



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Bethesda, MD 20205

June 2, 1986

FROM: Director, Office of Biologics Research and Review

SUBJECT: Reduction of the Maximum Platelet Storage Period to 5 Days  
in an Approved Container.

TO: All Registered Blood Establishments

On February 13, 1986, the Blood and Blood Products Advisory Committee reviewed data pertaining to bacterial contamination of platelets for transfusion. They concluded that there was cause for concern, that more information was needed, and that a reasonable interim measure was reduction of the maximum storage period for platelets from 7 days to 5 days for containers of all manufacturers now approved for storage for 7 days.

Background:

1. The platelet storage period was increased from 3 to 5 days in 1981 with the introduction of new plastics. The storage period was further increased to 7 days in 1984, using the same container materials.
2. There has been an increase in the number of reported cases of post-transfusion sepsis. Data derived from fatal reaction reports made to the FDA and from manufacturers' complaint files were summarized and showed one report in 1980, one in 1982, three in 1983, three in 1984, and eleven in 1985.
3. Data were presented showing that while low-level inocula may yield relatively little growth at 2 or 3 days, significant levels may be seen in 5 to 7 days of storage.

In view of these data OBRR recommends the following:

1. Since the major route of contamination is the donor's skin, renewed attention to skin preparation is in order. Blood establishments should review their procedures and training relevant to donor skin preparation.
2. Until safety data can be presented to support 7-day storage, platelets shall be stored for a maximum of 5 days in an approved container. Compliance with this change in dating period should become effective within 30 days of this notice.

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for Elaine C. Esber, M.D.