Par Pharmaceutical, Inc.
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CONFIDENTIAL

November 20, 2013

Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, California 94304

Jazz Pharmaceuticals International Limited
2 Church Street
Hamilton HM 11
Bermuda

EUSA Pharma (USA), Inc.
1717 Langhorne Newtown Rd #201
Langhorne, PA 19047-1085

EUSA Pharma (Europe), Ltd.
The Magdalen Centre
Oxford Science Park
Oxford OX4 4GA
England

VIA REGISTERED EXPRESS MAIL
RETURN RECEIPT REQUESTED

Re: Sodium Oxybate 500 mg/ml Oral Solution (XYREM®)
United States Patent Nos. 6,780,889; 7,262,219; 7,668,730; 7,765,106; 7,765,107; 7,851,506; 7,895,059; 8,263,650; 8,324,275; and 8,457,988
Notice of Paragraph IV Certification

Dear Sirs:

This is a notice of certification letter on behalf of Par Pharmaceutical, Inc., ("Par") pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act ("the Act") and 21 U.S.C. § 355(j)(2)(B)(ii) and § 314.95 of Title 21 of the Code of Federal Regulations:

1. An Abbreviated New Drug Application ("ANDA") containing any required bioavailability or bioequivalence data or information has been submitted under § 505(j) of the Act for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration date of United States Patent Nos. 6,780,889; 7,262,219; 7,668,730; 7,765,106; 7,765,107; 7,851,506; 7,895,059; 8,263,650; 8,324,275; and 8,457,988, listed in the *Approved Drug Products with Therapeutic Equivalence*

Evaluations (the "Orange Book"). The Food and Drug Administration ("FDA") has received this ANDA for substantive review.

2. The ANDA number is 205403.

3. The established name of Par's proposed drug product is: Sodium Oxybate Oral Solution.

4. The active ingredient, strength, and dosage form of the proposed drug product is 500 mg/ml of sodium oxybate. The dosage form is an oral solution.

5. The Orange Book lists the following U.S. Patents for XYREM® tablets: (1) U.S. Patent No. 6,780,889 ("the '889 patent"), which is listed as expiring on July 4, 2020; (2) U.S. Patent No. 7,262,219 ("the '219 patent"), which is listed as expiring on July 4, 2020; (3) U.S. Patent No. 7,668,730 ("the '730 patent"), which is listed as expiring on June 16, 2024; (4) U.S. Patent No. 7,765,106 ("the '106 patent"), which is listed as expiring on June 16, 2024; (5) U.S. Patent No. 7,765,107 ("the '107 patent"), which is listed as expiring on June 16, 2024; (6) U.S. Patent No. 7,851,506 ("the '506 patent") which is listed as expiring on December 22, 2019; (7) U.S. Patent No. 7,895,059 ("the '059 patent") which is listed as expiring on December 17, 2022; (8) U.S. Patent No. 8,263,650 ("the '650 patent") which is listed as expiring on December 22, 2019; (9) U.S. Patent No. 8,324,275 ("the '275 patent") which is listed as expiring on December 22, 2019; and (10) U.S. Patent No. 8,457,988 ("the '988 patent") which is listed as expiring on December 17, 2022. The ANDA indicates that Par intends to market the product before the expiration of the '889, '219, '730, '106, '107, '506, '059, '650, '275, and '988 patents, and contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that in Par's opinion, these patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the product for which the application is submitted.

6. An Offer of Confidential Access to the ANDA, pursuant to § 505(j)(5)(C)(i)(III) of the Act accompanies this notice as a separate enclosure.

Attached is a detailed statement of the factual and legal bases of Par's patent certification. This information is supplied for the sole purpose of complying with the above-referenced statutes and regulations. Neither Par nor its attorneys waive any attorney-client privilege or work-product immunity concerning the subject matter of this communication.

Sincerely,

Michelle Bonom-Huvala

Michelle Bonom-Huvala
Senior Vice President Corporate Regulatory Affairs
Par Pharmaceutical, Inc.

Encl.: Detailed Statement of the Factual and Legal Bases for Par's Paragraph IV Patent Certification and Offer of Confidential Access

Duplicate with enclosure via FEDEX