



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 5 2001

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- Mr. Terry S. Coleman
Bennett, Turner & Coleman, LLP
1900 K Street, NW
Suite 750
Washington, DC 20006

Docket Number: 01P-0228/CP1

Dear Mr. Coleman,

This letter responds to your citizen petition submitted on May 8, 2001, requesting that the Food and Drug Administration initiate a rulemaking to delete the last sentence of 21 CFR 201.128 to make the regulation consistent with the concept of "intended use" embodied in the Federal Food, Drug, and Cosmetic Act, the implementing regulations, and case law.

I am writing to inform you that we have not yet resolved the issues raised in your petition because it identifies significant matters 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 yours,

Janet Woodcock, M.D.
Director

Center for Drug Evaluation and Research

01P-0228

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