



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 14, 2020

Shepard G Bentley
Bentley Biomedical Consulting, LLC
28241 Crown Valley Parkway Suite 510
Laguna Niguel, CA 92677

Dear Petitioner: sbentley@bentleybiomed.com

Your petition to the Commissioner of Food and Drug Administration requesting that FDA designate Sandoz Ceftriaxone (Application Number 065169) as the Reference Listed Drug (RLD) for the Abbreviated New Drug Approval (ANDA) 211841 for Ceftriaxone was received by this office on 09/12/2020.

It was assigned docket number FDA-2020-P-1873. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)