URGENT Information on ACH-Sitagliptin – Accord Healthcare Inc. – Voluntary Type I Recall of Four Lots



August 9, 2024

Dear Healthcare Professional:

Subject: Accord Healthcare Inc. - Voluntary Type 1 Recall of Four Lots of ACH-Sitagliptin

Product: ACH-Sitagliptin

DINs: 02512475 (25 mg), 02512483 (50 mg), 02512491 (100 mg)

Product Code (Strength and Format): 22211 (25 mg 30 tablets bottle), 22311 (50 mg 30 tablets bottle), 22412 (100 mg

90 tablets bottle)

Lot numbers:

- P2206573 (25 mg) - Expiry Date: Oct-2024

P2206574 (50 mg) – Expiry Date: Oct-2024

- P2206575 (100 mg) – Expiry Date: Oct-2024

P2206981 (100 mg) – Expiry Date: Oct-2024

This letter provides urgent information concerning a voluntary Type I recall for ACH-Sitagliptin for the above-mentioned lot numbers.

<u>Issue/Reason for Recall:</u> Possibility of presence of carcinogenic nitrosamine impurities in product.

What should you do?

- Immediately stop selling the affected products.
- Please contact consumers who may have received the affected lots of ACH-Sitagliptin to take appropriate action.

If you ordered product direct from Accord Healthcare Inc, you will be provided a recall package that includes a returns form. If you have purchased through a wholesaler, please return all products to your point of purchase. Your account will receive a credit for all returns.

Accord Healthcare Inc can be contacted at:

- by e-mail: safety@accordhealth.ca and by Phone: 1-866-296-0354 (Select Option 1)

This recall is being conducted with the knowledge of Health Canada. To satisfy Health Canada recall effectiveness requirements, it is imperative that all consignees within 24 hours:

Acknowledge receipt of the recall communication via email and provide number of units of the recall lot in inventory

Thank you for your immediate attention to this urgent matter. We appreciate your cooperation.

Sincerely,

Pranay Pandya

Director, Quality Assurance and Regulatory Affairs

Accord Healthcare Inc., 3535 Boul. St. Charles, Suite 704 (6th floor), Kirkland, QC, H9H 5B9