



Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

OB-NDA 20-0952

March 31, 1999

BioTime, Inc.
Attention: Ronald G. Leonardi, Ph.D.
935 Pardee Street
Berkeley, CA 94710

Re: NDA 20-0952 Hextend, High Molecular Weight Hydroxyethyl Starch 6%
(Hetastarch) in Buffered Electrolyte Dextrose Solution

Dear Dr. Leonardi:

Please refer to your March 30, 1998 new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hextend, High Molecular Weight Hydroxyethyl Starch 6% (Hetastarch) in Buffered Electrolyte Dextrose Solution.

We acknowledge receipt of your amendment dated November 27, 1998.

This application provides for the use of Hextend as a plasma volume expander for treatment of hypovolemia during surgery.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed marked-up draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling must be identical to the enclosed marked-up draft labeling. Marketing the product with final printed labeling that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen copies of the final printed labeling as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-0952. Approval of this submission by FDA is not required before the labeling is used.

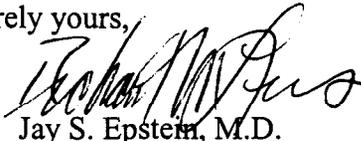
Should additional information relating to the safety and effectiveness of the drug becomes available, revision of that labeling may be required.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Should you have any questions, please contact:
Mr. Martin Northern
301-827-3524.

Sincerely yours,

Jr



Jay S. Epstein, M.D.

Director

Office of Blood Research and Review

Center for Biologics

Evaluation and Research

Enclosure