

FDA Fines Red Cross For Bad Blood

By KEVIN FREKING/AP

(WASHINGTON) — The Food and Drug Administration has fined the Red Cross an additional \$4.6 million for the distribution of "unsuitable blood products," bringing penalties against the organization to more than \$19 million in recent years.

The FDA issued a letter Wednesday stating that it reviewed 113 recalls of blood products by the Red Cross from April 2003 to April 2006. The recalls involved the release of an estimated 4,094 unsuitable blood components.

Agency officials noted that having to conduct a recall shows that safety protocols were breached. For example, a donor may not have been appropriately asked about international travel or intravenous drug use.

FDA spokeswoman Peper Long said the agency didn't find any evidence of serious health consequences as a result of the safety breaches.

Red Cross officials said it was taking several steps to find problems in the collection and distribution of blood supplies. It's increasing supervision at blood drives and consolidating processing facilities. Its goal is to meet the FDA's standards for quality and safety, officials said.

"It takes time and it takes resources, but we're committed to doing whatever's necessary to meet that goal," said Red Cross spokeswoman Stephanie Millian.

Millian stressed that the fine would not be paid through donations but through the operating fees that it charges those who get blood units, such as hospitals.

The latest fine is being added to a tally of nearly \$15 million in previous FDA penalties for violation of blood-safety laws, regulations and the terms of a 2003 consent decree.

That settlement resolved charges that the Red Cross had committed "persistent and serious violations" of federal blood safety rules dating back 17 years.

In 2004, the Red Cross implemented a plan, with the FDA's blessing, to detect, investigate, monitor and correct the sorts of problems repeatedly cited by government investigators.