

**From:** Qian, Jiahua  
**To:** ["ROFI \(Robert Fischer\)"](#)  
**Subject:** Novothirteen- BLA 125398\0\_IFU request  
**Date:** Monday, June 03, 2013 1:10:00 PM

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Bob,

We are reviewing your PPI and have the following request:

As Novothirteen is to be used prophylactic ally and will be self-administered, please generate a patient Information For Use (IFU) document for review by the FDA. You may use the IFU for Advate as an example.

Since we are approaching the due date of June 28, I'd like to have your response by Monday, June 10th.

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