

This electronic submission has been formatted per the information provided in the Guidance for Industry, "Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (April 2018), and is being sent through the Electronic Submission Gateway.

The submission was scanned and certified as virus free using the most current version of Microsoft Security Essentials available as of the date of this submission.

Synchrogenix Regulatory Services
(888) 840-9580