

Transmittal Memo

TO: Lorrie McNeill, Director, OCOD

FROM: Basil Golding, MD, OBRR/DHRR

RE: Action Package for STN 125426/0, Coagulation Factor IX (Recombinant) [IXINITY]

DATE: April 29, 2015

Product Office Point of Contact: Edward Thompson

The attached list identifies the documents in CBER's Electronic Document Room (EDR) that are the official Action Package for Posting under Section 916 of FDAAA.

This list identifies the documents for the Action Package that are available in MS Word, MS Excel or, for emails, Rich Text Format (RTF) or Text (TXT) format. The list also identifies the documents for which, after a thorough search, MS Word, MS Excel or, for emails, Rich Text Format or Text format copies are not available. We are providing these in the formats noted in the list (or in PDF or hardcopy if all the same).

Please review and redact these documents and post on CBER's Web page.