

Interquim S.A. - Close Out Letter 8/17/17



FDA U.S. FOOD & DRUG
ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

August 17, 2017

Dr. Francese Xavier Camps, Director
Interquim S.A.
Carrer Joan Buscalla 10
Sant Cugat del Valles, Barcelona, 08173
Spain

Reference: FEI 3002807304

Dear Dr. Camps:

The Food and Drug Administration (FDA) has completed an evaluation of your firm's corrective actions in response to our Warning Letter: 320-17-08 dated November 22, 2016. Based on our evaluation, it appears that you have addressed the deviations contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The FDA expects you and your firm to maintain compliance with current good manufacturing practices and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should deviations be observed during a subsequent inspection or through other means.

Sincerely,
/S/
Runa Musib
Compliance Officer
Division of Drug Quality II