



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 22, 2017

Alicia Henk
Ceva Animal Health, LLC
8735 Rosehill Road
Lenexa, KS 66215

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner determine that an ANDA filing is suitable for a generic un-encapsulated cyclosporine oral solution that differs in dosage form was received by this office on 12/21/2017.

It was assigned docket number FDA-2017-V-6968. 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,

A handwritten signature in black ink, appearing to read "D Bigby", is located below the "Sincerely," text.

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