U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

"Getting More Information"

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

Mail: Office of Surveillance and Biometrics (HFZ 510)
1350 Piccard Drive
Rockville, MD 20850

FAX: 240-276-3356

Phone: 240-276-3357

Email: mailto:phann@cdrh.fda.gov

November 30, 1983

FDA SAFETY ALERT
DIALYZERS: FIRST USE SYNDROME

Medical Director
Dialysis Services

Dear Doctor:

Since 1982, the Food and Drug Administration (FDA) has been monitoring report concerning severe hypersensitivity reactions with new dialyzers (also called first-use syndrome) that occur in end-stage renal disease patients. These anaphylactic-like reactions occur in patients within the first few minutes of a dialysis treatment and require that the dialysis procedure be stopped immediately. Manifestations include nausea, malaise, weakness, a sensation of burning or heat throughout the body, profuse perspiration, respiratory distress and in some instances hypotension and cardiopulmonary arrest. Although the frequency of occurrence of these severe reactions is low (3 to 4 reactions per 100,000 dialyzers sold in the U.S. during 1982), they may be life threatening and require that resuscitative measures be initiated.

Experts at the "Symposium on Hypersensitivity in Hemodialsis" held in Louisville, Kentucky, on July 21 and 22, 1983, discussed possible causes of this reaction. One potential cause is traces of residual material from the manufacturing process in the dialyzer blood path. The discussants believed that water is the most effective flushing agent known for removing any residues, and emphasized the importance that the user strictly adhere to the manufacturer's rinsing and priming recommendations, as this procedure serves not only to remove air but also to reduce any trace amounts of residual material that might be left from the manufacturing process. They also noted that residual material might not be completely removed by the rinsing procedure performed by manufacturers, who cannot use water for rinsing if the dialyzer is to be sold dry. (The proceedings of this workshop will be published in Artificial Organs).

FDA has examined case reports and found that about sixty percent of the severe hypersensitivity reactions reported in 1982 occurred with the dialyzers that were rinsed using procedures other than those recommended by the manufacturer.

In view of the above, it would seem reasonable to assume that improved rinsing of the dialyzer by the user should minimize the risk of a patient having a hypersensitivity reaction. Therefore, FDA recommends:

1) Strict adherence to the dialyzer rinsing and priming procedure given in the labeling of the device, as a minimum.

2) That all personnel concerned with the dialyzer preparation be informed that if appropriate rinsing and priming procedures are not followed susceptible patients may be at greater risk of having hypersensitivity reactions

3) That all hypersensitivity reactions be fully and promptly reported to the dialyzer manufacturer.

If you have any questions, please contact Dr. Fernando Villarroel, Director, Division of Gastroenterology-Urology and General Use Devices at (301) 427-7750.

Sincerely,
Marlene E. Haffner, M.D. F.A.C.P.
Acting Director
Office of Health Affairs (HFK-200)
National Center for Devices
and Radiological health.