DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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June 18, 2013

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

Dear Dr. Worrell:

Your petition to the Food and Drug Administration requesting to refrain from approving any ANDA referencing ALBENZA unless it includes information showing bioequivalence based on systemic levels of the primary metabolite, albendazole sulfoxide, in addition to the parent drug, albendazole; the same labeling, including safety information relevant to the drug product's use in the pediatric population; and simulated use testing or other analyses demonstrating that the drug product can be chewed and crushed, and swallowed by young children with a drink of water without posing an unacceptable choking hazard, was received by this office on 06/18/2013. It was assigned docket number FDA-2013-P-0766/CP1, and it was filed on 06/18/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)