October 7, 2021

LABELING CHANGE REQUEST

Dear Manufacturer,

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is aware of a potential postmarket safety issue regarding the use of ENFit low dose tip (LDT) syringes and concerns with dose accuracy. These devices are regulated under the classification regulation 21 CFR 876.5980 with product code PNR (enteral syringes with enteral specific connectors). The FDA received a complaint regarding possible problems with dose accuracy and the potential for overdose if the user does not clear the moat area around the tip of the ENFit LDT syringe before administering a medication.

The FDA reviewed the device labeling for ENFit LDT syringe provided by several manufacturers. Based on this review, the FDA determined that while some manufacturers included adequate information about the potential for overdose and steps users can take to optimize dose accuracy, not all manufacturers included this information or the information they provided may be incomplete.

It is important that the labeling for each device clearly and completely convey important information to device users. Therefore, FDA is requesting manufacturers who currently manufacture or market and distribute ENFit LDT syringes to review your most recent labeling (i.e., instructions for use) and training materials to assess the need for updates to clearly convey how users should optimize dose accuracy. In addition, FDA requests that all applicable ENFit LDT syringes manufacturers consider adding the following information in the labeling, similar to the following:

> ***Warning***: To optimize dose-accuracy using ENFit LDT syringes, users should:
> - Ensure the syringe is free of air bubbles and the moat of the syringe is free from fluids by tapping or flicking the tip of the syringe before administering the medication.
> - Use a filling adapter, such as an ENFit compatible cap or medication straw, to prevent fluid and medications from entering the moat area of the syringe tip.
> - Be aware that using a medicine cup to fill may cause fluid or medications to enter the moat of the syringe and lead to possible overdose.
> - Use a new syringe to flush the medication or fluid after administering any medication to prevent overdose due to the dead space (the remaining fluid in the tip of the syringe after administration) in the syringe.

Please refer to FDA's guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device[1]," which provides guidance to manufacturers on deciding when to submit a 510(k) for a change to an existing device. For the labeling changes requested above, we do not believe that a new 510(k) is necessary; however, the appropriate internal documentation of your decision-making process and the basis for that conclusion is necessary. Although it is not specifically recommended in the guidance, should you believe submission of a new 510(k) is not necessary for this or additional IFU changes to address this issue, we request that you update your existing 510(k) with your revised labeling by submitting an amendment in hard copy and electronic copy (eCopy) formats referencing the original 510(k) number to the Document

[1] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm514771.pdf

Control Center at the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please note. If you choose to modify your labeling to address this issue, but plan to deviate from the suggested language above, we are providing you the opportunity to receive FDA feedback on your language prior to your implementation and submission of a new 510(k), or amendment to your existing 510(k). Please contact Shani Haugen at Shanil.Haugen@fda.hhs.gov, if you choose to pursue this option. Additionally, please keep in mind FDA's Guidance on Medical Device Patient Labeling[2] when modifying your patient labeling. This guidance document outlines the recommended sequence for important information, as well as how to present that information in ways that are appropriate and comprehensible for lay users.

Please acknowledge receipt of this email within 3 business days by replying to Kathleen.White@fda.hhs.gov and Shani.Haugen@fda.hhs.gov. In addition, within 30 days of receipt of this request, please inform us (via the same email addresses) of your plans to address the requested labeling changes, your timeframe for implementing the changes, and your plans for informing users of the changes. As noted above, any new 510(k) submission or amendment to the existing 510(k) must be submitted to the Document Control Center at CDRH in both paper copy and eCopy format. For more information on eCopies, please see FDA's guidance, "eCopy Program for Medical Device Submissions[3]."

If you have questions about this request, please contact Shani Haugen, PhD at Shanil.Haugen@fda.hhs.gov or by telephone at 301-796-0301.

Sincerely,

Glenn B. Bell -S

Glenn B. Bell, Ph.D.
Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

[2] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070801.pdf
[3] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf