

Citizen Petition

Designation of Sandoz Ceftriaxone as the Reference Listed Drug for ANDA 211841 Date: 12Sep2020

The undersigned submits this petition under 21 CFR Part 10 Subpart B §10.30 to request the Commissioner of Food and Drugs to designate the drug Sandoz Ceftriaxone as the reference listed drug (RLD) for the ANDA 211841.

A. Action Requested

The petition requests the Commissioner to designate Sandoz Ceftriaxone (Application Number 065169) as the Reference Listed Drug (RLD) for the Abbreviated New Drug Approval (ANDA) 211841 for Ceftriaxone.

B. Statement of Grounds

According to the Orange Book, the RLD is the Roche Ceftriaxone "Rocephin", that has been discontinued in the market not for any reason of safety or efficacy. At present Sandoz Ceftriaxone is the reference standard; however, the sponsor of ANDA 211841 cannot use the Sandoz Ceftriaxone as the RLD unless a citizens petition is filed.

C. Environmental Impact

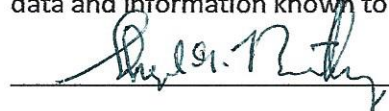
We claim categorical exclusion under 25.30, 25.31, 25.32, 25.33, or 25.34 of this chapter or an environmental assessment under 25.40 of this chapter.

D. Economic Impact

Economic impact information will be submitted upon request of the commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



(Signature)

Shepard G. Bentley

(Name of petitioner)

Bentley Biomedical Consulting, LLC

28241 Crown Valley Parkway, Suite 510, Laguna Niguel, CA 92677 (Mailing address)

(949) 374 – 9187

(Telephone number)