

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: 08-May-2013 09:00 AM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Information Request

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Telecon Summary:

Labeling Information Request

FDA Participants: Drs. Nisha Jain, Zuben Sauna, Timothy Lee

Non-FDA Participants: Robert Fischer

Telecon Body:

FDA requested teleconference to discuss NN labeling supplement dated April 30, 2013

The following were discussed:

1. FDA recommended NN not to use “tall man” lettering in the middle of the trade name, such as T in NovoThirteen.
2. Under “indications and use”: FDA suggested that the statement, “Do not use with Congenital Factor XIII B subunit deficiency” be replaced with “Not for use with Congenital Factor XIII B subunit deficiency”.
3. Under “dosage and administration”: FDA sought clarification on the dose adjustment that would be required as well as the target trough level that should be maintained. FDA indicated to Novo Nordisk that appropriate changes will have to be made in the PI.
4. Under “dosage forms and strengths”: FDA suggested that as the PI provides a range with respect to the units of FXIII per vial a range should also be provided for IU/mL.
5. Under “use in specific populations”: FDA sought clarification for the dilution procedure for patients who weigh less than 24 kg.

6. FDA and Novo Nordisk agreed that additional queries and/or comments would be provided by FDA in the “track changes” mode for Novo Nordisk to respond to.

END