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1845. Addendum to Development of New Products 1986/87FVIII (Intermediate-Purity, Non-infective)

The heat-treatment procedure now being applied to FIX concentrates (PFC & 8PL) and to FVIII (8PL) may well be effective in ensuring non-infectivity of products. (Smith, personal communication).

It is generally believed that heat treatment of this severity can only be achieved with high-purity products (eg 8PL, FVIII is 5 iu/mg). However recent research at PFC has shown that this is not the case and that severe heating can be tolerated even at low purity if key process steps are carefully controlled prior to heat treatment.

This information will enable a non-infective product to be achieved using intermediate-purity material without compromising the development of the very high purity product noted in para 5.1.

The advantages of this course of action are:-

- (i) Provides non-infective FVIII product more quickly than will be possible with the very high purity product.
- (ii) Will allow the new very high purity product to be properly assessed and phased-in without undue haste.
- (iii) May be effective in the treatment of Von Willebrands disease (pending the development of a specific product for this purpose).
- (iv) Is expected to be available at a higher yield (300 iu/l plasma) and purity (0.6 iu/mg) than the current product (220 iu/l and 0.3 iu/mg).

It is likely that a product of this type will be available for evaluation in April 1986.