## Form Approval: OMB No. 0910-0016 **COLOR ADDITIVE PETITION SUBMISSION** Expiration Date: 8/31/2010 See Reverse for OMB Statement DEPARTMENT OF HEALTH AND HUMAN SERVICES FOR FDA USE ONLY FOOD AND DRUG ADMINISTRATION PETITION PETITION RECEIVED DATE **TYPE NUMBER** APPLICATION TO MARKET A NEW USE OF A COLOR ADDITIVE (Title 21, Code of Federal Regulations, 71) **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 6. AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP code, Telephone & FAX number) IF APPLICABLE Code or Mail Code) Name **Number and Street** Agent Name Street Address **Number and Street** City and State Agent Address City State Code City and State Country Zip Code or Mail Code City ST Zip Zip Code or Mail Code **Telephone No.** (Include area code) Zip Code Facsimile (Fax) No. (Include area code) **SUBMISSION DESCRIPTION** 7. PETITION TITLE **8. ADDITIVE FUNCTION** 9. PRODUCT Food ☐ Cosmetic ☐ Drug Device ☐ Food use new listing (\$3,000) 10. FEE ENCLOSED Nonfood use new listing (\$2,600) Food use amendment (\$1,800) Nonfood use amendment (\$1,600) (Attach check made out to: U.S. Food and Drug Administration) 11. CHEMICAL IDENTITIES CHEMICAL **CHEMICAL NAME** TRADE NAME (IF ANY) **STRUCTURE CAS NUMBER** TYPE\* 00000000 \* P – Primary chemical, C – Constituents (including residual monomers, residual solvents, impurities, by-products, catalysts, and etc.)

FDA-3504 (09/07) Page 1 of 2

|                                                                                                                                                                    | 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 FOLL                                                                                                                                 | OWING ITEMS: (Check all that apply)                                       |
| 16 Cover Letter***                                                                                                                                                 |                                                                           |
| Petition Table of Contents (TC                                                                                                                                     | )C)                                                                       |
| Executive Summary 21 CFR 71.1 (C)                                                                                                                                  |                                                                           |
|                                                                                                                                                                    |                                                                           |
| 17 ■ SECTION A – C: Chemistry Sect  Chemistry Table of Contents (TOC                                                                                               |                                                                           |
| Identity Use                                                                                                                                                       | ☐ Intended Technical Effect ☐ Analytical and Methodology                  |
| Studies                                                                                                                                                            | Interface Technical Effect                                                |
| References                                                                                                                                                         |                                                                           |
| 18 • SECTION D: Safety Section**                                                                                                                                   |                                                                           |
| Safety of TOC                                                                                                                                                      |                                                                           |
| Safety Summary                                                                                                                                                     |                                                                           |
| Studies Studies To init Studies                                                                                                                                    |                                                                           |
| Genetic Toxicity Studies                                                                                                                                           |                                                                           |
| Acute Toxicity Studies                                                                                                                                             |                                                                           |
| Short Term Toxicity Studies B                                                                                                                                      |                                                                           |
| Subchronic Toxicity Studies 90                                                                                                                                     |                                                                           |
| Chronic Toxicity Studies Betw                                                                                                                                      | een 6 Months and 2 Year                                                   |
| Carcinogenicity Studies                                                                                                                                            |                                                                           |
| Carcinogenicity Studies with in                                                                                                                                    |                                                                           |
| Combined Chronic Toxicity ar                                                                                                                                       | d Carcinogenicity Studies                                                 |
| Reproductive Toxicity Studies                                                                                                                                      |                                                                           |
| Reproductive Toxicity with Te                                                                                                                                      | ratology Phase                                                            |
| ☐ Teratology Studies                                                                                                                                               |                                                                           |
| ☐ Immunotoxicity Studies                                                                                                                                           |                                                                           |
| Allergenicity Studies                                                                                                                                              |                                                                           |
| ☐ Metabolism and Pharmacokine                                                                                                                                      | etic Studies                                                              |
| Neurotoxicity Studies                                                                                                                                              | r.                                                                        |
| ☐ Neurobehavioral Toxicity Stud                                                                                                                                    | lies                                                                      |
| ☐ Epidemiology Studies ☐ Human Clinical Studies                                                                                                                    |                                                                           |
| Nutrition Studies                                                                                                                                                  |                                                                           |
| Other Studies, e.g., Microbiolo                                                                                                                                    | )gv                                                                       |
| References                                                                                                                                                         | <u> </u>                                                                  |
| 19 • SECTION E - I: Administrative S                                                                                                                               |                                                                           |
|                                                                                                                                                                    | ble Exposure Information Batch Certification Exemption                    |
| Required Fee (See box 10 of page 1                                                                                                                                 |                                                                           |
| SECTION J: Environmental Sect     Environmental TOC                                                                                                                | ion                                                                       |
| Environmental Assessment                                                                                                                                           | Categorical Exclusion                                                     |
| Studies                                                                                                                                                            |                                                                           |
| References                                                                                                                                                         |                                                                           |
| 21. SIGNATURE OF RESPONSIBLE OFFICE                                                                                                                                | CIAL OR 22. TYPED NAME AND TITLE 23. DATE                                 |
| AGENT                                                                                                                                                              |                                                                           |
|                                                                                                                                                                    |                                                                           |
| * 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.      |                                                                           |

FDA-3504 (09/07) Page 2 of 2