Janssen Inc.

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November 30, 2011

URGENT VOLUNTARY TYPE II DRUG RECALL
NOTIFICATION TO WHOLESALERS & PHARMACIES
[PR] VELCADE®* bortezomib mannitol boronic ester for Injection, 3.5 mg/vial bortezomib, Antineoplastic Agent
(Sourced from Ben Venue Laboratories)

Dear Wholesaler/Pharmacist:

We are writing to inform you that Janssen Inc., in consultation with Health Canada, is conducting a precautionary and voluntary recall to the wholesaler hospital and pharmacy level of *[PR] VELCADE® bortezomib mannitol boronic ester for Injection, 3.5 mg/vial bortezomib, Antineoplastic Agent* (DIN 02262452), for all batches manufactured at Ben Venue Laboratories (BVL), Ohio, United States.

The decision to recall has been made following an inspection of the BVL manufacturing facility, in November 2011, where inspection findings revealed deficiencies in sterility assurance at BVL. All VELCADE® batches released to the market complied with release specifications and procedures.

Please see Table 1, below, for a list of BVL batches being recalled.

Table 1: BVL VELCADE® batches being recalled

Batch Number (Expiry Date)	Batch Number (Expiry Date)
9AZT000 (Dec-11)	ACZX600 (Feb-13)
9AZT001 (Dec-11)	ACZX601 (Feb-13)
9DZTI00 (Mar-12)	AGZSH00 (Jun-13)
9DZTI01 (Mar-12)	AIZTY00 (Aug-13)
9EZT000 (Apr-12)	AIZTY01 (Aug-13)
9EZT001 (Apr-12)	BDZS300 (Mar-14)
9EZT002 (Apr-12)	BFZS001 (May-14)
9EZT004 (Apr-12)	BFZS002 (May-14)

IMMEDIATE ACTIONS TO BE TAKEN

- Please examine your inventory and quarantine the BVL batches referenced in Table 1, above.
- Complete and return the RECALL RESPONSE FORM, whether you have product on hand or not.
- Return any **unopened** vials of recalled product back to your point of purchase via your regular return procedure (your wholesaler or directly to MedTurn if product was purchased from Janssen.) **Unopened** vials will be reimbursed at 100% of purchase price.
- If you have **reconstituted** vials, **DO NOT RETURN** them. **Reconstituted** vials will be reimbursed based on the remaining quantities indicated on the RECALL RESPONSE FORM. Once

reimbursement from Janssen has been received, **reconstituted** product can be destroyed on site as per your normal process.

- Please note that as per our return policy, there will be no reimbursement for returns of non-affected batches.

[PR] VELCADE® bortezomib mannitol boronic ester for Injection, 3.5 mg/vial bortezomib, Antineoplastic Agent for injection, is also supplied in Canada by Pierre Fabre Medicament Production (PFMP). The VELCADE® batches most recently distributed in Canada have been sourced from PFMP. It is anticipated that this recall of BVL material will have no impact on the availability of VELCADE® to patients. There are alternative batches available.

Note that the batches listed in Table 2, below, were manufactured by PFMP and have already been distributed. They are **NOT BEING RECALLED**.

Table 2: PFMP batches **NOT BEING RECALLED**:

Batch Number (Expiry Date)	Batch Number (Expiry Date)
BCZSM00 (Feb-14)	AAZTK00 (Dec-12)
BFZSK00 (May 14)	ABZT000 (Jan 13)
BFZSK02 (May 14)	ADZW801 (Mar 13)
BGZT800 (June 14)	[redacted]

If you have any medical questions or if you are aware of an adverse event related to this issue please contact Janssen Inc. at 1-800-567-3331 or 1-800-387-8781.

If you have any questions or need assistance with product return, please contact Client Services at 1-800-567-5667.

We appreciate your immediate attention and cooperation in this matter. We apologize for any inconvenience caused.

Sincerely,
Janssen Inc.