Citizen Petition
Date: 11th February 2020

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to remove the requirement for adequate directions for use to be supplied with the medical devices and accessories listed in premarket submission K170371.

A. Action Requested

The action requested is for the Commissioner to remove the requirement for the medical devices and accessories contained within premarket submission K170371 to be supplied with adequate directions for use. The devices and accessories listed in the original premarket submission K170371 are as follows:

Note - The enteral syringes listed below have been subject to rebranding and then subsequently assigned the codes listed in the column labeled "Part No. assigned due to rebrand" below.

Part No.in K170371	Description in K170371	Part No. assigned due to rebrand	Description assigned due to rebrand
13011100	10 mL DASH 3™ - Single Use ENFit Enteral Syringe	EISO-10	Enteral ISOSAF Syringe 10ml
13011200	20 mL DASH 3™ - Single Use ENFit Enteral Syringe	EISO-20	Enteral ISOSAF Syringe 20ml
13011700	100 mL DASH 3™ - Single Use ENFit Enteral Syringe	EISO-100	Enteral ISOSAF Syringe 100ml
13011610	60 mL DASH 3™ Eccentric - ENFit Enteral Syringe	EISO-60	Enteral ISOSAF Syringe 60ml
13011017	1 mL DASH 3™ - Single Use Low Dose Tip ENFit Syringe	ELDISO-1	Enteral ISOSAF Syringe 1ml Low Dose Tip
13011127	2.5 mL DASH 3™ - Single Use Low Dose Tip ENFit Syringe	ELDISO-2.5	Enteral ISOSAF Syringe 2.5ml Low Dose Tip
13011055	5 mL DASH 3™ - Single Use Low Dose Tip ENFit Syringe	ELDISO-5	Enteral ISOSAF Syringe 5ml Low Dose Tip
13041001	DASH 3™ - ENFit Syringe Cap	Not Applicable	Not Applicable
13041002	DASH 3™ - PP ENFit Syringe Cap	Not Applicable	Not Applicable
13051050	DASH 3™ - ENFit Drawing up Straws 50mm	Not Applicable	Not Applicable
13051100	DASH 3™ - ENFit Drawing up Straws 100mm	Not Applicable	Not Applicable
13051150	DASH 3™ - ENFit Drawing up Straws 150mm	Not Applicable	Not Applicable
13031001	DASH 3™ - ENFit Bottle Adapter – Size 1	Not Applicable	Not Applicable
13031002	DASH 3™ - ENFit Bottle Adapter – Size 2	Not Applicable	Not Applicable

13031003	DASH 3™ - ENFit Bottle Adapter – Size 3	Not Applicable	Not Applicable
13031004	DASH 3™ - ENFit Bottle Adapter – Size 4	Not Applicable	Not Applicable

Table 1. Devices included in the original submission of premarket submission K170371

Having determined that there was no requirement for submission of a 510(k), as per FDA Guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device", the following enteral syringes have also been included within premarket submission number K170371 via documentation (Letters to File).

Part No.	Description
EISO-1	Enteral ISOSAF Syringe 1ml
EISO-3	Enteral ISOSAF Syringe 3ml
ELDISO-3	Enteral ISOSAF Syringe 3ml Low Dose Tip
EISO-5	Enteral ISOSAF Syringe 5ml
EISO-35	Enteral ISOSAF Syringe 35ml
ELDISONN-1	ENFit NN LDT single use syringe 1ml
ELDISONN-3	ENFit NN LDT single use syringe 3ml
EISONN-5	ENFit NN single use syringe 5ml
EISONN-10	ENFit NN single use syringe 10ml
EISONN-20	ENFit NN single use syringe 20ml
EISONN-60	ENFit NN single use syringe 60ml
ELDISO-PFC-1	Enteral ISOSAF Syringe 1ml Low Dose Tip and Push Fit Cap
ELDISO-PFC-3	Enteral ISOSAF Syringe 3ml Low Dose Tip and Push Fit Cap
ELDISO-PFC-6	Enteral ISOSAF Syringe 5ml Low Dose Tip and Push Fit Cap
EISO-PFC-12	Enteral ISOSAF Syringe 10ml and Push Fit Cap
EISO-PFC-20	Enteral ISOSAF Syringe 20ml and Push Fit Cap
EISO-PFC-35	Enteral ISOSAF Syringe 35ml and Push Fit Cap
EISO-PFC-60	Enteral ISOSAF Syringe 60ml and Push Fit Cap

Table 2. Devices included in premarket submission K170371 via Letters to File

B. Statement of Grounds

A request to remove the requirement for provision of directions for use is made, as the use of the enteral syringes and accessories contained within premarket submission K170371 (and subsequent Letters to File) is commonly known. Therefore, they are considered as being exempt from the requirement for provision of directions for use, in accordance with Code of Federal Regulations Title 21, Chapter I, Subchapter H, Subpart D, Section 801.116.

The enteral syringes and accessories contained within K170371 can be used safely without directions for use as they are prescription devices, restricted to sale by or on the order of a physician. The medical devices can therefore not be bought over the counter without a prescription, thus cannot be bought inadvertently, or by individuals unaware of the common practises for use of the medical devices and accessories.

Code of Federal Regulations Title 21, Chapter I, Subchapter H, Subpart A, Section 801.5, requires that the following is stated to the layman;

(a) Statement of conditions / purposes for which the device is intended / prescribed / recommended / suggested / commonly used,
(b) Quantity of dose,
(c) Frequency of administration or application,
(d) Duration of administration or application,
(e) time of administration or application,
(f) Route or method of administration, and
(g) Preparation for use.

For the enteral syringes and accessories within K170371 (and subsequent Letters to File), the above requirements are satisfied by the labeling provided with them.

(a) is satisfied by the device label identifying its intended use (e.g. Enteral Syringe and the Intended Use description)
(b), (c), (d), (e) are not applicable to these medical devices as they are used to draw up and administer feed / medication / fluids via the enteral route and are intended for use with a broad range of enteral feeds / medications / fluids. Therefore, the dose quantity, frequency of administration, duration of use and time of administration will vary dependent upon the fluid chosen, the patient and the condition to be treated. These requirements are determined by physician advice and prescription.
(f) the route of administration is clearly stated on the device label (e.g. Enteral Syringe).
(g) not applicable as the enteral syringes and accessories are supplied sterilized by ethylene oxide, clearly indicated on the labeling by the presence of a 'sterile by ethylene oxide' symbol as per ISO 15223-1 (recognized consensus standard 5-117). There is no requirement for temperature adjustment or other manipulation or process prior to use of the enteral syringes or their accessories. The enteral syringes and accessories are for single use only and are labelled with the 'single use' and 'do not use if packaging damaged' symbols as per ISO 15223-1, ensuring the user is informed that the device and accessories are single use, to be disposed of after one use.

The sterile enteral syringes (ENFit ISOSAF single use syringes, ENFit ISOSAF single use Low Dose Tip (LDT) syringes, ENFit NN single use syringe and Enteral ISOSAF Syringe with push fit cap) are all provided sterile by ethylene oxide in a single unit blister pack. These are then packaged into shelf boxes, which are then packaged into cartons. The quantities regarding the shelf boxes and cartons are dependent on the syringe sizes.

An example of the labelling supplied with the enteral syringes are appended to this document in appendices 1-4. See table 3 below.

The accessories listed in table 1 are not currently marketed in the USA and therefore the accessories have not been subject to rebrand. Thus, their labelling has not yet been updated from that proposed and submitted within premarket notification K170371. The accessories if marketed in the USA would be supplied non-sterile in a single unit blister pack. These would then be placed into a shelf box, subsequently placed into a carton. The quantities regarding the shelf boxes and cartons are dependent on the accessory and its size.
Prior to the accessories being placed on the market in the USA, the current listed accessories will undergo rebranding and all artwork will be updated as appropriate. The process contained in FDA Guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" will be utilized to determine whether a 510(k) or manufacturer documentation would be required for the accessory rebranding.

An example of the proposed labelling regarding the enteral syringe accessories are appended to this document in appendices 5-7. See table 3 below.

Example images of EISO-10, ENFit ISOSAF single use syringe, and ENFit ISOSAF single use syringe LDT, ELDISO-1, in their blister, shelf box and carton packaging configurations are given in Appendix 8. The ENFit NN single use syringes, Enteral ISOSAF Syringe and Push Fit Cap products have not yet been manufactured so images are not yet available. However, their packaging will be the same as that provided for EISO-10 and ELDISO-1, with the labelling as per appendix 3 and 4 respectively. Regarding the accessories, as these are not currently marketed in the USA no example images are available.

Part No.	Description	Packaging level	Units	Location
EISO-10	Enteral ISOSAF Syringe 10ml	Blister	1	Appendix 1
EISO-10	Enteral ISOSAF Syringe 10ml	Shelf box	100	Appendix 1
EISO-10	Enteral ISOSAF Syringe 10ml	Carton	1500	Appendix 1
ELDISO-1	Enteral ISOSAF Syringe 1ml Low Dose Tip	Blister	1	Appendix 2
ELDISO-1	Enteral ISOSAF Syringe 1ml Low Dose Tip	Shelf box	100	Appendix 2
ELDISO-1	Enteral ISOSAF Syringe 1ml Low Dose Tip	Carton	3600	Appendix 2
EISONN-5	ENFit NN single use syringe 5ml	Blister	1	Appendix 3
EISONN-5	ENFit NN single use syringe 5ml	Shelf box	100	Appendix 3
EISONN-5	ENFit NN single use syringe 5ml	Carton	2400	Appendix 3
EISO-PFC-20	Enteral ISOSAF Syringe 20ml and Push Fit Cap	Blister	1	Appendix 4
EISO-PFC-20	Enteral ISOSAF Syringe 20ml and Push Fit Cap	Shelf box	100	Appendix 4
EISO-PFC-20	Enteral ISOSAF Syringe 20ml and Push Fit Cap	Carton	900	Appendix 4
13041001	DASH 3™ - ENFit Syringe Cap	Blister	Not given - example labels	Appendix 5
13041001	DASH 3™ - ENFit Syringe Cap	Shelf box	Not given - example labels	Appendix 5
13041001	DASH 3™ - ENFit Syringe Cap	Carton	Not given - example labels	Appendix 5
13031003	DASH 3™ - ENFit Bottle Adapter – Size 3	Blister	Not given - example labels	Appendix 6
13031003	DASH 3™ - ENFit Bottle Adapter – Size 3	Shelf box	Not given - example labels	Appendix 6
13031003	DASH 3™ - ENFit Bottle Adapter – Size 3	Carton	Not given - example labels	Appendix 6

13051100	DASH 3™ - ENFit Drawing up Straws 100mm	Blister	Not given - example labels	Appendix 7
13051100	DASH 3™ - ENFit Drawing up Straws 100mm	Shelf box	Not given - example labels	Appendix 7
13051100	DASH 3™ - ENFit Drawing up Straws 100mm	Carton	Not given - example labels	Appendix 7

Table 3. Example labels provided

The removal of directions for use will not significantly affect the safety or effectiveness of the enteral syringes and accessories as;
(1) the requirements set out in Code of Federal Regulations Title 21, Chapter I, Subchapter H, Subpart A, Section 801.5 are satisfied by labeling supplied with the device, and
(2) the use of enteral syringes and their accessories are commonly known to the user.

C. Environmental Impact

No known adverse environmental impact is predicted.
A reduction in waste is expected when using the devices and accessories, due to a reduction in printed labeling materials provided.

D. Economic Impact

Economic impact information will be submitted upon request of the commissioner.

E. Certification
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature:

Dr. Steve Curran, Regulatory Affairs Manager

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