

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020164, S015

MICROBIOLOGY REVIEW(S)

2. AMENDMENT: None
3. RELATED DOCUMENTS: NDA 20-164
4. ASSIGNED FOR REVIEW: June 24, 1997
5. DATE OF CONSULT REQUEST: June 16, 1997

C. REMARKS:

Identical chemistry sections were submitted in both supplements S-015 and S-016. The submissions provide for the qualification of new syringes and a new line (line 4) for the manufacture of Lovenox Injection.

D. CONCLUSIONS:

The submissions are recommended for approval for issues concerning microbiology.

APPEARS THIS WAY ON ORIGINAL

/SI

Brenda Uratani, Ph.D.
Review Microbiologist

/SI

8/5/97

8/5/97

cc:

NDA 20-164/S-015, S-016
HFD-180/ Div. File
HFD-805 /Uratani
HFD-180/CSO/ K. Oliver
drafted by: Brenda Uratani, 8/5/97
R/D initialed by P.Cooney, 8/5/97