mayo

Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905
507-284-2511

S. Breanndan Moore, M.D.
Department of Laboratory Medicine
and Pathology

2635 '02 FEB 13 A11 :33

February 6, 2001

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

Re: Comments on 21 CFR Parts 606 and 610 : Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection ("Lookback"); Proposed Rule

To Whom It May Concern:

We wish to comment on the proposed regulations as follows:

1. The proposed regulations as written relative to the extent of time to be "looked back" are clearly unfair to institutions which have the best records for the longest period of time since they stipulate an "indefinite" lookback period for computerized electronic records and until January 1, 1988 for other "readily retrievable records". What is your definition of "readily"?

   It would seem intuitively unfair and counterproductive to demand indefinite lookback for hospitals who keep the most complete records. The message this gives is – "do not keep indefinite records because FDA may punish you with an extra lookback burden because you were too careful and thorough in your record keeping". We believe that a finite date should be set irrespective of the method of record keeping of the center or hospital.

2. This same stipulation regarding "indefinite" lookback is internally inconsistent if a hospital or center has computerized records for one type of product (e.g., for RBC) but only paper records for another (e.g., platelets) because they phased in the computerization of records (as we did)!

Sincerely,

S. Breanndan Moore

S. Breanndan Moore, M.D.
Chair, Division of Transfusion Medicine

SBM:mct
cc: R. Fehrenkamp
J. Kruger
T. Motschman
M. Foss
L. Shepherd

C1

99N-2337

mayo

Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905

PRESORTED FIRST CLASS

ROCHESTER MN FEB 08'01

PB METER 7036157 U.S. POSTAGE $0.27

T1D **DSDF MAILED FROM ZIP 554**

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

20857 AUMB