DEPARTMENT OF THE ARMY
ARMED SERVICES BLOOD PROGRAM OFFICE
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO ATTENTION OF

2134 '03 OCT 28 P4:02

ASBPO (40-2b)

28 October 2003

MEMORANDUM FOR DIVISION OF DOCKETS MANAGEMENT (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE, 1061
ROCKVILLE, MD 20852

SUBJECT: Comments to Proposed Rule, 21 CFR Parts 600, 606, 610 and 640, Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma, Docket No. 2003N-0211

1. The Armed Services Blood Program Office (ASBPO) was established by the Assistant Secretary of Defense for Health Affairs to coordinate the blood programs of the Military Services and the Unified Commands. In that respect, the ASBPO is submitting comments to the proposed rule for 21 CFR Parts 600, 606, 610, and 640, Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma.

2. The ASBPO fully endorses the Food and Drug Administration's (FDA) proposed changes to the CFR to combine and simplify container labeling requirements, as well as facilitate the use of labeling systems using machine-readable information that would be acceptable as a replacement for the "ABC Codabar" system for labeling blood and blood components. ASBPO has long been a strong proponent of standardized technologies, such as bar coding, that reduce the risk of human error and potentially save the lives of our patients. The proposed changes to 606.121 to allow use of the facility identification numbers other than the FDA registration number, such as the ISBT facility code, is an excellent advancement.

3. ASBPO **does not concur** with the proposed revisions related to temperature requirements for storage and shipment of frozen non-cellular blood components in 610.53, 640.34 and 640.54. The FDA proposes changing the current storage and shipping temperatures to guard against degradation of the heat labile clotting factors referencing a European study. The proposed change is from storage at –18°C or colder with a 12 month outdate to 3 months if stored between -18°C and -25°C, along with an extension to 24 months if stored at or below –25°C. We believe the study does not support the 1-year to 3-month expiration change for storage at –18°C. In fact, the study concludes that FFP can be stored at –20°C for two years with no statistically significant changes in factor assay results. There is also concern about the variability in the manufacturing steps used in this study and that they were not consistent with current US FDA requirements for the manufacture of Fresh Frozen Plasma (FFP) and Cryoprecipitate.

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4. Additionally, "the agency believes that (the proposed changes) in fact reflect current industry practice and (would) not impose an additional burden." The proposed amendments, in fact, are not consistent with current practice in the United States. Current practice has been well defined by the FDA, as well as the Standards of the American Association of Blood Banks. FFP and Cryoprecipitate stored at –18°C or colder have an expiration date of 12 months. We are not aware of any studies that have shown negative clinical outcomes from the use of these products. The US Navy, US license 611, has an FDA-approved license for storage of FFP at –65°C for 7 years. However, conversion to the colder temperature of storage has proven logistically challenging especially with regard to shipment and subsequent storage at higher temperatures. Such changes to higher storage temperatures require expiration date changes and subsequent relabeling. Consequently, little if any FFP is manufactured with the 7-year expiration because of these challenges.

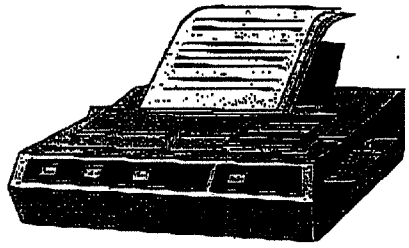
5. Further considerations omitted by the agency in its proposal, are the impact on equipment. These changes will require alteration of freezer temperatures. Unless the facility has ultra-low storage, new freezers or additional compressors for walk-in freezers will have to be procured. Alarm systems will have to be reset if possible or new systems will have to be obtained. Our current field freezers do not support the colder storage, hence, all FFP shipped in support of contingency operations would have a 3-month expiration in field conditions. Given that we currently experience a very high breakage rate due to long shipment chain with multiple on-loading/off-loading steps, the shortened expiration time will only exacerbate an already challenging supply problem. These proposed changes will have a significant negative impact on delivery of haemostatic agents to our casualties.

6. Finally, changes to storage temperatures and expiration times must be made to our computer system, the Defense Blood Standard System (DBSS). Changes to 510K cleared computer systems take time. Changes to computer systems developed within the Department of Defense (DOD) that operates on a 5-year budget cycle take even longer. We are currently programming for FY 06-11 this year and DBSS requirements for out years are already being set. These sorts of changes can't be made quickly and will be costly. Proposed changes such as these that have such far-reaching consequences will require more than 180 days implementation as proposed with this rule.

7. In conclusion, the ASBPO supports the portions of the Proposed Rule that simplify and update the specific regulations applicable to the container label and the use of ISBT 128 labels. We do not support the proposed changes to shorten the expiration date of frozen non-cellular products since they do not appear to be based on sound scientific or clinical evidence, while imposing unnecessary burdens on DOD's blood establishments and the delivery of essential medical care to our wounded soldiers, sailors, airmen and marines in combat environments. Thank you for the opportunity to comment on your proposed rule.

RUTH D. SYLVESTER
Lt Col, USAF, BSC
Director

TELECOPIER HEADER SHEET



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REMARKS: COMMENTS TO DOCKET NO 2003N-0211

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