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DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 4, 1999

Alexander H. Hao
E-Z Quit, Inc.
3240 Riverdale Avenue
Riverdale, NY 10463

Ref: NYK 1999-026

Dear Mr. Hao:

This letter concerns E-Z QUIT SMOKELESS ARTIFICIAL CIGARETTE currently marketed by your firm. This product consists of a plastic tubular inhaler, simulating a cigarette in size, color and shape, and cartridges, which according to the labeling, contain peppermint and mint oils, menthol, and vanillin. Based on this product's labeling and promotion, it is intended as an aid for smoking cessation or as a smoking deterrent and for treating the accompanying symptoms of nicotine addiction.

You convey the intended uses noted above through claims on the immediate container label, accompanying labeling, and your Internet home page (<http://www.ezquit.com>). These include statements such as ". . . you can CUT DOWN or QUIT SMOKING with E-Z QUIT . . .," ". . . developed and flavored to simulate a real cigarette . . .," ". . . just inhale this device whenever you get the urge to smoke, and it helps carry you over each crisis . . .," ". . . use the E-Z QUIT cigarette over and over again until you have cut down or kicked the smoking habit. As you inhale, you draw the fresh taste of the scientifically flavored E-Z QUIT cartridge into your mouth to satisfy your urge to smoke . . .," ". . . As your body responds to this E-Z QUIT program, there will be less and less amounts of nicotine in your bloodstream . . . more oxygen for your lungs . . .," "What Doctors Say: . . . The smokers in our survey give E-Z QUIT the highest rating of any non-prescription quit-smoking aid," "CLINIC TESTED DOCTOR RECOMMENDED," "CONTROLS ORAL ADDICTION," and "Helps ease the cravings, even during those 'tough times.' "

Based on the claims cited above, E-Z QUIT SMOKELESS ARTIFICIAL CIGARETTE is a "drug" as described in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). It is also subject to Title 21 of the Code of Federal Regulations (CFR) Part 310.544. Under that regulation, E-Z QUIT SMOKELESS ARTIFICIAL CIGARETTE is a "new drug" as defined by section 201(p) of the Act. Thus, it may not be legally marketed in the United States without an

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approved new drug application (NDA) required under section 505(a) of the Act. In addition, this product is misbranded under section 502(f)(1) of the Act, because its labeling fails to bear adequate directions for use.

Statements, such as those described above, suggest that E-Z QUIT SMOKELESS ARTIFICIAL CIGARETTE is generally recognized among experts as safe and effective for its intended uses. Since we do not know of any data to substantiate this representation, such statements are false and misleading. Thus, this product is also misbranded under section 502(a) of the Act.

The violations of the Act described above are not meant to be an all-inclusive list of deficiencies by your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with the Act. Federal agencies are advised of the issuance of all warning letters about drugs and devices so they may consider this information when considering the award of contracts.

We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include a seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You should send your reply to the Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Attention: Fabio L. Mattiasich, Compliance Officer. If you have any questions regarding the content of this letter, Mr. Mattiasich can be reached at (718) 340-7000, ext. 5292.

Sincerely,



Brenda J. Holman
District Director