



DEPARTMENT OF HEALTH & HUMAN SERVICES

DEC 23 2015

Food and Drug Administration
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Silver Spring, MD 20993

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Re: Docket No. FDA-2015-P-0578

Dear Petitioners:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on February 24, 2015. Your petition requests that the Agency immediately require the removal from the market of the oral form of the antifungal agent ketoconazole.

FDA has been unable to reach a decision on your petition because it raises significant and 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,

A handwritten signature in blue ink that reads "Carol J. Bennett".

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research