5.2 TABULAR LISTINGS OF ALL CLINICAL STUDIES

Table 5.1 – Listing of Clinical Studies

Type of Study	Study Identifier	Location of Study Report	Objective(s) of the Study	Study Design and Type of Control	Test Product(s); Dosage Regimen; Route of Administration	Number of Subjects	Healthy Subjects or Diagnosis of Patients	Duration of Treatment	Study Status; Type of Report
Phase 1 (abuse liability)	CEG-P1-078	CSR_22nd Century Group.pdf	The primary objective of the study was: • To evaluate the abuse liability of VLN™ mentholated cigarettes relative to mentholated own-brand cigarettes and nicotine polacrilex gum under Controlled Use and Uncontrolled Use conditions. The secondary objectives of the study were: • To compare the nicotine pharmacokinetic profiles of VLN™ mentholated cigarettes relative to mentholated own-brand cigarettes and nicotine polacrilex gum under Controlled Use and Uncontrolled Use conditions. • To characterize product use behavior of VLN™ mentholated cigarettes, mentholated own-brand cigarettes, and nicotine polacrilex gum.	Crossover;	Two cigarette and one gum formulations; **Part A:** *Ad libitum* use for 4 hours of one of the 3 study products **Part B:** One product per day for 3 consecutive days as follows: 1) Controlled Use Session (10 puffs from the subject's mentholated own-brand cigarette or VLN™ menthol cigarette, or use of the nicotine polacrilex gum for 10 minutes); and 2) an Uncontrolled Use Session (use of one unit *ad libitum* for 10 minutes). Smoked or chewed	**Part A:** 61 **Part B:** 60	Healthy adult male and female exclusive smokers	Controlled and/or *ad libitum*	Complete; Full

Section 5.2 – Tabular listings of all clinical studies