



Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

MEMORANDUM

Date: July 24, 2003
To: Dockets Management Branch (HFA-305)
From: Sarah Seager, Esq. (GCF-1) *SS*
Subject: Docket Nos. 01P-0572 and 02P-0075

On March 31, 2003, Bill Schultz, Esq. (outside counsel for the National Center for Tobacco-Free Kids et al.) called Michael M. Landa, Esq. and myself regarding the above-referenced citizen petitions seeking regulation of Ariva. He reiterated petitioners' position that Ariva should be regulated as a food or a drug under the Federal Food, Drug, and Cosmetic Act, as well as their belief that the Supreme Court's decision in *Brown & Williamson* does not bar FDA jurisdiction over this product. He also stated that if the agency declined to regulate Ariva, it would discourage drug companies from developing smoking cessation products.

Please file this summary in the above-referenced dockets. Thank you.

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