From: Samir Shah

To: Leann Nguyen
Date: October 04, 2016

Subject: Request for Info - File # 1420-EX-ST-2016

Message:

Leann,

Thank you for your quick responses to our STA.

Teva is conducting a clinical study using an experimental inhaler to treat respiratory disease. The inhaler includes the medicine (albuterol sulfate) and an electronics module (with a Bluetooth transmitter) used to record and transmit inhaler usage data. The patient may choose to download this information from the inhaler via a Bluetooth connection to a mobile device. As part of the clinical trial, the patient will receive monthly calls from the investigator (physician) to assess symptoms of respiratory disease. The data from the inhalers will then be downloaded for additional analysis.

The inhaler with the electronics unit is not yet approved by the FDA and Teva will be conducting several studies with the inhaler and submitting the results to the FDA for final approval of the product. The electronics module has a standard Bluetooth chip (nRF51822), antenna and custom circuitry and Teva is in the process of conducting required tests to support certification and obtain equipment authorization for the RF device to allow for importation of product in the future.

This clinical study is scheduled to start in November 2016 as patients are more likely to experience respiratory illness in the winter season. Unfortunately, Teva would not have obtained equipment authorization for the RF device in the inhaler by this time. We are requesting this STA so we can import the inhalers from our facilities in Jerusalem, Israel, and allow for testing in this short-term clinical study. All test product will be returned to Teva by the patients and will not be marketed or sold commercially.

A large number of patients are usually required for analysis when testing drug products for approval. We are requesting importation of 3000 inhalers to account for the number of patients in this study and 1000 empty inhalers for training and demonstration purposes (total of 4000 units).

This clinical study is being conducted under the FDA lND (Investigation New Drug) number: 104532

If you have any further questions, feel free to contact me.

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