

BONFILS  **BLOOD CENTER**

Colorado's Community Blood Center

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February 4, 2002

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

Attention: Indira Hewlett, PhD

RE: Draft Guidance for Industry, December 2001 -- Docket No. 01D-0584

Dear Doctor Hewlett:

Clarification of the statement in Part IV Implementation should be made. In this part you say that after approval for use of a licensed HIV-1 and HCV NAT, the establishment may continue using an alternative NAT testing under an approved IND. This statement continues; provided that the manufacturer implements the approved test at the same time. It is not clear what the meaning of that statement is. If a licensed Source Plasma operation has access to the now ongoing blood donor IND for HCV and HIV, such as a licensed blood center with a Source Plasma license, this testing should be acceptable in lieu of using the NGI license test or any other test. This is particularly cogent since blood centers are using a 24-donor pool as opposed to a much larger pool in the Source Plasma process.

Sincerely,



W. C. Dickey, MD
President/CEO

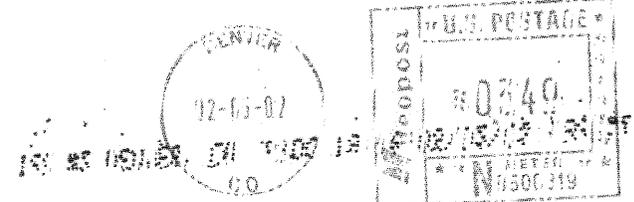
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Colorado's Community Blood Center
717 Yosemite Street Denver CO 80230



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