Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

22 May 2014

FDA Advisory
No. ~~2014~~ 037

SUBJECT: PUBLIC HEALTH WARNING AGAINST BORTEZOMIB (VELCADE) 3.5 mg LYOPHILIZED POWDER FOR INJECTION (IV/SC) UNDER BATCHES OF 102424, 102430, 102501, 102502 & 102648

The public is hereby warned by the Food and Drug Administration (FDA) that certain batches of Bortezomib (Velcade) 3.5 mg Lyophilized Powder for Injection has been reported from US and German markets to have cracked vials. The details of the subject product are as follows:

REGISTRATION NUMBER	**DR-XY42460**
BATCH NUMBERS	**102424 / 102430 / 102501 / 102502 / 102648**
MANUFACTURING NAME AND ADDRESS	**BSP PHARMACEUTICALS, S.r.l. VIA APPIA KM. 65, 561 04013 LATINA SCALO (Lt), ITALY**
IMPORTER	**JOHNSON & JOHNSON (PHILIPPINES), INC. PARAÑAQUE CITY**

Consumers and Health Practitioners are advised to inspect all vials of the subject product for any crack or damage before use. If you happen to buy batches of Velcade® that present such defects, please report to FDA via report@fda.gov.ph or to Janssen Pharmaceutica at tel.: +632 824 8968 or e-mail at: Janssendrugsafety_Phil@its.jnj.com.

For more information and inquiries, please e-mail us at info@fda.gov.ph. Any suspected adverse reaction experienced from the aforementioned product should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the ADR Report tab, proceed and fill-out all of the required fields.

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Acting Director General