



*John E. Hammer, C.O. 7-30-99*

Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: 313-226-6260

*M2828n*

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

July 29, 1999

WARNING LETTER

99-DT-11

Donald W. Barnhart, Director  
Saturn Biomedical, Inc.  
3266 N. Meridian St., Suite 302  
Indianapolis, Indiana 46208

Dear Mr. Barnhart:

An inspection of your facility was conducted on July 1 - 8, 1999 by the Food and Drug Administration. The inspection revealed significant deviations from Current Good Manufacturing Practice Regulations for Blood and Blood Products, Title 21, Code of Federal Regulations, Part 606 and 640 (21 CFR 606 and 640). These deviations cause your product, Source Plasma, to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), Section 501(a)(2)(B), as follows:

1. Failure to establish/follow written procedures for next-day blood cell reinfusion [21 CFR 606.100(b)];
2. Failure to calibrate equipment used in the collection and storage of Source Plasma as required [21 CFR 606.60(a)];
3. Failure to follow Standard Operating Procedure (SOP) regarding documentation of freezer/thaw events [21 CFR 606.100(b)].

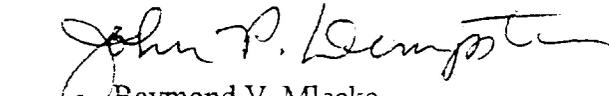
The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your center is in full compliance with the Act and regulations promulgated thereunder.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as license suspension, license revocation, seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay, and the time in which the corrections will be completed.

Your response should be directed to this office to the attention of Ms. Kathleen M. Lewis, Compliance Officer.

Sincerely yours,

  
Raymond V. Mlecko  
District Director  
Detroit District