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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Workshop on Standards for Inactivation and Clearance of Infectious Agents in the Manufacture of Plasma Derivatives from Nonhuman Sources for Human Injectable Use; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Standards for Inactivation and Clearance of Infectious Agents in the Manufacture of Plasma Derivatives from Nonhuman Sources for Human Injectable Use." The purpose of the public workshop is to discuss whether infectious agent inactivation and clearance steps should become standard industry practice in the manufacture of human injectable products from nonhuman source plasma.

Date and Time: The public workshop will be held on Monday, October 25, 1999, from 9 a.m. to 3:30 p.m.

Location: The public workshop will be held at the National Institutes of Health (NIH), NIH Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Contact:

For information regarding the public workshop and registration: Therese Burke, Laurel Consulting Group, 1815 Fort Meyer Dr., suite 300, Arlington, VA 22209, 703-351-7676, FAX 703-528-0716, e-mail: tburke@lcnnet.com.

For information regarding this document: Nathaniel L. Geary, Center for Biologics Evaluation and Research (CBER) (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210, FAX 301-594-1944.

NMI

SUPPLEMENTARY INFORMATION:

FDA is considering the requirement of inclusion of steps for the inactivation and clearance of infectious agents in the manufacture of products from nonhuman source plasma. This is an effort to level the regulatory requirements for all plasma derivatives regardless of their source and to continue to ensure high levels of safety for injectable blood products.

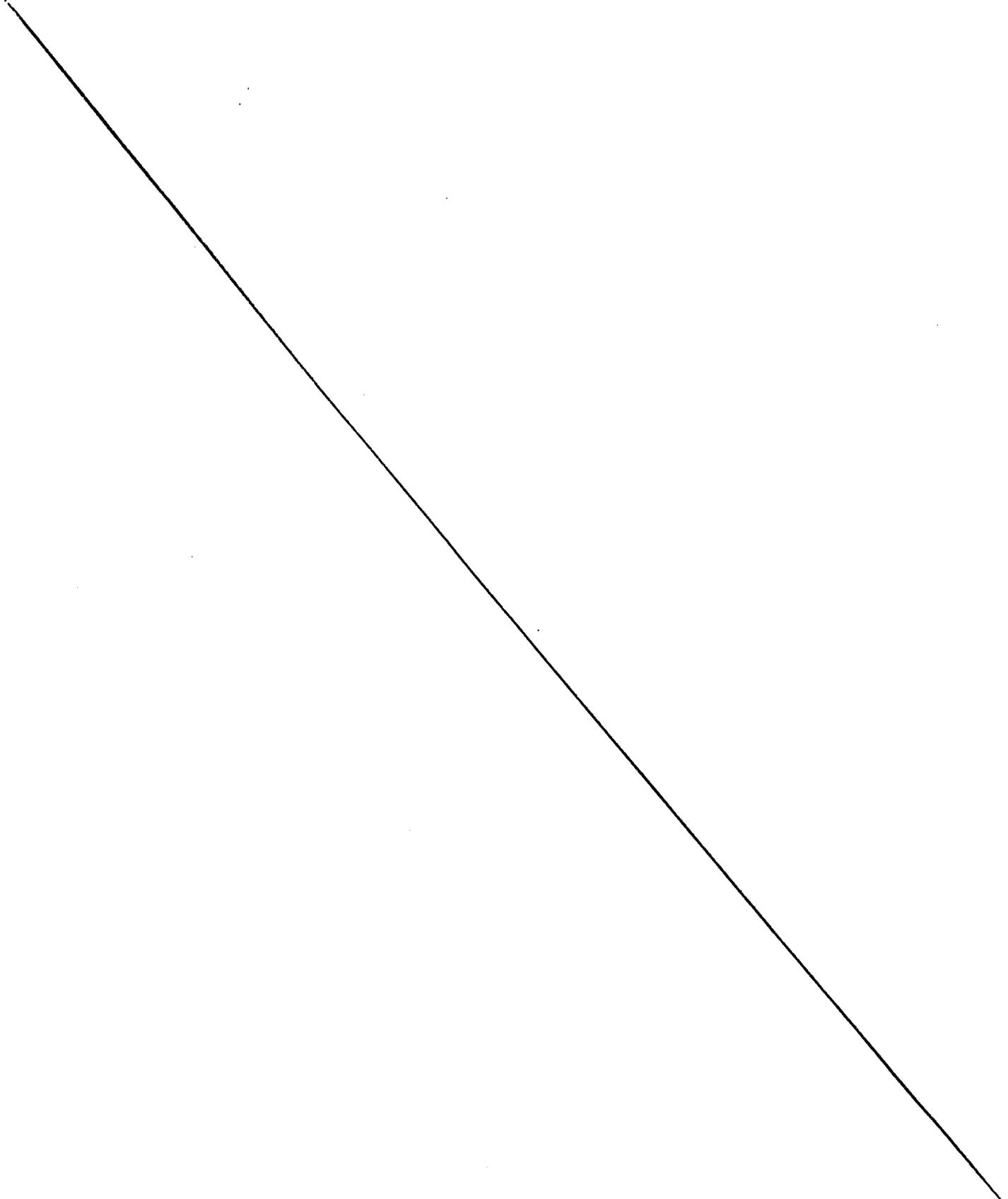
Many plasma derivatives represent product lines that are of critical use to a limited number of patients. Some of these products are used chronically, some acutely. For those products that utilize human plasma as a raw material, standards have been set that require inactivation procedures to be included in the manufacturing process. The risk of plasma derivatives manufactured from nonhuman raw materials has been more difficult to define. With the development of gene therapy, somatic cell therapy, and xenotransplantation, concerns are growing regarding the effect of xenobiotics on patients. Concerns have also been expressed about the use of plasma derivatives manufactured from nonhuman source plasma.

In an effort to address the needs of patients to have safe and effective blood products and to set realistic requirements for blood derivative manufacturers, FDA is sponsoring a public workshop to discuss these issues. Specifically, blood products manufactured from equine (horse), lapine (rabbit), ovine (sheep), caprine (goat), and porcine (pig) plasma and formulated into injectable products will be discussed.

Registration: Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Therese Burke (address above) by Friday, October 8, 1999. Onsite registration will be done on a space available basis on the day of the public workshop, beginning at 7:30 a.m. There is no registration fee for the public workshop. Space is limited, therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Therese Burke at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16,



Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The meeting transcript will be available on CBER's website at "http://www.fda.gov/cber/minutes/workshop-min.htm".

Dated: 9/16/99
September 16, 1999



William K. Hubbard
Senior Associate Commissioner for Policy, Planning and Legislation

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