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August 28, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Availability of Licensed Donor Screening Tests Labeled for
Use with Cadaveric Blood Specimens**

Dear Sir:

SACRAMENTO BLOOD CENTER
1625 Stockton Boulevard
Sacramento, CA 95816-7089
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FAX 916/452-9232

NORTH STATE BLOOD CENTER
1880 Park Marina Drive
Redding, CA 96001
TEL 530/243-0160
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NORTH VALLEY BLOOD CENTER
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CENTER FOR BLOOD RESEARCH
1631 Stockton Boulevard
Sacramento, CA 95816-7089
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Thank you for the opportunity to comment on the recent Guidance for Industry entitled, "*Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens.*" While I can appreciate that there is concern at CBER re using tests licensed and approved for use on blood donor specimens for testing of cadaveric specimens which may be hemolyzed or lipemic, I wish to know whether or not this is truly a "guidance document," or whether it is a requirement already specified in the Code of Federal Regulations, specifically per 21 CFR 1270.21(d).

Our blood center tests specimens from two organ procurement agencies, which also work with tissue banks. To require us to carry out tests licensed by a single manufacturer, Genetic Systems, for two of the tests which we already perform, by January 31, 2001, will result in duplicative testing of specimens and the onerous task of having two technologies to carry out the same assays. Further, if yet another manufacturer comes out with a different test qualified for use on cadaveric specimens, it would appear that we would have to add yet another technology to do another test that is already approved for use on blood donor specimens. If it is not necessary to repeat the testing of cadaveric specimens from donors which have already been tested prior to the implementation date, and these tests have been perfectly adequate for the past several years, why must they be implemented on or before January 31, 2001 anyway? Further, it is my understanding that testing hemolyzed specimens, or those that are lipemic, is more likely to result in false positive or invalid tests than false negative ones, which should be your major concern.

Among tests which are currently awaiting FDA licensure are those for Abbott's PRISM. I believe several of the tests which will be available on the PRISM have been validated on cadaveric specimens. I urge you to approve the licensure of the reagents for this machine, which is itself licensed, but cannot be used until reagents are similarly licensed. We would like to switch to assays on the PRISM as soon as they are available. This would permit us to have a single technology to

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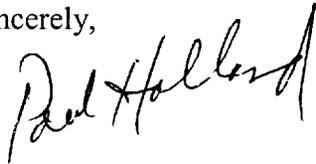
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test both blood donor specimens as well as cadaveric samples. It is my urgent hope that this will take place long before the deadline of January 31, 2001. I implore you to facilitate this licensure. I have seen the Abbott PRISM apparatus in use in a number of countries over the past few years. It certainly meets and exceeds its expectations. It is unfortunate that Americans do not similarly have access to this technology.

Thank you for your attention to the above.

Sincerely,

A handwritten signature in black ink that reads "Paul Holland". The signature is written in a cursive, slightly slanted style.

Paul V. Holland, M.D.
Medical Director/Chief Executive Officer
Clinical Professor of Medicine
Division of Hematology/Oncology
University of California at Davis Medical Center

PVH:rc 276.00

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SACRAMENTO MEDICAL FOUNDATION

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Return Service Requested

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