MESSAGE

To whom it may concern

OnDosis develops and manufacture Dosage manages for Medicines/ Drugs.
Medicines/ Drugs that benefit from using the OnDosis dosage managers are drugs that enables the user to adapt the dose very precise. These can be highly regulated drugs or other vital Medicines/ Drugs that require precise dosing.
In the FDA regulations the OnDosis dosage manager is defined as the "device constituent part of a Combination product".
This means that according to the FDA, the device itself is not the actual product. This is because the device must be configurated to the drug.
OnDosis collaborate with multiple drug manufacturers, and the OnDosis dosage manager ODM01 with the control unit CU1 will be used for many different types of Medicines/ Drugs manufactured by many different Medicine/ Drug manufacturers.
Because of the many different variants of drugs and dosing schemes, the Control unit CU1 (including the radio) will be configurated to allow only to dispense a specific Medicine/ Drug.
The Device (CU01) itself will be identical, down to the actual dosing scheme that is configurated in the embedded software and the labelling (Legal manufacturer, drug type, etc.).
This means that the Pictures of the product and the IFU (User manual) will be finalized by the Medicine/ Drug manufacturer. The IFU includes important information about the Medicine/ Drug, Dosing scheme and legal manufacturer. For this reason, we are asking the FCC to keep the IFU and Pictures of the OnDosis generic device confidential. There is a risk that it can confuse the user of the Product. The user will be provided with a IFU from the Medicine/ Drug manufacturer that is based on the generic IFU that OnDosis has created.
The Medicine/ Drug manufacturer will base the Medicine/ Drug specific IFU on the OnDosis generic IFU and add the following information:

- Medicine/ Drug name (Brand name)
- Dosing scheme
- Warnings and Cautions
- Other Medicine/ Drug specific features
- Legal manufacturer name
- Contact information to Legal manufacturer
- Pictures of the product with the Medicine/ Drug name printed on the device

We do respect the FCC regulations, and we would normally not ask for confidentiality of the IFU or pictures of the device unless it could impact the patient safety of the Drug device combination product.
I do hope that this letter explains the reason for the request to keep the IFU and pictures of the device confidential.

Kind regards

Stefan Kristo
Head of Design and Development
OnDosis.com

END OF MESSAGE

This is an example of the Label on the CU01 that will be used by the company that we have the NDA with