Date: February 3, 1995

From: Director, Center for Biologics Evaluation and Research

Subject: Timeframe for Licensing Irradiated Blood Products

To: All Registered Blood Establishments

Introduction

On July 22, 1993, the Center for Biologics Evaluation and Research (CBER), FDA, issued a memorandum entitled, "Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products". The memorandum advised blood establishments that licensure is required for these types of products. This notice is being issued to emphasize the licensing requirement and to advise blood establishments that FDA intends to pursue its legal remedies for unlicensed blood products shipped in interstate commerce after the timeframe stated in this memorandum. In the interim, FDA will continue to inspect blood establishments and review, among other things, standard operating procedures, including those for irradiating blood products. The primary focus of these inspections will be to assess compliance with good manufacturing practice.

Irradiated blood products shipped in interstate commerce for sale, barter, or exchange are biological products subject to license under section 351 of the Public Health Service Act. In the July 22, 1993 memorandum, CBER provided information on preparing blood products irradiated with gamma radiation. The memorandum did not, however, specify a timeframe for submission of product license supplements.

Timeframe for Licensure

This is to advise that after **September 30, 1995,** FDA expects blood establishments that intend to ship irradiated blood products in interstate commerce to have obtained approved product license supplements. Prospective licensees should submit product license supplements to CBER containing the information requested in the July 22, 1993 memorandum no later than **April 1, 1995.**

Questions concerning the information required for licensure of these products or other needed assistance in preparing and filing applications can be sent to the Division of Blood Applications, Office of Blood Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM-370), 1401 Rockville Pike, Rockville, MD 20852, FAX: (301)-594-6431 or (301) 594-1973.

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