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RESEARCH**

*APPLICATION NUMBER:*

**22-138**

**20-164 S-075**

**CHEMISTRY REVIEW(S)**

Initial Quality Assessment  
Branch I

<b>OND Division:</b>	Division of Cardiovascular and Renal Products
<b>NDA:</b>	22-138
<b>Applicant:</b>	Sanofi Aventis
<b>Letter Date:</b>	17 Nov 2006
<b>Stamp Date:</b>	17 Nov 2006
<b>PDUFA Date:</b>	17 May 2007
<b>Tradename:</b>	Lovenox
<b>Established Name:</b>	enoxaparin sodium
<b>Dosage Form:</b>	Injection, 100 mg/mL and 150 mg/mL
<b>Route of Administration:</b>	Subcutaneous and intravenous injection
<b>Indication:</b>	Treatment of acute ST-segment elevation Myocardial Infarction (STEMI) including patients to be managed medically or with subsequent Percutaneous Coronary Intervention (PCI)
<b>Assessed by:</b>	Kasturi Srinivasachar
<b>ONDQA Fileability:</b>	Yes
<b>Comments for 74-Day Letter:</b>	No

**Summary**

This is an electronic Type 6 NDA for a drug product (NDA 20-164) that was approved by the Division of Gastrointestinal and Coagulation Drug Products on March 29, 1993 for the prophylaxis and treatment of deep vein thrombosis as well as the prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin. The only difference between NDA 20-164 and NDA 22-138 is that the indications have been expanded to include treatment of acute STEMI. NDA 20-164 was reviewed by Joseph Sieczkowski.

Enoxaparin sodium is a low molecular weight heparin (average molecular wt. of 4500 daltons) which is obtained by alkaline depolymerization of heparin benzyl ester derived from porcine intestinal mucosa. The drug product is marketed in 100mg/mL (pre-filled syringes, graduated pre-filled syringes and a multidose vial) and 150 mg/mL (graduated pre-filled syringes) strengths and labeled for subcutaneous use. The product is now proposed for iv use in STEMI patients as the first bolus dose, administered via an intravenous line using 100mL infusion bags containing 0.9% saline or 5% dextrose in water.

Compatibility studies have been performed on Lovenox Injection with typical infusion bags used in the US and made of polyvinyl chloride and polyethylene and containing either 5% dextrose in water or 0.9% saline i.e. a total of 4 conditions. For each condition the infusion bags were prepared to give the following concentrations of enoxaparin sodium to reflect usual clinical practices:

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/s/

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Kasturi Srinivasachar  
5/11/2007 11:56:36 AM  
CHEMIST

Ramesh Sood  
5/11/2007 12:25:34 PM  
CHEMIST