DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

DEC 4 2013

Christopher J. Worrell, R. Ph.
Chief Executive Officer
Amedra Pharmaceuticals LLC
2 Walnut Grove Drive, Suite 190
Horsham, PA 19044-7707

Re: Docket No. FDA-2013-P-0766

Dear Mr. Worrell:

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 June 18, 2013. Your petition requests that the Agency refrain from approving any ANDA for a generic version of ALBENZA (albendazole) Tablets unless the proposed generic product: (1) is shown to be bioequivalent with respect to both albendazole and the primary active metabolite, albendazole sulfoxide; (2) has the same labeling as ALBENZA, including the instructions in ALBENZA's labeling concerning safe pediatric administration; and (3) can be crushed or chewed and swallowed by young children with a drink of water, and without choking, as demonstrated through simulated use testing or other analyses.

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