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.

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**Appears this way on original**

/Sp/ [Signature]

8/5/97

Brenda Uratani, Ph.D.
Review Microbiologist

/Sp/ [Signature]

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