DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 3, 2000

OB-NDA: 98-0123

Haemonetics Corporation
Attention: Velda M. Hamilton
Director, Regulatory Affairs, Solutions
400 Wood Road
Braintree, MA 02184

RE: NDA 98-0123 Anticoagulant Sodium Citrate 4% w/v Solution, U.S.P.

Dear Ms. Hamilton:

Please refer to your January 22,1998 new drug application and your resubmissions dated January 29, 1999 and November 2, 1999, respectively submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Anticoagulant Sodium Citrate, 4% w/v Solution U.S.P.

This new drug application provides for the manufacture of the product at a Haemonetic's facility as well as purchase from another FDA-approved manufacturer.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate tha the drug is safe and effective for use as recommended. Accordingly, the application is approved effective on the date of this letter.

Please submit one market package of the product when it is available.

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

If you have any questions, please contact:

Martin E. Northern,SBB(ASCP)
Consumer Safcty Officer
(301) 827-3524

Sincerely yours,

Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics