Jazz Pharmaceuticals

www.JazzPharmaceuticals.com

June 18, 2012

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Karen Kennard
Director, Division of Dockets Management
Office of Public Information and Library Services
Office of Shared Services
Office of Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

RE: FDA-2012-P-0499-0001/CP

Dear Ms. Kennard:

Thank you for your May 18, 2012 letter indicating the Food and Drug Administration's acceptance of the citizen petition filed by Jazz Pharmaceuticals, Inc. on May 18, 2012, to which the FDA has assigned the above-referenced docket number. Upon review, it appears that your May 18, 2012 letter acknowledges only two of the three actions requested in the referenced petition. Therefore, Jazz respectfully requests that the FDA amend the acceptance of this petition to include all three of the actions requested therein:

1. Immediately publish in the Orange Book bioequivalence requirements specifying whether in vitro or in vivo bioequivalence studies, or both such studies, are required for abbreviated new drug applications (ANDAs) referencing Xyrem (sodium oxybate) oral solution.

2. Not accept for review, review, or approve any ANDA referencing Xyrem (sodium oxybate) oral solution unless and until FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both such studies, are required for ANDAs referencing Xyrem (sodium oxybate) oral solution.

3. Require in vivo bioequivalence studies, including fasted and fed bioequivalence studies and a demonstration of onset of drug action equivalent to Xyrem (sodium oxybate) oral solution, for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem (sodium oxybate) oral solution to the extent such sodium oxybate drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants.

Thank you for your assistance in addressing this matter.

Sincerely,

Philip J. Homerkamp
Vice President, Strategic Operations
On behalf of Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, CA 94304

2012-5322

3180 Porter Drive, Palo Alto, CA 94304
p 650.496.3777 f 650.496.3781

1818 Market Street, Suite 2350, Philadelphia, PA 19103
p 215.832.3750 f 215.832.3789

FDA-2012-P-0499

AMD

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Theresa Perez
Jazz Pharmaceuticals
3180 Porter Drive

Palo Alto, CA 94304

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Karen Kennard
Food and Drug Administration
5630 Fisher Lane
Room 1061, HFA-305
Rockville, MD 20852

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