

## **SETTLEMENT AGREEMENT**

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice Consumer Protection Branch and the United States Attorney’s Office for the District of Columbia and on behalf of the Food and Drug Administration (“FDA”) of the Department of Health and Human Services (collectively the “United States”), and Novo Nordisk Inc. (“NNI”) (collectively referred to as “the Parties”), through their authorized representatives.

### **RECITALS**

A. WHEREAS, at all relevant times, NNI was a U.S. company and a subsidiary of Novo Nordisk U.S. Holdings, Inc., which in turn is a subsidiary of Novo Nordisk A/S. NNI’s headquarters are in Plainsboro, New Jersey. NNI distributed, sold, and marketed pharmaceutical products throughout the United States, including the drug liraglutide with the tradename Victoza<sup>®</sup> (“Victoza<sup>®</sup>”). NNI introduced Victoza<sup>®</sup> into interstate commerce for shipment throughout the United States;

B. WHEREAS, the United States alleges that from February 2010 through and including December 2012, NNI shipped in interstate commerce Victoza<sup>®</sup> that was misbranded pursuant to 21 U.S.C. § 352(y), in violation of the Federal Food, Drug and Cosmetic Act (“the FDCA”), 21 U.S.C. § 331. These allegations are explained in detail in a complaint filed by the United States in the United States District Court for the District of Columbia, attached hereto as Exhibit A. The allegations in the complaint and any unalleged violations of NNI’s REMS obligations for Victoza<sup>®</sup> under the FDCA from February 2010 through and including December 2012 are referred to herein as the “Covered Conduct”;

C. WHEREAS, the United States contends that through its distribution of misbranded drugs, NNI obtained gains including proceeds and profits to which it was not lawfully entitled, and that the United States is entitled to equitable disgorgement;

D. This Agreement is made in compromise of disputed claims. This Agreement is not an admission of liability by NNI nor a concession by the United States that its claims are not well-founded. NNI admits to the facts elaborated in recitals D(1)-D(5) below as true. These facts are consistent with certain allegations included in the complaint attached hereto as Exhibit A but NNI denies that it engaged in conduct that violated the provisions of the Victoza<sup>®</sup> REMS or the

FDCA. Neither this Agreement or its execution, nor the performance of any obligation arising under it, including any payment, nor the fact of settlement, is intended to be, or shall be understood as, an admission of liability or other expression reflecting on the merits of the dispute by any party to this Agreement.

1. During the launch training for Victoza<sup>®</sup> in January 2010, NNI trained its sales representatives to comply with the REMS by communicating information regarding the unknown risk of a rare form of cancer called medullary thyroid carcinoma (“MTC”) elaborated in the drug’s boxed warning. In doing so, NNI trained its representatives that the REMS-required information could be communicated after a discussion of the benefits of Victoza<sup>®</sup>.
2. NNI also trained its sales representatives that, in addition to communicating the MTC warning to prescribers, they were permitted to inform physicians that there were no cases of MTC in the clinical trials for Victoza<sup>®</sup>.
3. During the launch training for Victoza<sup>®</sup>, in addition to training the sales force on its obligation to communicate the boxed warning to prescribers, certain NNI employees performed a skit for the entire sales force during which one joked: “do you [FDA] think we’re treating mice and rats? I mean really!”
4. Following the launch of Victoza<sup>®</sup>, certain NNI sales representatives informed prescribers about published scientific information regarding the differences between human and rodent thyroid C-cells. Certain NNI sales representatives suggested to or told prescribers that, based on this information, Victoza<sup>®</sup> only posed a risk of MTC to rats or rodents and posed no risk to humans.
5. In April 2011, FDA modified the Victoza<sup>®</sup> REMS to require a communication be directed to primary care physicians (“PCPs”) as a result of survey data suggesting roughly half of PCPs were unaware of the unknown risk of MTC highlighted in the Victoza<sup>®</sup> REMS and the boxed warning. The survey also showed PCPs’ awareness at rates significantly lower than surveyed endocrinologists. The REMS modification required by FDA was intended, in part, to increase PCPs’ awareness of the unknown risk of MTC associated with Victoza<sup>®</sup>. In implementing the REMS modification, a NNI Vice President of Marketing sent a voicemail to the Victoza<sup>®</sup> sales force regarding a communication that was required to be delivered to PCPs. The voicemail message stated, “...when you are in front of your primary care physicians, make sure you provide context. Qualify with them that there are no new safety concerns. Again, there are no new or additional safety concerns reported. Remind them that this is part two of the REMS requirement, and that you had the same discussion a year ago. Then transition to the promotional messaging....” This message contradicted the REMS modification that FDA deemed to be “new safety information.”

NNI's sales representatives provided the required letter to PCPs but also delivered a verbal message consistent with the instruction from the Vice President of Marketing.

E. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as set forth below.

### **TERMS AND CONDITIONS**

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. NNI shall pay to the United States the sum of twelve million one hundred and fifty thousand dollars (the "Settlement Amount") and interest on the Settlement Amount at a rate of 1.625% from December 21, 2016, continuing until and including the day before payment is made (the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States, and NNI shall pay the Settlement Amount by electronic funds transfer pursuant to written instructions from the United States no later than five (5) business days after this Agreement is fully executed by the Parties.

2. Upon verified receipt by the United States of the full Settlement Amount, the United States shall file its Complaint and the United States and NNI shall file a joint stipulation providing for the dismissal with prejudice of the Complaint. The stipulation shall provide that the Parties shall each bear their own costs and attorneys' fees incurred in connection with the action and that all rights of appeal are waived.

3. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon NNI's payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agencies, and departments) agrees to release NNI and its current and former direct and indirect parent corporations and limited liability companies ("Parents"); its and their affiliates, direct and indirect subsidiaries, brother and sister corporations, and divisions; and its and their respective current and former owners, officers, directors, employees, and agents, individually or collectively; and the predecessors, successors, transferees, and assigns of any of

them from any civil claims, sanctions or remedies (whether legal or equitable) that the United States has or may have based on the Covered Conduct and actionable under the FDCA.

4. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person are the following claims of the United States:

- a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
  - b. Any claims that the United States may have under the False Claims Act, 31 U.S.C. §§ 3729, et seq;
  - c. Any criminal liability;
  - d. Any administrative liability, including mandatory and permissive exclusion from Federal health care programs;
  - e. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
  - f. Any liability based upon obligations created by this Agreement; or
  - g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.
5. Unallowable Costs.
- a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of NNI in connection with:
    - i. the matters covered by this Agreement;
    - ii. the United States' audit(s) and investigation(s) of the matters covered by this Agreement;
    - iii. NNI's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
    - iv. the negotiation and performance of this Agreement;
    - v. the payment NNI makes to the United States pursuant to this Agreement including costs and attorneys' fees,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

- b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by NNI and NNI shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, NNI shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by NNI from the United States. NNI agrees that the United States, at a minimum, shall be entitled to recoup from NNI any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine NNI's books and records and to disagree with any calculations submitted by NNI regarding any Unallowable Costs included in payments previously sought by NNI, or the effect of any such Unallowable Costs on the amount of such payments.

6. NNI expressly warrants that it has reviewed its financial situation and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following payment of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to NNI, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which NNI was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

7. This Agreement is intended to be for the benefit of the United States and NNI, and except to the extent provided for in Paragraph 3 above, by this instrument the Parties do not

waive, compromise, or release any claims or causes of action against any other person or entity not expressly released by this Agreement.

8. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

9. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

10. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Columbia.

11. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any party for that reason in any subsequent dispute.

12. This Agreement constitutes the complete agreement between the Parties with respect to the issues covered by the Agreement. This Agreement may not be amended except by written agreement signed by the Parties specifically referring to this Agreement.

13. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

14. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

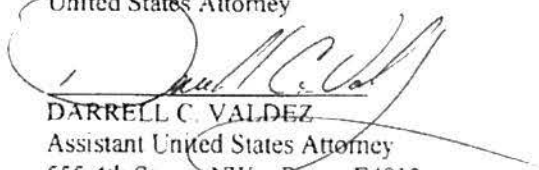
15. This Agreement is binding on NNI's successors, transferees, heirs, and assigns.

16. The Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

17. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement).

**For the United States:**

CHANNING D. PHILLIPS  
United States Attorney

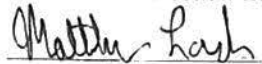


DARRELL C. VALDEZ  
Assistant United States Attorney  
555 4th Street, NW - Room E4913  
Washington, DC 20530  
Tel 202.252.2507  
darrell.valdez@usdoj.gov

CHAD A. READLER  
Acting Assistant Attorney General  
Civil Division

JOSHUA I. WILKENFELD  
Director  
Consumer Protection Branch

JILL FURMAN  
Deputy Director  
Consumer Protection Branch



MATTHEW J. LASH  
Trial Attorney  
Consumer Protection Branch  
450 Fifth Street, NW  
Room 6400 - South  
Washington, DC 20001  
202 514 3764  
matthew.j.lash@usdoj.gov

**For the Defendant:**



CURT OLTMANS  
General Counsel, Novo Nordisk Inc.



PAUL E. KALB  
JAIME L.M. JONES  
Sidley Austin LLP  
Counsel for Novo Nordisk Inc.