Table E2: FDA Web site Report of Cases of PDE5I associated NAION as of 2005

In 2005, the FDA reported through its web site that: "As of May 18, 2005, a total of 43 cases of ischemic optic neuropathy among patients using the marketed PDE5I (sildenafil, tadalafil, vardenafil) have been reported to the FDA's Adverse Event Reporting System. Since approval, 38 cases have been identified in association with sildenafil, 4 cases have been identified in association with tadalafil and one case has been identified in association with vardenafil. Most of these cases (25/43) appear to be the non-arteritic anterior ischemic optic neuropathy (NAION) subtype. Thirty-six of the 43 cases reported accompanying visual loss, and 26 of these 36 cases reported the visual loss as continuing or permanent. Most of the patients in these cases reported vascular risk factors for NAION that overlap with vascular risk factors for erectile dysfunction (such as age over 50, low cup to disc ratio, hypertension, diabetes, smoking, etc), making direct attribution to PDE5I not possible. However, the clinical attributes of some of the cases (e.g., a temporal relationship in 19 sildenafil cases, 4 tadalafil cases, and the one vardenafil case, and the report of recurrent ocular symptoms that might reflect NAION in five sildenafil cases and one tadalafil case), raise concern with regard to the role of PDE5I."