

APPLICATION INFORMATION

12. TYPE OF SUBMISSION (Check One)

New Additive Petition Amendment* Supplement * Other

13. REASON FOR SUBMISSION

14. NUMBER OF VOLUMES SUBMITTED

15. THIS SUBMISSION IS (Check One)

Paper Paper and Electronic Electronic

THIS APPLICATION CONTAINS THE FOLLOWING ITEMS: (Check all that apply)

- 16** Cover Letter***
 Petition Table of Contents (TOC)
 Executive Summary

21 CFR 171.1 (C)

17 • **SECTION A – D: Chemistry Section**

- Chemistry (TOC)
 Identity Use Intended Technical Effect Analytical and Methodology
 Studies
 References

18 • **SECTION E: Toxicology Section****

- Safety TOC
 Safety Reports
 Studies
 Genetic Toxicity Studies
 Acute Toxicity Studies
 Short Term Toxicity Studies Between 14 Days and 28 Days
 Subchronic Toxicity Studies 90 Days
 Chronic Toxicity Studies Between 6 Months and 2 Year
 Carcinogenicity Studies
 Carcinogenicity Studies with in Utero Exposure
 Combined Chronic Toxicity and Carcinogenicity Studies
 Reproductive Toxicity Studies
 Reproductive Toxicity with Teratology Phase
 Teratology Studies
 Immunotoxicity Studies
 Allergenicity Studies
 Metabolism and Pharmacokinetic Studies
 Neurotoxicity Studies
 Neurobehavioral Toxicity Studies
 Epidemiology Studies
 Human Clinical Studies
 Nutrition Studies
 Other Studies, e.g., Microbiology _____
 References

19 • **SECTION F & G: Administrative Section***

- Administrative TOC
 Proposed Tolerance Proposed Regulation

20 • **SECTION H: Environmental Section**

- Environmental TOC
 Environmental Assessment Categorical Exclusion
 Studies
 References

21. SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT

22. TYPED NAME AND TITLE

23. DATE

* The cover letter for Supplement or Amendment should be placed in Administrative folder, e.g., Administrative->Correspondences->Incoming->Supplement Cover Letter.pdf.

** All of the categories in Safety Section should be placed inside of Studies folder in Safety Folder.

*** Original Submission only.

Public reporting burden for this collection of information is estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CFSAN (HFS-265)
 5100 Paint Branch Parkway
 College Park, MD 20740

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it display a currently valid OMB number.