FOOD ADDITIVE PETITION SUBMISSION

Form Approval: OMB No. 0910-0016
Expiration Date: 8/31/2010
See Reverse for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW USE OF A FOOD ADDITIVE
(Title 21, Code of Federal Regulations, 171)

FOR FDA USE ONLY

PETITION TYPE	PETITION NUMBER	RECEIVED DATE

APPLICANT INFORMATION

1. NAME OF APPLICANT	2. DATE OF SUBMISSION

3. TELEPHONE NO. *(Include Area Code)*	4. FACSIMILE (FAX) NO. *(Include Area Code)*

5. APPLICANT ADDRESS *(Number, Street, City, Country, and ZIP Code or Mail Code)*	6. AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP code, Telephone & FAX number)* **IF APPLICABLE**
Number and Street Street Address	**Name** Agent Name
City and State City State Code	**Number and Street** Agent Address
Country	**City and State** Zip Code or Mail Code City ST Zip
Zip Code or Mail Code Zip_Code	**Telephone No.** (Include area code) Phone Number **Facsimile (Fax) No.** (Include area code)Agent Fax Number

SUBMISSION DESCRIPTION

7. PETITION TITLE

8. ADDITIVE FUNCTION	9. PRODUCT
☐Direct ☐Indirect	

10. TECHNICAL EFFECT

11. CHEMICAL IDENTITIES

CHEMICAL TYPE*	CAS NUMBER	CHEMICAL NAME	TRADE NAME (IF ANY)	STRUCTURE
P	000000000			

* P – Primary chemical, C – Constituents (including residual monomers, residual solvents, impurities, by-products, catalysts, and etc.)

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.