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 K170900.

A. Action Requested

The action requested is for the Commissioner to remove the requirement for the below listed medical devices and accessories contained within premarket submission K170900 to be supplied with adequate directions for use. The devices and accessories listed in the original premarket submission K170900 are as follows:

Part No.	Description
15011010	DASH 6® 1 mL Lock Syringe [Sterile]
15011030	DASH 6® 3 mL Lock Syringe [Sterile]
15011050	DASH 6® 5 mL Lock Syringe [Sterile]
15011100	DASH 6® 10 mL Lock Syringe [Sterile]
15011200	DASH 6® 20 mL Lock Syringe [Sterile]
15011600	DASH 6® 60 mL Lock Syringe [Sterile]
15021010	DASH 6® 1 mL Slip Syringe [Sterile]
15021030	DASH 6® 3 mL Slip Syringe [Sterile]
15021050	DASH 6® 5 mL Slip Syringe [Sterile]
15021100	DASH 6® 10 mL Slip Syringe [Sterile]
15021101	DASH 6® 10 mL Plastic Loss of Resistance (LOR) Device [Sterile]
15021200	DASH 6® 20 mL Slip Syringe [Sterile]
15041001	DASH 6® NRFit Syringe Cap [Sterile]
15281100	DASH 6® NRFit 5 µm Drawing up Filter Straw (100mm) [Sterile]
15291050	DASH 6® NRFit 5 µm Blunt Drawing up Filter Needle 18-gauge x 50 mm [Sterile]
15491050	DASH 6® NRFit Blunt Drawing up Needle 18-gauge x 50 mm [Sterile]
15231022	DASH 6® NRFit 0.22 µm Bacterial Disc Filter [Sterile]
15311022	DASH 6® NRFit 0.22 µm Epidural Flat Filter [Sterile]
15300001	DASH 6® NRFit Tuohy Borst Adapter [Bulk non-sterile]
15111001	DASH 6® NRFit Needle Hub Cap [Sterile]
15171001	DASH 6® NRFit Syringe to Syringe Adapter [Sterile]
15200001	DASH 6® NRFit Epidural Catheter Feeder [Bulk non-sterile]

Table 1. Devices included within premarket submission K170900

B. Statement of Grounds

A request to remove the requirement for provision of directions for use is made, as the use of the neuraxial syringes and accessories contained within premarket submission K170900 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 neuraxial syringes and accessories contained within K170900 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 neuraxial syringes and accessories within K170900, the above requirements are satisfied by the labeling provided with them.

(a)is satisfied by the device label identifying its intended use (e.g. DASH 6 Syringe and the Intended Use description). Reference to NRFit and ISO 80369-6 is also made on the device labelling, thus it is clear to the user the devices are only intended for neuraxial use and are only compatible with those devices which are ISO 80369-6 compliant. The device itself also indicates to the user the conditions / purposes for which the device is intended / prescribed / recommended / suggested / commonly used as components of the neuraxial syringes and accessories are coloured yellow. All major manufacturers are using yellow as the colour to identify devices compliant with ISO 80369-6 and intended for neuraxial use. Therefore, the yellow colour of GBUK devices acts as a visual prompt to indicate the purposes for which the device is intended.
(b), (c), (d), (e) are not applicable to these medical devices as they are used to draw up and administer medication / anaesthetic via the neuraxial route and are intended for use with a broad range of neuraxial medications and anaesthetics. Therefore, the dose quantity, frequency of administration, duration of use and time of administration will vary dependent upon the medication / anaesthetic 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. Intended for the administration of medication or anaesthetic via the Neuraxial route). This is further illustrated on the labels by reference to ISO 80369-6 compatibility, thus users are aware such device is only intended for administration via the neuraxial route. The intended route of administration relating to the neuraxial syringes and accessories is also highlighted to the user via a visual prompt. The intended route of administration is also highlighted by the use of yellow components as a visual prompt, in common with industry practice for ISO 80369-6 devices.

(g) is not applicable to the sterile variants of the neuraxial syringes and accessories as such are supplied sterilized by ethylene oxide. The sterility of the devices is 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 neuraxial syringes and accessories listed in Table 1. In addition, the neuraxial 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.
With regards to the bulk non-sterile neuraxial syringes and accessories, these are provided in a bulk non-sterile state to customers who place the devices within a kit, therefore removing the GBUK IFU. The devices and accessories are not supplied directly to customers by such businesses or by GBUK Group Ltd in their bulk non-sterile state.
The businesses placing such devices or accessories within a kit are responsible for the sterilization of such devices and accessories before supplying to customers for use.
It is therefore the responsibility of the business placing the device or accessory within a kit for use by the end user to supply directions for use document if necessary, containing all relevant instructions for adequate preparation for use of the kit.
The bulk non-sterile devices and accessories supplied by GBUK Group Ltd 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, however the ultimate responsibility of the labeling of such devices and accessories lies with the businesses repackaging the devices and accessories. Thus, the user will reply upon labelling provided to them by the re-packer who places the sterile variant(s) of the devices and/or accessories on the market.

The neuraxial syringes and accessories provided in Table 1 above, 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 size and accessory type.
The neuraxial accessories which are provided bulk non-sterile are provided bulk in Polypropylene bags. These are then packaged into cartons. The quantities at each packaging level is dependent on the accessory type.

An example of the labelling supplied with the neuraxial syringes and accessories are appended to this document in appendices 1-13. See table 2 below.

Part No.	Description	Packaging level	Units	Location
15011050	DASH 6® 5 mL Lock Syringe [Sterile]	Blister	1	Appendix 1
		Shelf	100	Appendix 1
		Carton	1500	Appendix 1
15021050	DASH 6® 5 mL Slip Syringe [Sterile]	Blister	1	Appendix 2
		Shelf	100	Appendix 2
		Carton	1500	Appendix 2
15021101	DASH 6® 10 mL Plastic LOR Device Slip [Sterile]	Blister	1	Appendix 3
		Shelf	50	Appendix 3
		Carton	600	Appendix 3
15041001		Blister	1	Appendix 4

	DASH 6® NRFit Syringe Cap [Sterile]	Shelf	100	Appendix 4
		Carton	800	Appendix 4
15281100	DASH 6® NRFit 5 µm Drawing up Filter Straw (100mm) [Sterile]	Blister	1	Appendix 5
		Shelf	100	Appendix 5
		Carton	800	Appendix 5
15291050	DASH 6® NRFit 5 µm Blunt Drawing up Filter Needle 18-gauge x 50 mm [Sterile]	Blister	1	Appendix 6
		Shelf	100	Appendix 6
		Carton	800	Appendix 6
15491050	DASH 6® NRFit Blunt Drawing up Needle 18-gauge x 50 mm [Sterile]	Blister	1	Appendix 7
		Shelf	100	Appendix 7
		Carton	800	Appendix 7
15231022	DASH 6® NRFit 0.22 µm Bacterial Disc Filter [Sterile]	Blister	1	Appendix 8
		Shelf	100	Appendix 8
		Carton	1200	Appendix 8
15311022	DASH 6® NRFit 0.22 µm Epidural Flat Filter [Sterile]	Blister	1	Appendix 9
		Shelf	100	Appendix 9
		Carton	1200	Appendix 9
15300001	DASH 6® NRFit Tuohy Borst Adapter [Bulk non-sterile]	Bulk bag	1000	Appendix 10
		Carton	5000	Appendix 10
15111001	DASH 6® NRFit Needle Hub Cap [Sterile]	Blister	1	Appendix 11
		Shelf	100	Appendix 11
		Carton	800	Appendix 11
15171001	DASH 6® NRFit Syringe to Syringe Adapter [Sterile]	Blister	1	Appendix 12
		Shelf	100	Appendix 12
		Carton	800	Appendix 12
15200001	DASH 6® NRFit Epidural Catheter Feeder [Bulk non-sterile]	Bulk bag	1000	Appendix 13
		Carton	15000	Appendix 13

Table 2. Example labels provided

Example images of the NRFit single use lock syringes, needle hub caps and blunt drawing up filter needles in their blister, shelf box and carton packaging configurations are given in Appendix 14, 15 and 17.

The same packaging configuration of the NRFit single use lock syringes can be applied to NRFit single use slip syringes and NRFit single use Loss of Resistance device.

The same packaging configuration of the NRFit needle hub caps can be applied to NRFit Bacterial Disc Filter, NRFit Epidural Flat Filter, NRFit Syringe to Syringe Adapter and NRFit syringe caps.

The same packaging configuration of the NRFit blunt drawing up filter needle can be applied to NRFit Blunt Drawing up Needle and NRFit 5 µm Drawing up Filter Straw.

Example images of the NRFit single use epidural catheter feeder in bulk pack and carton packaging configurations are given in Appendix 16. The same packaging configuration can be applied to the NRFit Tuohy Borst Adapter, with the only differences being that contained on the label.

The removal of directions for use will not significantly affect the safety or effectiveness of the neuraxial 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 neuraxial syringes and their accessories are commonly known to the user.

C. Environmental Impact

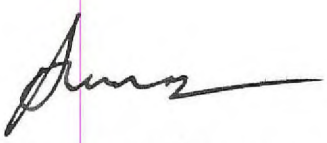
No known adverse environmental impact is predicted.
A reduction in waste is expected when using the devices and accessories, due to a reduction in printed labeling materials provided.

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: 

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