

TO: Human Research Review Committee  
FROM: J. H. Robinson  
SUBJECT: Plasma Nicotine Study: XB Prototypes, STT Prototypes

March 26, 1991

**A. BACKGROUND:** The Acceptance/ Biobehavioral XB Team is charged with developing data on the effects of new cigarette technologies (e.g., levulinic acid, KDN extract) in the areas of human smoking behavior, smoker acceptance, and plasma nicotine concentrations in humans smoking XB prototype cigarettes. The purpose of this proposal is to obtain approval for a test designed to study the effects of varying levels of levulinic acid or KDN extract in sheet tobaccos on human smoking behaviors, physiological responses, plasma nicotine concentrations following smoking and smoker acceptance.

**B. NEED FOR HUMAN SUBJECTS:** Human smoking characteristics, plasma nicotine concentrations, and physiological responses following smoking can only be obtained using human subjects.

**C. SCIENTIFIC AFFAIRS REVIEW:** Relevant data on the XB prototypes to be used in this study were presented to the HRRC on 3/24/91 (HRRC Proposal R9115). Relevant data on the STT filter prototypes to be tested in this study have been discussed earlier today.

**D. PRODUCTS:** Two series of products will be tested in this study. The first series of products were presented to the HRRC and approved for limited testing on 3/14/91 (HRRC Proposal R9115). These products incorporate varying levels of levulinic acid and/ or KDN extract obtained through differential addition of G-7 sheet tobaccos in the blend, according to the following test design:

TABLE I

G-7 sheet comprises 25% of the total blend for all prototypes.  
Numbers shown indicate percentage of total sheet in each prototype.

Prototype	G7-1	G7-1 w/ ~5.65% L.A.	G7-1 w/ ~4.5% KDN	G7-18 w/ L.A. + KDN
A	100			
B		100		
C			100	
D				100
E	50	50		
F	50		50	
G	50			50
H		50	50	
I		50		50
J			50	50
C-10	100			

All products are at 5 mg of 'tar', except for product C-10 which is a 10 mg control made with the same blend of tobaccos as Prototype A. (These are cigarettes AN 10342 AA-AJ and AN 10342 AQ on HRRC approved proposal R9115).

Cigarettes for the STT filter portion of the test have been presented earlier

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