CLASS I RECALL ACKNOWLEDGEMENT

7/7/17

Dear Member,

This is to inform you of a device recall involving NovaPen Echo, specifically for the below batches. These batches were shipped from Novo Nordisk between August 1, 2016 and June 22, 2017

The NovoPen Echo® is used for insulin treatment by people with diabetes.

The recall is due to an increase in complaints related to cracked or broken insulin cartridge holders on NovoPen Echo®.

MUTUAL ITEM #	PRODUCT	DEVICE #	BATCH #'s
113-670	**NOVOPEN ECHO REUSABLE INSULIN DELIVERY PEN**	**185459**	**EVG1221-3 EVG1226-2 EVG1226-3 FVG7149-1 FVG7458-3 FVG8134-2 FVG8135-2**

Please acknowledge receipt of this Class I Recall and return this letter to NC Mutual Wholesale Drug. You may return by fax to (919) 596-1453 or by e-mail to: bslaughter@mutualdrug.com

Store Name_____ Customer #_____

Printed Name_____

Signature_____

Date_____

CONSUMER LEVEL
CLASS I RECALL

7/7/17

Dear Member,

This is to inform you of a device recall involving NovaPen Echo, specifically for the below batches. These batches were shipped from Novo Nordisk between August 1, 2016 and June 22, 2017

The NovoPen Echo® is used for insulin treatment by people with diabetes.

The recall is due to an increase in complaints related to cracked or broken insulin cartridge holders on NovoPen Echo®.

If you have further distributed these batches, please identify your customers and notify them at once of this device recall. In your notification to your customers, please include a copy of the attached Patient letter.

PRODUCTS RECALLED BY NOVO NORDISK

MUTUAL ITEM #	PRODUCT	DEVICE#	BATCH #S
113-670	**NOVOPEN ECHO REUSABLE INSULIN DELIVERY PEN**	**185459**	**EVG1221-3 EVG1226-2 EVG1226-3 FVG7149-1 FVG7458-3 FVG8134-2 FVG8135-2**

With this recall, you are asked to:

- Check your products for the affected batches.
- Immediately discontinue distribution of the product being recalled.
- Notify any patients that you may have further distributed this product to.
- **DO NOT RETURN ANY AFFECTED PRODUCTS TO MUTUAL DRUG**
- **Contact Genco at 855-419-8827 to arrange for return and credit**
- Contact Brent Slaughter if you have additional questions.

URGENT: MEDICAL DEVICE RECALL

RE: NOVOPEN ECHO®, DEVICE LIST NUMBER 185459

Batch Number (device carton)	Batch Number (device)	Activate By Date
EVG1221-3	EVG1221	2017-11-30
EVG1226-2	EVG1226	2017-11-30
EVG1226-3	EVG1226	2017-11-30
FVG7149-1	FVG7149	2017-12-31
FVG7458-3	FVG7458	2018-02-28
FVG8134-2	FVG8134	2018-03-31
FVG8135-2	FVG8135	2018-03-31

July 10, 2017

Dear Valued Patient:

This is to inform you of a device recall involving NovoPen Echo®, specifically for batches listed above, shipped from Novo Nordisk between August 1, 2016 and June 22, 2017.

The batch numbers are printed on the NovoPen Echo® as indicated below in the red box (Figure 1).

***Figure 1**: Red square shows where the batch number is located on the NovoPen Echo® (e.g. the batch number is FVG7364)*

Novo Nordisk has detected that the insulin cartridge holder used in a small number of NovoPen Echo® batches may crack or break if exposed to certain chemicals, for example certain cleaning agents and/or household substances (sunscreen, food grease, etc.).

Novo Nordisk urges diabetes patients using a NovoPen Echo® from one of the affected batches to replace the cartridge holder as some could be damaged. Please check your device batch number (either carton or device) against the chart above.

A picture of the cartridge holder is shown below (Figure 2).

Figure 2. Picture of cartridge holder used for NovoPen Echo®

Description of the problem:

If the cartridge holder comes in contact with certain chemicals, against guidance in the Instructions for Use, it can crack or break.

Using a device with a cracked/broken cartridge holder may result in the device delivering a reduced dose of insulin which could potentially lead to high blood sugar. Novo Nordisk believes the risk of experiencing high blood sugar when using a device with an affected cartridge holder is low. Patients using an affected pen may want to check their blood sugar level more frequently until receiving a new cartridge holder.

The warning symptoms of high blood sugar (hyperglycemia) normally appear gradually and can be flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, feeling thirsty; losing your appetite, feeling or being sick (nausea or vomiting). You might not experience any physical signs of high blood sugar, but only be able to see it in your blood sugar measurements.

Immediately examine your product to determine if you have pens from the impacted batches.

- If you have a device from a recalled batch, do not discard your product and do **not** stop treatment without consulting your health care provider.
- Be attentive to your blood sugar levels and be aware of symptoms of hyperglycemia. If you note these symptoms, measure your blood sugar levels as instructed by your health care provider and take appropriate action.
- In the event that you experience symptoms of high blood sugar, contact your health care provider for advice.
- Contact FedEx Supply Chain to request a replacement cartridge holder.

  A dedicated phone number has been established for you to receive a new cartridge holder and provide support:

  855-419-8827, Monday – Friday, 8am – 6pm EDT

Please report any complaints and adverse events to Novo Nordisk's Customer Care, which can be reached at 1-800-727-6500, Monday – Friday, 8:30am – 6pm EDT.

If you are using a NovoPen® Echo® device with a batch number **not** listed above, there is no reason for concern and you can continue to use your device as prescribed.

Novo Nordisk is committed to delivering high-quality products and sincerely apologizes for this unfortunate situation and the concerns and inconvenience it may cause patients and health care professionals. We are working closely with the U.S Food and Drug Administration to ensure patient safety and minimize the disruption this situation causes.

Sincerely,

Michael Sacco
Executive Director, Product Safety and Quality Assurance
Novo Nordisk, Inc.