



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 13 2004

25 2 4 '04 10 11 19 29

James Demas
Winston Laboratories, Inc.
100 Fairway Drive, Suite 134
Vernon Hills, IL 60061

Re: Docket No. 2004P-0265/CP1

Dear Mr. Demas:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on June 14, 2004. Your petition requests that the Agency designate a new official name for zucapsaicin (cis-8-methyl-N-vanillyl-6-nonenamide).

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0265

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