DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

March 22, 2019

Boyd Lund
Cardinal Health Regulatory Sciences
7400 W 110th Street
Overland Park, KS 66210

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner determine whether CLAFORAN (Cefotaxime Sodium for Injection, 500 mg, 1g, 2g, and 10g/vial, NDA 050547) held by US Pharmaceutical Holdings II LLC have been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or efficacy reasons was received by this office on 3/21/2019.

It was assigned docket number FDA-2019-P-1366. 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,

Karen Malvin Digitally signed by Karen Malvin
Date: 2019.03.22 12:01:47 -04'00'

Karen P. Malvin
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)