

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125398/0 Office: OBRR

Product:

Coagulation Factor XIII A Subunit (Recombinant)

Applicant:

Novo Nordisk Inc.

Telecon Date/Time: 14-Nov-2013 01:30 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Information Request

Author: Jiahua Qian

Telecon Summary:

Novothirteen proprietary name

FDA Participants: Nisha Jain, Lisa Stockbridge, Loan Nguyen, Tim Lee, Zuben Sauna

Non-FDA Participants: Lewis Pollack

Related STNs: None

Related PMCs: None

Telecon Body:

FDA had a teleconference with Novo Nordisk (NN) regarding the proprietary name, Novothirteen.

FDA informed NN that the medication error has occurred between NN's products, insulin and Factor. The name of both products starts with "Novo". Things such as illegible handwriting, unfamiliarity with drug names, similar packaging may increase the probability of medication errors.

To avoid drug name confusion, FDA asked NN to either propose new proprietary names or provide solid safety justification for keeping the current name.

NN said that Novothirteen will be distributed through specialized pharmacies and hemophiliac treatment centers. FDA asked NN to take the situation in emergency rooms in to consideration.

NN acknowledged FDA concerns and requests and will submit the response by next Wednesday, November 20th, 2013