

Notice Information: - Recall
17 June 2011

Part 1. Product Information

- a) Title: Ezy Dose Baby Care Kits, Ezy Dose Pacifier Syringe Nursers, Ezy Dose Medicine Spoons* & Flents Paediatric Urine Collectors * Includes 'Duffy Dog' and 'Kyle Crocodile' Medicine Spoons
- b) Product Name/Type: Ezy Dose Baby Care Kits, Ezy Dose Pacifier Syringe Nursers, Ezy Dose Medicine Spoons* & Flents Paediatric Urine Collectors * Includes 'Duffy Dog' and 'Kyle Crocodile' Medicine Spoons
- c) Reference: IMB Safety Notice: SN2011(15)
- d) Manufacturer/Supplier: Manufacturer: Apothecary Products, USA

Part 2. Target Audience

- a) Target Audience: General public
Pharmacies

Part 3. Problem/Issue

- a) Problem/Issue: Non-compliant Ezy Dose Baby Care Kits, Ezy Dose Pacifier Syringe Nursers, Ezy Dose Medicine Spoons and Flents Paediatric Urine Collectors have been provided to pharmacy outlets in Ireland. These dosage products are not CE marked.

Part 4. Background Information

a) Background Information:

The Irish Medicines Board (IMB) is advising that non-compliant Ezy Dose Baby Care Kits, Ezy Dose Pacifier Syringe Nursers, Ezy Dose Medicine Spoons and Flents Paediatric Urine Collectors have been provided to pharmacy outlets in Ireland.

These medicine feeders are marketed for the administration of liquid medicines. As they are not CE marked, it cannot be guaranteed that these products have been manufactured to the appropriate standards and therefore may not reach the required standards of safety and quality, as required by the European medical device legislation.

To date, there have been no incidents reported to the IMB in relation to the use of these medical devices within Ireland. As a precautionary measure, the IMB advises all consumers to stop using Ezy Dose Baby Care Kits, Ezy Dose Pacifier Syringe Nursers, Ezy Dose Medicine Spoons and Flents Paediatric Urine Collectors.

Part 5. Action to be taken

a) Action to be taken:

Advice for Pharmacies

Pharmacies should examine their stock to determine if they have any Ezy Dose Baby Care Kits, Ezy Dose Pacifier Syringe Nursers, Ezy Dose Medicine Spoons and Flents Paediatric Urine Collectors.

If you find that you have these products, cease sale of these products immediately and quarantine all stock and contact Apothecary Products Inc. immediately to obtain further instruction and guidance.

Please advise the IMB should you discover any other similar brands of dosage spoons, dosage droppers or medicines feeders that:

(a) Do not carry the CE mark

(b) Carries a CE mark but the CE mark is not accompanied by a four digit Notified Body number

Advice for Consumers

Consumers should check their medicine feeders to determine if their device is branded Ezy Dose Baby Care Kits, Ezy Dose Pacifier Syringe Nursers, Ezy Dose Medicine Spoons and Flents Paediatric Urine Collectors.

If you find that you have one of these devices, discontinue use immediately and seek an alternative. Consumers with health concerns should consult with their general practitioner.

Part 6. Enquiries

- a) All enquiries should be made to:

Enquiries should be addressed to the manufacturer:

Apothecary Products Inc.

11750 12th Ave South

Burnsville, MN 55337-1295

USA

Contact person: Ms. Jennifer Fulford

Telephone: +1- 952-808-8341

Email: jfulford@apothecaryproducts.com

All adverse incidents relating to a medical device should be reported to the:

Human Products Monitoring

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971 P

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

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