



U.S. Food and Drug Administration
Office of Regulatory Affairs
12420 Parklawn Dr.
Rockville, MD 20852
www.fda.gov

Via UPS Worldwide Saver (Express)
Return Receipt Requested

11 December 2018

Ms. Sonia Martínez
Technical Director and Quality Control Manager
Ercros S.A.
Paseo del Deleite s/n
Aranjuez, Madrid, Spain 28300

Dear Ms. Martínez,

The U.S. Food and Drug Administration (FDA) reviewed an inspection conducted by Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) at Ercros S.A. located at Paseo del Deleite s/n, Aranjuez, Madrid, Spain, 28300 from 19-22 June 2018. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI").¹ Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards to current good manufacturing practice (CGMP).

A VAI inspection classification indicates that, although documented objectionable conditions were found during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any deviations noted during the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" ("OAI").

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of VAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product-and application-specific facility assessment conducted by CDER's Office of Pharmaceutical Quality. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

If you have any questions regarding this letter, please contact us at: ORAMRAInspectionReview@fda.hhs.gov.

Sincerely,

Digitally signed by Maya M. Davis -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Maya M. Davis -
S,
0.9.2342.19200300.100.1.1=2000361096
Date: 2018.12.11 15:12:08 -05'00'

Maya M. Davis
Consumer Safety Officer
Mutual Reliance Inspection Review Team

FEI: 3003562118

¹ See Inspection Classification Definitions at <http://www.fda.gov/ICECI/Inspections/ucm223231.htm>