Department of Health and Human Services
Food and Drug Administration

FOOD ADDITIVE PETITION (FAP)
COLOR ADDITIVE PETITION (CAP)
FOOD MASTER FILE (FMF)
COLOR MASTER FILE (CMF)

Form Approved: OMB No. 0910-0016; Expiration Date: xx/xx/xxxx
(See last page for OMB Statement)

FDA USE ONLY

SUBMISSION NUMBER

DATE OF RECEIPT

Transmit completed form and attachments electronically via the Electronic Submission Gateway (see Instructions); OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740-3835.

PART I - INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Complete a. or b. below)*

a. If New Submission, check one of the following.

☐ New Food Additive Petition (21 CFR 171.1) ☐ New Color Additive Petition (21 CFR 71.1)

☐ New Food Master File ☐ New Color Master File

b. If Additional Information/Incoming Correspondence, check one of the following.

☐ Update ☐ Amendment

Enter the appropriate number applicable to this update or amendment.

FAP Number _____ FMF Number _____

CAP Number _____ CMF Number _____

2. ☐ All electronic files included in this submission have been checked and found to be virus free. (*Check box to verify*)

3a. For New Submissions Only: Enter the date of most recent presubmission consultation (if any) with FDA on the subject substance (yyyy/mm/dd): _____

3b. For Amendments only: Is your amendment submitted in response to a communication from FDA? *(Check one)* ☐ Yes ☐ No If yes, enter the date of communication (yyyy/mm/dd): _____

PART II - INFORMATION ABOUT THE PETITIONER OR PERSON RESPONSIBLE FOR MASTER FILE

1a. Petitioner or Person Responsible for Master File

Name of Contact Person	Position
Company *(if applicable)*	
Mailing Address *(number and street)*	

City	State or Province	Zip Code/Postal Code	Country

Telephone Number	Fax Number	E-Mail Address

1b. Agent or Attorney *(if applicable)*

Name of Contact Person	Position
Company *(if applicable)*	
Mailing Address *(number and street)*	

City	State or Province	Zip Code/Postal Code	Country

Telephone Number	Fax Number	E-Mail Address

PART III - GENERAL ADMINISTRATIVE INFORMATION

1. Title of Submission

2. Submission Format *(Check appropriate box(es))*

☐ Electronic Submission Gateway
☐ Paper
☐ Electronic files on physical media with paper signature page

If applicable, give number and type of physical media

3. For paper submissions only

Number of volumes:

Total number of pages:

4. Does this submission incorporate any information in FDA's files by reference? *(Check one)*

☐ Yes *(Proceed to item 5)* ☐ No *(Proceed to item 6)*

5. The submission incorporates by reference information from a previous submission to FDA as indicated below. *(Check all that apply)*

☐ a) Food Additive Petition No. FAP
☐ b) Food Master File No. FMF
☐ c) Color Additive Petition No. CAP
☐ d) Color Master File No. CMF
☐ e) GRAS Notice No. GRN
☐ f) GRAS Affirmation Petition No. GRP
☐ g) Other or additional information (briefly describe or enter information in a format similar to a) through f))

6. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information? *(Check one)*

☐ Yes, see attached designation of confidential information
☐ Yes, information is designated at the place where it occurs in the submission ☐ No

7. Have you attached a redacted copy of some or all of the submission? *(Check one)*

☐ Yes, redacted copy of complete submission
☐ Yes, redacted copy of part(s) of submission ☐ No

PART IV.A - FOOD ADDITIVE PETITION ONLY

1. Additive Type *(Check one)*

☐ Direct ☐ Secondary Direct
☐ Indirect ☐ Source of Radiation

2. Does the intended use of the additive include any use in meat, meat food product, or poultry product? *(Check one)*

☐ Yes ☐ No

The undersigned submits the attached petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to (state the name of the food additive and its proposed use)

PART IV.B - COLOR ADDITIVE PETITION ONLY

1. Regulated products that would contain additive *(Check applicable)*

☐ Food (including meat, meat food product or poultry product)
☐ Food (excluding meat, meat food product or poultry product)
☐ Food-contact material
☐ Cosmetics ☐ Drugs ☐ Medical devices

2. Fee enclosed *(Check one)*

☐ New listing for color additive for use in food ($3,000)
☐ New listing for color additive for use in cosmetics, drugs, or medical devices ($2,600)
☐ Amendment for color additive for use in food ($1,800)
☐ Amendment for color additive for use in cosmetics, drugs, or medical devices ($1,600)

The petitioner submits the attached petition pursuant to section 721(b)(1) of the Federal Food, Drug, and Cosmetic Act requesting listing by the Commissioner of the color additive

as suitable and safe for use in or on

subject to the conditions that

PART IV.C - FOOD MASTER FILE OR COLOR MASTER FILE ONLY

1. Reason for the submission

2. When applicable, other information not addressed or listed on this form

PART V - IDENTITY
(Including all constituents)

Note: When entering information in the table below, abbreviate Primary as P, and Constituents as C. (Include residual monomers, residual solvents, impurities (including carcinogenic impurities), catalysts, etc.)

Chemical Type	CAS* Registry Number	Chemical Name	Link To Chemical Structure	Trade Name (If any)

* CAS = Chemical Abstracts Service

Add Continuation Page

PART VI - OTHER ELEMENTS IN YOUR SUBMISSION

(check the list below to help ensure your submission is complete. check all that apply.)

1. ☐ **Administrative**

- 1.1 ☐ Designation of Nondisclosable Information
- 1.2 ☐ Redacted Document
- 1.3 ☐ Incoming Correspondence
  - 1.3.1 ☐ Amendment
  - 1.3.2 ☐ Update

2. ☐ **Administrative Technical**

- 2.1 ☐ Proposed Regulation
- 2.2 ☐ Proposed Tolerance
- 2.3 ☐ Exempt from Certification *(Color additive only)*

3. ☐ **Chemistry**

- 3.1 ☐ Identity
- 3.2 ☐ Use and Technical Effect
- 3.3 ☐ Labeling
- 3.4 ☐ Manufacturing Method
- 3.5 ☐ Residues
- 3.6 ☐ Specifications
- 3.7 ☐ Exposure Estimates
- 3.8 ☐ Studies
  - 3.8.1 ☐ Stability
  - 3.8.2 ☐ Intended Effect
  - 3.8.3 ☐ Migration
  - 3.8.4 ☐ Other Studies
- 3.9 ☐ Methods
- 3.10 ☐ References
  - 3.10.1 ☐ Literature Publications
  - 3.10.2 ☐ Other (including unpublished, etc.)

4. ☐ **Safety**

- 4.1 ☐ Toxicology Narrative
- 4.2 ☐ Studies
  - 4.2.1 ☐ Genetic Toxicity Tests
  - 4.2.2 ☐ Short Term Toxicity Studies Rodents
  - 4.2.3 ☐ Short Term Toxicity Studies Non-Rodents
  - 4.2.4 ☐ Subchronic Toxicity Studies Rodents
  - 4.2.5 ☐ Subchronic Toxicity Studies Non-Rodents
  - 4.2.6 ☐ One-Year Toxicity Studies Non-Rodents
  - 4.2.7 ☐ Chronic Toxicity Studies Rodents
  - 4.2.8 ☐ Carcinogenicity Studies Rodents

4. **Safety *(Continued)***

- 4.2 Studies *(Continued)*
  - 4.2.9 ☐ Combined Chronic Toxicity/ Carcinogenicity Studies Rodents
  - 4.2.10 ☐ In Utero Exposure Phase for Addition to Carcinogenicity Studies Rodents
  - 4.2.11 ☐ Reproduction Studies
  - 4.2.12 ☐ Developmental Toxicity Studies
  - 4.2.13 ☐ Immunotoxicity Studies
  - 4.2.14 ☐ Metabolism and Pharmacokinetic Studies
  - 4.2.15 ☐ Neurotoxicity Studies
  - 4.2.16 ☐ Human Studies
  - 4.2.17 ☐ Dermal Studies
  - 4.2.18 ☐ Ocular Studies
  - 4.2.19 ☐ Other Studies
- 4.3 ☐ References
  - 4.3.1 ☐ Literature Publications
  - 4.3.2 ☐ Other (including unpublished, etc.)

5. ☐ **Environmental**

- 5.1 ☐ Environmental Assessment
- 5.2 ☐ Claim of Categorical Exclusion
- 5.3 ☐ Confidential Environmental Information
- 5.4 ☐ Studies
- 5.5 ☐ References

6. ☐ Other (Information in original submission that does not fall under any of the above subfolders)

PART VII - SIGNATURE

Signature of Responsible Official, Agent or Attorney	Printed Name and Title	Date *(mm/dd/yyyy)*

PART VIII - LIST OF ATTACHMENTS

List your attached files or documents containing your petition or master file, forms, updates, or amendments and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Element Number/Folder Location ***(see Part VI above)***	**Name of Attachment**	**Page Number(s) for Paper Copy Only**

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OMB Statement: Public reporting burden for this collection of information is estimated to average 1 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: Department of Health and Human Services, Food and Drug Administration, Office of Operations, Paperwork Reduction Act (PRA) Staff, PRAStaff@fda.hhs.gov. (Please do NOT return the form to this address.) An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.