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CONFIDENTIAL

VIA FEDERAL EXPRESS

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9,919,024; 9,925,231; 10,011,637 Pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act

To whom it may concern:

Pursuant to Sections 505(j)(2)(B)(i), (ii), (iii), and (iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95, MSN Laboratories Private Ltd. ("MSN"), MSN House, Plot No. C-24, Industrial Estate, Sanath Nagar, Hyderabad, Teleangana, 500018 India, hereby provides notice of the following information to Salix Pharmaceuticals Inc. ("Salix"), as holder o approved New Drug Application ("NDA") N208745 for TRULANCE®, plecanatide; 3 mg, oral tablet according to the records of the U.S. Food and Drug Administration ("FDA"), and to Bausch Health Ireland Limited, as owner of U.S. Patent Nos. 7,041,786 ("the '786 patent"); 9,610,321 ("the '321 patent"); and 9,616,097 ("the '097 patent") according to the records of the United States Patent and Trademark Office ("USPTO"); and to Synergy Pharmaceuticals Inc. ("Synergy") as owner of U.S. Patent Nos. 9,919,024 ("the '024 patent"); 9,925,231 ("the '231 patent"); and 10,011,637 ("the '637 patent") according to the records of the USPTO. Salix is a wholly-owned subsidiary of Bausch Health Companies Inc. ("Bausch"), and Bausch acquired most of Synergy's assets, including all rights to TRULANCE® (plecanatide) and the related intellectual property. As such, Salix, Bausch, and Synergy collectively are referred to herein as "Salix".

I. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), we advise you that the FDA has received an Abbreviated New Drug Application ("ANDA") from MSN for plecanatide; 3 mg, oral tablet. The ANDA contains the required bioavailability and/or bioequivalence data from studies on the plecanatide oral tablet drug product, which is the subject of the ANDA. The ANDA was submitted under 21 U.S.C. § 355(j)(1) and (2)(A). The ANDA includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use and/or sale of plecanatide; 3 mg, oral tablet, before the expiration of the '786, '321, '097, '024, '231, and '637 patents, which are listed in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

II. Pursuant to 21 C.F.R. § 314.95(c)(2), we advise you that the FDA has assigned MSN's ANDA the number 215780.

the dosage form of the proposed drug product is an oral tablet.

VI. Pursuant to 21 C.F.R. § 314.95(c)(6), we advise you that the patents alleged to be invalid, unenforceable and/or not infringed in the paragraph IV certification are the '786, '321, '097, '024, '231, and '637 patents, which are listed in the Orange Book in connection with Salix's NDA N208745 for TRULANCE®, plecanatide oral tablet, 3 mg. According to information provided by Salix to the FDA that is published in the Orange Book, the '786 patent will expire on 30 January 2028; the '321 patent will expire on 15 September 2031; the '097 patent will expire on 20 August 2032; the '024 patent will expire on 15 September 2031; the '231 patent will expire on 15 September 2031; and the '637 patent will expire on 5 June 2034.

VII. It has been certified to the FDA, that in our opinion and to the best of our knowledge, the '786, '321, '097, '024, '231, and '637 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in MSN's ANDA. Therefore, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), detailed statements of the legal and factual bases of MSN's position for the paragraph IV certification set forth in MSN's ANDA is attached hereto and made a part hereof. MSN reserves the right to develop additional grounds, reasons, or authorities that any or all of the claims of the '786, '321, '097, '024, '231, and '637 patents are invalid or not infringed and/or unenforceable.

Pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8), this notice letter includes an Offer of Confidential Access to Application. As required by § 355(j)(5)(C)(i)(III), MSN offers to provide confidential access to certain information from its ANDA No. 215780 for the sole and exclusive purpose of determining whether an infringement action referred to in § 355(j)(5)(B)(iii) can be brought. Requests for access under this Offer of Confidential Access should be made to:

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Counsel for MSN Laboratories Private Ltd.

Enclosures: Offer of Confidential Access to Application and MSN's Confidential Detailed Factual and Legal Bases for its Paragraph IV Certification that U.S. Patent Nos. 7,041,786; 9,610,321; 9,616,097; 9,919,024; 9,925,231; and 10,011,637 are Invalid, Unenforceable and/or Will Not Be Infringed

its knowledge, the claimed subject matter of U.S. Patent No. 7,041,786 is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, offer for sale or importation of the drug product described in MSN's Abbreviated New Drug Application ("ANDA") No. 215780. MSN reserves its rights to raise any additional defenses relating to invalidity, unenforceability, and non-infringement should litigation ensue.

I. TRULANCE® (plecanatide) Oral Tablets, Exclusivity Information, and Orange Book Patents

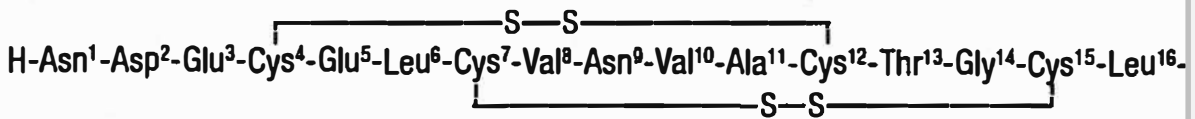
On January 19, 2017, the FDA approved NDA 208745 held by Salix Pharmaceuticals Inc. ("Salix") and related to TRULANCE® (plecanatide) oral tablet (3 mg). Information related to TRULANCE® oral tablets is based on the TRULANCE® prescribing information, as of October 2020 ("TRULANCE® Label").

A. TRULANCE® (plecanatide) Oral Tablets

TRULANCE® is indicated in adults for the treatment of chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C).

TRULANCE® (plecanatide) is a guanylate cyclase-C (GC-C) agonist. Plecanatide is a 16 amino acid peptide with the following chemical name: L-Leucine, L-asparaginyl-L-α-aspartyl-L-α-glutamyl-L-cysteinyl-L-α-glutamyl-L-leucyl-L-cysteinyl-L-valyl-L-asparaginyl-L-valyl-L-alanyl-L-cysteinyl-L-threonylglycl-L-cysteinyl-, cyclic (4→12), (7→15)-bis(disulfide).

The molecular formula of plecanatide is $C_{65}H_{104}N_{18}O_{26}N_4$ and the molecular weight is 1682 Daltons. The amino acid sequence for plecanatide is shown below:



The solid lines linking cysteines illustrate disulfide bridges.

Plecanatide is an amorphous, white to off-white powder. TRULANCE tablets are supplied as 3 mg tablets for oral administration. The inactive ingredients are magnesium stearate and microcrystalline cellulose.

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