

Castanheira do Ribatejo,  
Portugal, October 7

Cippan SA active pharmaceutical ingredients (API) plant went through an inspection by the FDA. The aim of the inspection *“was to determine if products are manufactured following current good manufacturing practice regulations for human pharmaceuticals”*. The inspection was triggered by an ANDA filing of one of Cippan’s customers in the US and was conducted by Ms Marybeth Lopez, Investigator from the Center for Drug Evaluation and Research (CDER) and Ms Linda Thai, Investigator from the Los Angeles District Office, as team leader. The inspection was held from September 28<sup>th</sup> to October 1<sup>st</sup> 2009 (four days) and no Form 483 was issued. Ms Marybeth Lopez said they were happy with all they had seen, congratulated Cippan for its CGMP system and highlighted the knowledge and the efficacy of the whole Cippan team.

Manuel Eduardo Fernandes, Cippan Plant Manager, said that *“the inspection focused on how production activities were controlled on the shop floor and on the documentation system. The investigators wanted to know how OOS, change control, deviations, and supplier’s qualification, were managed, documented and recorded. Production batch records, analytical methods, process validation, annual product reviews, equipment qualifications, personnel training and pure water system were also under the investigators scrutiny”*. *“We were glad to see that Cippan’s continuous improvement mindset was rewarded and that Cippan has been able to maintain a high level of regulatory compliance in an environment on which the standards are continuously being placed higher and higher”*.

Cippan started its operations in 1963 and exports API’s to the US since 1965 after being successfully inspected by the FDA for the first time. Since then Cippan has been regularly inspected by the FDA, hosting five inspections since 1994.

Cippan is a Portuguese API manufacturer with strong know-how on the production of semi-synthetic Tetracyclines and Clavulanic Acid. Cippan exports its API’s to some of the most regulated markets such as the US and EU.



Cippan