Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: August 28, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Insulet Corporation – RECALL [Medical Device]

AFFECTED PRODUCT: OmniPod (Pod) Insulin Management System

SUMMARY: Unclassified Recall; This field corrective action is due to the possibility that some of the Pods from these lots may have a higher rate of failure than Insulet's current manufacturing standards.

The following OmniPod lots have been voluntarily recalled:

Distribution	Catalog Number	Description	Lot Number
United States	POD-ZXP420	OmniPod® Insulin Management System	L40806 L40811 L40895 L40976 L41014 L41025 L41067 L41162 L41171 L41197 L41198 L41250

OmniPods from the affected lots were distributed to customers from December 2013 to March 2015.

SUGGESTED ACTION: For consumer inquiry only. Consumers with questions may contact the Company via telephone at 1-855-407-3729 at any time.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Insulet Corporation Issues Voluntary Recall of OmniPod® Insulin Management System

Contact:
Consumer:
1-855-407-3729

FOR IMMEDIATE RELEASE – August 27, 2015 – Billerica, MA – On July 8, 2015, Insulet Corporation (Insulet or the Company) initiated a lot-specific voluntary recall of 40,846 boxes (10 Pods per box) of the OmniPod (Pod) Insulin Management System. This field corrective action is due to the possibility that some of the Pods from these lots may have a higher rate of failure than Insulet's current manufacturing standards. This recall does not affect the OmniPod Personal Diabetes Manager (PDM).

There are two ways in which these Pods can fail at a rate that is higher than Insulet's current standard. The cannula may either completely retract or fail to fully deploy, which may result in the patient not receiving the expected insulin dose. Or the Pod may trigger an audible alarm indicating it will no longer deliver insulin and will need to be replaced. Both situations can result in the interruption of insulin delivery that can cause hyperglycemia, which, if left untreated, can result in diabetic ketoacidosis (DKA).

The affected Pod lots have resulted in 90 Medical Device Reports of which 13 required medical intervention. No serious injuries or deaths have been reported in patients using OmniPod devices from the affected lots.

Please check to determine if you have Pods from any of the lots listed below. The lot number is located on the Pod tray lid label and is also laser etched on the side of each individual Pod. The lot number is also located on the box of OmniPods. Consumers who have Pods from the affected lots should stop using them and return the pods for replacement.

The following OmniPod lots have been voluntarily recalled:

Distribution	Catalog Number	Description	Lot Number
United States	POD-ZXP420	OmniPod® Insulin Management System	L40806 L40811 L40895 L40976 L41014 L41025 L41067 L41162 L41171 L41197 L41198 L41250
International	14810	OmniPod® Insulin Management System	L40771 L40892 L40901 L40905 L40997 L41199 L41208

OmniPods from the affected lots were distributed to customers from December 2013 to March 2015.

Insulet has notified its distributors and customers by email, FedEx, and phone calls and is arranging for return and replacement of all recalled product. Consumers with questions may contact the Company via telephone at 1-855-407-3729 at any time.

Insulet has notified all applicable regulatory agencies of this voluntary action, including U.S. Food and Drug Administration and the Competent Authorities in Austria, Germany, Italy, Netherlands, Norway, Sweden, Switzerland and the UK.

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

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm.
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1800-332-1088 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.

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