DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	04/27/2011 - 05/06/2011* FEI NUMBER 3005615655

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Janne LT Wissel, Senior Vice President Chief Regulatory Officer

FIRM NAME	STREET ADDRESS
Jazz Pharmaceuticals, Inc	3180 Porter Dr
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Palo Alto, CA 94304-1212	Sponsor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Not all adverse drug experiences that are both serious and unexpected have been reported to FDA within 15 calendar days of initial receipt of the information.

Specifically,
On 4/21/2011, your firm was made aware of seventy four (74) confirmed death reports for drug product Xyrem retained by your specialty pharmacy during the time period of November 2002-April 2011 that were not expeditiously reported within 15 calendar days to the agency. These seventy four (74) confirmed death reports were previously undetected through the monitoring of your specialty pharmacy.

A representative sample of these seventy four (74) confirmed death reports exceeding the 15-day reporting time-frame and that are more than 2000 days late are summarized as follows:

Jazz Pharmaceuticals, Inc Xyrem Death Reports Submitted Late (>2000 days late)

Specialty Pharmacy Report ID#	Date Information Received at Specialty Pharmacy	15-Day Report Submission Due Date	15-Day Report Submission Date	Days Late
(b) (4)	7/1/2003	7/16/2003	5/6/2011	2851
	7/29/2003	8/13/2003	5/6/2011	2823
	11/3/2003	11/18/2003	5/6/2011	2726
	12/3/2003	12/18/2003	5/6/2011	2696
	3/17/2004	4/1/2004	5/6/2011	2591
	4/16/2004	5/1/2004	5/6/2011	2561
	6/17/2004	7/2/2004	5/6/2011	2499
	7/13/2004	7/28/2004	5/6/2011	2473
	8/19/2004	9/3/2004	5/6/2011	2436
	9/24/2004	10/9/2004	5/6/2011	2400
	10/19/2004	11/3/2004	5/6/2011	2375

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Daniel J. Roberts, Investigator

DATE ISSUED
05/06/2011

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Specialty Pharmacy Report ID#	Date Information Received at Specialty Pharmacy	15-Day Report Submission Due Date	15-Day Report Submission Date	Days Late
(b) (4)	11/17/2004	12/2/2004	5/6/2011	2346
	2/22/2005	3/9/2005	5/6/2011	2249
	4/15/2005	4/30/2005	5/6/2011	2197
	5/6/2005	5/21/2005	5/6/2011	2176
	7/18/2005	8/2/2005	5/6/2011	2103
	8/12/2005	8/27/2005	5/6/2011	2078
	8/12/2005	8/27/2005	5/6/2011	2078
	8/26/2005	9/10/2005	5/6/2011	2064
	8/29/2005	9/13/2005	5/6/2011	2061
	9/1/2005	9/16/2005	5/6/2011	2058
	9/21/2005	10/6/2005	5/6/2011	2038

OBSERVATION 2

Written procedures have not been developed for the surveillance, receipt, evaluation, and reporting to FDA of post marketing adverse drug experiences.

Specifically,
On 4/28/2011, your firm did not have approved procedures in place according to the conventions described in Jazz Pharmaceuticals Doc No. 0001, entitled, "Development and Maintenance of Standard Operating Procedures" for the following drug safety and pharmacovigilance activities:

A) Procedures regarding verification and monitoring of your 3rd party contract research organizations (CROs) and specialty pharmacy for processing and receipt of adverse event data on your behalf. Regarding this, on 4/21/2011 your firm was made aware of seventy four (74) confirmed death reports received and held by your specialty pharmacy without your firm's knowledge and undetected that were not expeditiously submitted or reported to the agency.
B) Determination of whether a reported event is considered serious.
C) Determination of whether a reported event is considered expected (labeled) or unexpected (unlabeled).
D) Instructions on how information is extracted and entered from source reports/documents for inclusion in your electronic drug safety database.
E) Instructions on how to document, capture and report follow-up information received from all

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sources. Including the four (4) basic data elements needed to submit a report (identifiable patient, identifiable reporter, suspect drug, and adverse drug experience).

F) Procedure describing the preparation of periodic safety reports.

G) Procedure for requiring and documenting job related employee training for drug safety and pharmacovigilance activities.

OBSERVATION 3

Individual ADEs which were not reported to FDA in a post marketing 15-day alert have not been included in a periodic safety report.

Specifically,

A) The following three (3) Luvox non-expedited Adverse Drug Experiences (ADEs) have not been reported to the agency in a periodic safety report submission:

Luvox Non-Expedited ADEs not included in a periodic submission	
MCN#	Date Reported to Jazz
JPI-P-009401	12/10/2009
JPI-P-008212	8/6/2009
JPI-P-004502	8/6/2008

B) The following two (2) Xyrem non-expedited Adverse Drug Experiences (ADEs) have not been reported to the agency in a periodic safety report submission:

Xyrem Non-Expedited ADEs not included in a periodic submission	
MCN#	Date Reported to Jazz
JPI-P-009062	2/6/2009
JPI-P-008319	3/8/2009

*** DATES OF INSPECTION:**
04/27/2011(Wed), 04/28/2011(Thu), 04/29/2011(Fri), 05/02/2011(Mon), 05/04/2011(Wed), 05/06/2011(Fri)

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."