Sandoz Inc.
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SANDOZ A Novartis Division

Important Correction of Drug Information

June 5, 2018

SUBJECT: Notice to Healthcare Professional Regarding Baxter's Premier ProRx INFUVITE® ADULT Multiple Vitamins Injection Error on Vial #2 Label

Dear Healthcare Professional:

The purpose of this letter is to inform you of an issue with respect to an error on the label on Vial # 2 of Baxter's Premier ProRx INFUVITE® ADULT Multiple Vitamins Injection. Baxter's Infuvite Adult Multiple Vitamins Injection is manufactured by Sandoz Canada Inc., and distributed by Baxter. The 5 mL, 10 pack contains five (5) of Vial #1 and five (5) of Vial #2. One of each vial is required for a single dose.

Summary of an Error in the 5 mL Vial #2 label

The strength of Folic Acid is erroneously stated as 600 mg on the Vial #2 label. The correct strength is 600 mcg, as stated on the package insert and the carton.

Sandoz Inc. has evaluated all the approved INFUVITE® ADULT Multiple Vitamins Injection labels and has determined that this error was only on the Premier ProRx product Vial #2 label.

The table below summarizes the lots with labels impacted by this error.

Material Description	Lot	Expiration Date	NDC Code
PRX INFUVITE Adult Single Dose 10LIVI US	GY5919	08. 2018	54643-7862-9
PRX INFUVITE Adult Single Dose 10LIVI US	GZ9290	08. 2018	54643-7862-9
PRX INFUVITE Adult Single Dose 10LIVI US	HG7655	12. 2018	54643-7862-9

Apart from the error in the label, the product has the appropriate quantity of Folic Acid and is used as a single dose for patient administration. The product itself is considered safe for the patient as its quality and efficacy is not affected.

If the product is administered by healthcare professionals as prescribed, there is no risk to the patient due to the error on the Vial #2 label.

If you have any questions or comments on the information provided in this letter, please contact: Sandoz Quality Compliance Call Center at 1-800-525-2492, Email: qa.drugsafety@sandoz.com.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, or regular mail, or by fax:

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm

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- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Thank you again for your support of INFUVITE® ADULT Multiple Vitamins Injection.

Sincerely,
SANDOZ INC.

Anthony Maffia III,
Vice President, Regulatory Affairs