FDA: Report on Red Cross amended to correct errors

The FDA's initial Red Cross inspection report on the case of Piedmont Hospital patient Rodney English, dated June 10, also cited these issues:

➤ An unnamed patient who died in January 2004 after a possible allergic reaction to a transfusion of fresh frozen plasma.

➤ An unnamed patient who died in July 2003 after receiving four units of blood, at least two containing an antigen called Fy(a). The patient had an antibody to Fy(a) the Red Cross failed to identify, the Red Cross said in responding to the FDA report. Neither the Red Cross nor the FDA has determined whether the mismatch caused the death.

➤ 11 people who had previously tested positive for hepatitis C or HTLV (human T-cell lymphotropic virus, which can cause T-cell leukemia) but were allowed to donate blood.

The Red Cross, in its Aug. 6 response to the FDA, said it had investigated the deaths properly. It said there was no evidence the plasma caused the January 2004 death, and that corrective actions were taken to prevent mismatches like those involving the July 2003 death.

The Red Cross said the 11 donations from ineligible donors occurred before it implemented an electronic blood donation record designed to check several databases to prevent donations by people with infectious viruses. Blood from the infected donors was destroyed and not used in transfusions.

In a recent statement the FDA partially explained why the Sept. 2 version of its Red Cross inspection report, known as a Form 483, was radically different from the initial version in June: "The 483 is reviewed internally at many levels within FDA to identify violations and confirm the accuracy and appropriateness of the citations. Where necessary, the 483 is amended to correct inaccuracies."

Dr. Jerry Squires of the Red Cross said the organization did not ask the FDA to alter the documents.

GA – 050 DAILY NEWSPAPER
ATLANTA JOURNAL – CONSTITUTION
Atlanta, GA
Morning Circulation – 397,097
Daily

NOVEMBER 3, 2004