



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

April 1, 2002

John R. Polito
Smoking Cessation Instructor
709 Black Oak Blvd.
Summerville, South Carolina 29485

Dear Mr. Polito:

I writing in response to your emails to Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, regarding studies completed for nicotine replacement therapy (NRT).

The information you have provided is being evaluated by both the Division of Over-the-Counter (OTC) Drug Products and Division of Anesthetic, Critical Care, and Addiction Drug Products.

Once they have evaluated the data you have provided regarding OTC NRT studies they will provide you with a detailed response of their findings.

If you have any further questions prior to receipt of our findings please contact me at my office, (301) 594-6779 or email lemleyl@cder.fda.gov. Thank you for writing to the Food and Drug Administration.

Sincerely,

A handwritten signature in cursive script that reads "Lee Lemley".

Lee Lemley
Policy Analyst
Executive Operations Staff (HFD-006)
Center for Drug Evaluation and Research

CDER Log No 2002-5629

Cc: HFD-560 (Katz/Cothran)
HFD-170 (McCormick)

Drafted: Llemley 4/1/02
Concur: Kroberts 4/1/02