



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

4967
Food and Drug Administration
Office of Policy, Planning, and
Legislation HF-11
5600 Fishers Lane
Rockville, MD 20857

AUG 7 2002

John R. Hughes, M.D.
Society for Research on Nicotine and Tobacco
7600 Terrace Avenue, Suite 203
Middleton, WI 53562-3174

Re: Docket No. 02P-0207

Dear Dr. Hughes:

This responds to your citizen petition, dated April 23, 2002, in which the Society for Research on Nicotine and Tobacco requested that the Food and Drug Administration (FDA) "regulate SF Garrett's Nicotine Water" (Petition at page 1).

As you may know, on July 3, 2002, we responded to a citizen petition submitted by Zuckerman Spaeder LLP and the National Center for Tobacco-Free Kids, Inc. (FDA docket number 01P-0573). The citizen petition was submitted on behalf of 18 different public health and other organizations, and requested, in part, that FDA:

- classify and regulate Nicotine Water as a "drug" under the Federal Food, Drug, and Cosmetic Act (the Act), or, in the alternative,
- classify and regulate Nicotine Water as a "food" containing an unapproved food additive.

We granted that petition and found, in relevant part, that Nicotine Water is an unapproved new drug under the Act and cannot be marketed as a dietary supplement (as claimed by the manufacturer). We also stated that we would notify the manufacturers of Nicotine Water (and Nico Water) that the product cannot be marketed without FDA approval. We have enclosed a copy of the petition response for your information.

02P-0207

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Dr. Hughes

2

We consider our July 3, 2002, response to Zuckerman Spaeder LLP to have addressed your petition's request and do not intend to take further action regarding your petition.

Sincerely,



Margaret M. Dotzel
Associate Commissioner for Policy

