



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

March 4, 2019

Eric S. Rossman
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Boise, ID 93702

Sent via email to: erossman@rossmanlaw.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner make a determination under 21 U.S.C. § 1604 (b)(3) regarding whether Lima Corporate S.P.A was required to register with the Secretary under 21 U.S.C. § 360 and/or list the hip implant device at issue with the Secretary under 21 U.S.C. § 360(j) was received by this office on 03/01/2019.

It was assigned docket number FDA-2019-P-1009. 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,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)