Cutter

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NEWS RELEASE

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FOR IMMEDIATE RELEASE

EMERYVILLE, CA, April 2, 1984 -- Cutter Laboratories said today it has instituted a new test procedure for donors of all plasma collected at its plasma centers throughout the country. Called an Antibody to Hepatitis B Core Antigen test, it can identify plasma that contains a marker indicating that the donor has at one time been infected with Hepatitis B, even if the condition was unknown to the individual.

"Hepatitis B has been found to be prevalent in the same populations that are at high risk for Acquired Immune Deficiency Syndrome (AIDS)," reported Bud Modersbach, Cutter spokesman, "and the transmissibility of Hepatitis B seems to parallel that of AIDS." "Although not a specific screen for AIDS, since the exact carrier or carriers are not known," he emphasized, "it provides a much more objective basis than has been available in the past to see that plasma from groups at-risk for AIDS is not used in the production of coagulation products used by individuals with hemophilia.

There have been reports of AIDS in persons with hemophilia, many of whom rely on frequent injections of a plasma clotting factor to replace that missing or deficient in their plasma. This has raised the possibility that an infectious agent or agents, not yet isolated, may be implicated in the cause of AIDS and might be transmitted through blood or blood products.

The test procedure, recommended by the Blood and Blood Products Advisory Committee of the Food and Drug Administration, is believed to be the first of its type instituted on a nationwide scale. It enhances the effectiveness of a plasma donor information and screening program instituted by Cutter early last year designed to eliminate plasma donations from individuals who could be at high risk for AIDS. "Until a specific test for any AIDS agent has been discovered," Modersbach said, "Cutter intends to take these precautionary measures to protect those with hemophilia who depend on our products." Products produced from plasma screened under the new test procedure will be available later this year.

The firm also revealed that it has received a license to include a heat treatment step in the production of Koate antihemophilic factor. The license was issued by the Office of Biologics, a unit of the Food and Drug Administration.

The new heat treatment process has been shown to inactivate a number of potentially harmful human viruses, including cytomegalovirus and herpes virus Type 1, as well as other viruses which were used as markers for determining the efficacy of the heat treated product.

"The cause of AIDS, or of any infectious agents that may transmit the condition, has not yet been determined," Modersbach said, "but certain viruses, including the cytomegalovirus inactivated by the Cutter process, have been suspected by some medical authorities as being associated with AIDS."

Cutter is a leader in the research and production of products for hemophilia and other specialized biological products. It owns or contracts with over 80 plasma centers throughout the country but maintains no centers in New York, San Francisco, Los Angeles or Miami, where the large majority of AIDS cases have been reported.