



3V
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Central Document Room
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Dear FDA Official:

Enclosed please find three copies of a revised Time and Extent Application for Uvasorb HEB. This Time and Extent Application is revised based upon telephone conferences between myself, Matthew Holman and Michael Koenig of FDA. This revision is for the public copy of the application only and includes the following:

- Revision to section III to include total dosage unit information.
- Revision to Table 1 to include customer identity.
- Inclusion of Table 2 label information.
- Inclusion of Table 5 product labels.
- Re-formatting to identify more clearly information redacted for confidentiality protection.

If there are any questions about this submission I can be reached at 843/520-5128 or by email at j.schroer@3vusa.com.

Sincerely,

John Schroer
Regulatory Manager
3V Inc.