Date: September 11, 2018
From: Tubies Against ENFit
Subj: Response to FDA letter dated Sept. 7, 2018

In a September 7, 2018 letter from the FDA to manufacturers of enteral feeding tubes, health care professionals, hospital purchasing departments, and distributors, the FDA states:

> *"FDA recommends hospitals and clinicians use enteral devices with connectors that meet the…*
> *ISO 80369-1*
> *or ISO 80369-3 standard,*
> ***or that are otherwise designed to reduce the risk of misconnections."***

The FDA letter:

- Is not a mandate to manufacture, purchase or exclusively use ENFit connectors.
- Recommends the use of connectors that are demonstrated to reduce misconnection events.
- Acknowledges that ENFit is not efficacious for certain tube feeders due to ENFit flow constriction. It seems to be an admission from the FDA that ENFit should not have received 510k clearance under the "substantially equivalent" metric as to "safety and efficacy."

It's unfortunate that GEDSA has mischaracterized the FDA letter. The GEDSA website states: "*The… FDA writes a letter reemphasizing the need to make the transition to ISO 80369-3 compliant connectors*." However, the FDA is clear that connectors simply must reduce the risk of misconnections, regardless of being ENFit or not.

Studies are ongoing with respect to infection potential from the narrow and deep moat area of the male patient side ENFit connector. The moat is as deep as 22mm - a depth unreachable by a toothbrush or commercial brush. Build-up of formula and debris in the ENFit moat area presents significant contamination concerns. Such a build-up may lead to bacterial proliferation, thereby increasing patient risk and adding to treatment costs. ENFit manufacturers stipulate that a complex 7 step cleaning process of the moat area is essential, apparently to prevent infection problems. It appears safety of the ENFit moat area is still unknown.

Moreover, it has been proven that the ENFit female syringe tip and ENFit formula pump set fit securely and snugly into an adult tracheostomy tube, creating the deadly potential of formula being administered into a patient's airway. ENFit creates a grave misconnection likelihood, and as such ENFit should be rejected by the medical community at large.

The ENFit design ignores the July 2000 FDA Document entitled, "Medical Device Use-Safety: Incorporating Human Factors Engineering" by Kaye and Crowle. This document states: "*…it is necessary to understand abilities and limitations of the intended users. Important characteristics of user populations include: Coordination (manual dexterity)*." It also states: *"Some degree of testing of the entire system under realistic conditions with representative users is warranted*." Many tube feeders have limited dexterity or the use of only one arm/one hand due to the side effects of radiation, making the ENFit screw thread design impossible for these, at present, independent individuals. For these users, the ENFit screw thread design destroys independence and creates dependency. Additionally, with the ENFit system, the tube to delivery set connection is positively locked. Therefore, if the delivery set tubing is tugged upon, the force of the tugging may be exerted upon the tube itself, lending to premature inadvertent tube removal and loss of administered formula. Further, we are unaware of any real world/real patient disclosed clinical field trials confirming performance of the ENFit connector utilizing all the various modes of delivery of enteral nutrition such as: Formula bolus syringe, formula gravity and pump feeding, blenderized food feedings.

Data received from the FDA in response to a Freedom of Information Act Request shows there were 26 reports of enteral misconnection events between January 1, 2005 and July 14, 2016. An analysis reveals that ENFit does not solve any of these reported incidents. Many of these events relate to the I.V. luer balloon inflation port on dangler type g-tubes. It should be noted that the main port of balloon low-profile devices features an I.V. luer engagement. These I.V. luer ports are key sources of misconnection, yet oddly are specifically exempt from ISO 80369-3/ENFit. These enteral products continue to be manufactured with I.V. luer ports which are a source of misconnection

In conclusion, Tubies recognize that catheter tip syringes and mating funnel ports have been proven safe and efficacious over the last 30 years and clearly comply with the September 2018 recommendation of the FDA. Accordingly, Tubies will continue to demand the tried and true, FDA cleared, safe and efficacious catheter tip syringes and funnel ports.

Tubies look forward to working and dialoguing with the FDA to help ensure that the needs of tube feeders are met.