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Intrinsic Contamination Prompts Recall of Albumin

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The US Food and Drug Administration has advised the public of a voluntary manufacturer's recall of all Albuminar brand human albumin and Plasma Plex brand plasma protein fraction because of reports of bacterial sepsis with *Enterobacter cloacae* associated with receipt of Centeon Albumin (Human), Albuminar-25, Lot no. P61205. On October 9, 1996, the manufacturer, Centeon, L.L.C. (King of Prussia, PA), after consultation with the FDA, announced the recall of all lots of Albuminar and Plasma Plex products. This includes Albumin, 5%, 20%, 25% (Human), U.S.P. (Albuminar -5, Albuminar -20, Albuminar -25), and Plasma Protein Fraction, (Human) U.S.P. 5% Solution Heated-Treated (Plasma-Plex, PPF), distributed under the Centeon or Armour label. This recall does not apply to any other Centeon products or to albumin or plasma protein fraction produced by other companies. Hospitals, dialysis centers, and other users should discontinue the use of all lots of Centeon/Armour Albuminar and Plasma-Plex, quarantine all vials, and contact their distributor or Centeon for instructions on how to return them.

Healthcare professionals should report any episode of infection associated with these products to the CDC's Hospital Infections Program, National Center for Infectious Disease, by telephoning 404-639-6413, or by faxing 404-639-6459. Episodes also should be reported to the FDA's Medwatch Program, by telephoning 800-332-1088, or by faxing 800-332-0178.

Health centers having difficulty obtaining alternative sources of albumin should contact the FDA's Biologics Supply Office, telephone 301-827-0379.

FROM: Food and Drug Administration. FDA advises public of voluntary worldwide recall of all Albuminar and Plasma-Plex Manufacturer by Centeon, L.L.C. Press Release October 9, 1996.

Centers for Disease Control and Prevention. Voluntary worldwide recall of Albuminar and Plasma-Plex by Centeon L.L.C. *MMWR* 1996; 45(41):892.