-proposed labeling, it should be in track-changes format)*	☒ Included See labeling attached to approval letter
• Original applicant-proposed labeling	☒ Included
❖ Labels (**full color** carton and immediate-container labels) *(write submission/communication date on upper right of first page of each submission)*	
• Most-recent draft labeling	☒ Included See labeling attached to approval letter
❖ Proprietary Name • Acceptability/non-acceptability letter(s) *(indicate date(s))* • Review(s) *(indicate date(s))*	Conditional approval letters: 2/27/2017 Review: 2/17/2017 (NDA) 10/9/2015 (IND)
❖ Labeling reviews *(indicate dates of reviews)*	RPM: 4/19/2017 DMEPA: ☐ None 11/24/2017; 12/1/2017; 12/4/2017 DMPP/PLT (DRISK): 11/9/2017 ☐ None OPDP: ☐ None 11/13/2017 SEALD: ☒ None CSS: ☒ None Product Quality 7/25/2017; see Chapter 2 of integrated quality assessment Other: ☐ None
Administrative / Regulatory Documents	

❖ RPM Filing Review[4]/Memo of Filing Meeting *(indicate date of each review)* ❖ All NDA 505(b)(2) Actions: Date each action cleared by 505(b)(2) Clearance Committee	4/20/2017 ☒ Not a (b)(2)
❖ NDAs/NDA supplements only: Exclusivity Summary *(signed by Division Director)*	☒ Completed (Do not include)
❖ Application Integrity Policy (AIP) Status and Related Documents http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm	
• Applicant is on the AIP	☐ Yes ☒ No

• This application is on the AIP
   o If yes, Center Director's Exception for Review memo *(indicate date)*
   o If yes, OC clearance for approval *(indicate date of clearance communication)*
	☐ Yes ☒ No
	
	☐ Not an AP action

❖ Pediatrics *(approvals only)* • Date reviewed by PeRC 11/1/2017 If PeRC review not necessary, explain: _____	
❖ Breakthrough Therapy Designation	☒ N/A
• Breakthrough Therapy Designation Letter(s) (granted, denied, an/or rescinded)	
• CDER Medical Policy Council Breakthrough Therapy Designation Determination Review Template(s) *(include only the completed template(s) and not the meeting minutes)*	
• CDER Medical Policy Council Brief – Evaluating a Breakthrough Therapy Designation for Rescission Template(s) *(include only the completed template(s) and not the meeting minutes)* *(completed CDER MPC templates can be found in DARRTS as clinical reviews or on the MPC SharePoint Site)*	
❖ Outgoing communications: letters, emails, and faxes considered important to include in the action package by the reviewing office/division (e.g., clinical SPA letters, RTF letter, Formal Dispute Resolution Request decisional letters, etc.) *(do not include OPDP letters regarding pre-launch promotional materials as these are non-disclosable; do not include Master File letters; do not include previous action letters, as these are located elsewhere in package)*	Included
❖ Internal documents: memoranda, telecons, emails, and other documents considered important to include in the action package by the reviewing office/division (e.g., Regulatory Briefing minutes, Medical Policy Council meeting minutes)	Included
❖ Minutes of Meetings	
• If not the first review cycle, any end-of-review meeting *(indicate date of mtg)*	☒ N/A or no mtg
• Pre-NDA/BLA meeting *(indicate date of mtg)*	☐ No mtg 8/2/2016
• EOP2 meeting *(indicate date of mtg)*	☐ No mtg 6/9/2010
• Mid-cycle Communication *(indicate date of mtg)*	☐ N/A 6/1/2017
• Late-cycle Meeting *(indicate date of mtg)*	☐ N/A 9/19/2017
• Other milestone meetings (e.g., EOP2a, CMC focused milestone meetings) *(indicate dates of mtgs)*	N/A

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