

January 31, 2019

Time Sensitive Patent Information

Central Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Received

FEB 01 2019

CDR

RE: Withdrawal and Request to Remove U.S. Patent No. 9,161,926 from Listing for NDA No. 207154 for ACZONE® (dapson) Gel, 7.5%, for Topical Use

Dear Sir or Madam:

In accordance with 21 C.F.R. § 314.53(f)(2), Almirall LLC, formerly Aqua Pharmaceuticals LLC, withdraws and requests removal of U.S. Patent No. 9,161,926 from the Food and Drug Administration's patent listing information for NDA No. 207154 for prescription ACZONE® (dapson) Gel, 7.5%, for topical use.

NDA No.: N207154

Product(s) to which request applies: ACZONE® (dapson) Gel, 7.5%, for topical use

Patent No.: USP 9,161,926

Please note that, as shown in the enclosed document, NDA holder Aqua Pharmaceuticals LLC changed its name to Almirall LLC on September 27, 2018. All rights in NDA No. 207154 are now owned by Almirall LLC, who is committed to all agreements, promises, and conditions made by Aqua Pharmaceuticals LLC regarding the NDA and contained therein. Almirall LLC has a complete copy of the NDA, including supplements and records that are required to be kept under 21 C.F.R. § 314.81.

Sincerely,



Ron Menezes
President and General Manager of Almirall LLC
On Behalf of Almirall LLC, formerly Aqua Pharmaceuticals LLC

Received

FEB 01 2019

CDR