

Contains Nonbinding Recommendations

Instructions for Completing Form FDA 3503

OMB No. 0910-0016 Expiration Date 09/30/2023

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)

I. General Instructions

II. Specific Instructions for Each Part of the Form

III. FDA Internet Resources

I. General Instructions

- Form FDA 3503 is intended to help you assemble and transmit a FAP, CAP, FMF or CMF submission to FDA. It is not intended to substitute for FDA's regulations in 21 CFR 171.1 (for a FAP) or in 21 CFR 71.1 (for a CAP).
- Completion of this form alone does not constitute a complete FAP or CAP. A complete FAP or CAP also includes the items listed in Part VI of Form 3503.
- To prepare your submission in electronic format, you should download a Petition and Master File foldering structure, and place your completed form and files in the applicable folders (see Appendix 15 in Internet Resource #1 in Section III of these instructions for a link to the downloadable foldering structure).
 - You may upload the completed Petition and Master File foldering structure to the Electronic Submission Gateway (ESG). For information on using the ESG, see Internet Resource #2 in Section III of these instructions; or
 - You may send the completed submission, either in hard copy (including the form and all attachments) or in electronic format on physical media, to: Office of Food Additive Safety, HFS-200, 5001 Campus Drive, College Park, MD 20740-3835.
- Additional information about FAPs and CAPs is available on FDA's Internet Site (see Internet Resource #1 in Section III of these instructions).

II Specific Instructions for Each Part of the Form

1. Part I – Introductory Information About the Submission

In Part I, you tell us:

- Whether your submission is a newly transmitted FAP, CAP, FMF or CMF, or is an amendment or update to a previous submission;
- Whether you have determined that all files provided in an electronic submission are free of computer viruses;

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- The date of your most recent presubmission consultation (if any) with FDA before transmitting a new FAP, CAP, FMF or CMF; and
- The date of any correspondence, sent to you by FDA, relevant to an amendment or update you are transmitting.

2. Part II - Information About the Person Responsible for the Submission

In Part II, you identify:

- The person (i.e., the individual, partnership, corporation, association or other legal entity) who is responsible for the petition or master file and the contact person for that person; and
- Any agent or attorney who is authorized to act on behalf of the person responsible for the submission. If the agent or attorney is the preferred contact person for the responsible person, write "See agent or attorney" in the box for "Name of Contact Person."

3. Part III - General Administrative Information

In Part III, you tell us:

- The title of your submission;
- The format of your submission (i.e., paper, electronic, or electronic with a paper signature page);
- The mode of transmission of any electronic submission (i.e., ESG or transmission on physical media such as CD-ROM or DVD);
- Whether you are referring us to information already in our files;
- Whether you have designated in your submission any information that you view as trade secret or as confidential commercial or financial information (see 21 CFR part 20 and Internet Resource #1 in Section III of these instructions); and
- Whether you have attached a redacted copy of some or all of the submission. A redacted copy is a copy modified to remove data or information that you view as trade secret or as confidential commercial or financial information.

4. Part IV.A - Information Specific to FAPs

In Part IV.A, you tell us the type of food additive (direct, secondary direct, indirect, or source of radiation). You also tell us whether the food additive is intended for use in products (such as meat, meat food product, poultry product, or egg product) subject to regulation by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture. If so, we will arrange for the simultaneous review of your petition by FSIS.

In Part IV.A, you also provide information to comply with the requirement (in 21 CFR 171.1(c)) for a FAP to inform us that you are submitting the petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act.

5. Part IV.B - Information Specific to CAPs

In Part IV.B, you tell us the type of regulated products (food, drugs, cosmetics, or medical devices) that would contain the color additive. If the intended use includes use in food products (such as meat, meat food product, poultry product, or egg product) subject to regulation by the Food Safety and Inspection

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Service (FSIS) of the U.S. Department of Agriculture, we will arrange for the simultaneous review of your petition by FSIS.

In Part IV.B, you also provide information about fees associated with color additive petitions and information to comply with the requirement (in 21 CFR 71.1(c)) for a CAP to inform us that you are submitting the petition pursuant to section 721(b)(1) of the Federal Food, Drug, and Cosmetic Act.

6. Part IV.C – Information Specific to FMFs and CMFs

In Part IV.C, you tell us why you are submitting the master file and provide any other information not addressed by, or listed on, the form.

7. Part V - Identity

In Part V, you list information about the identity of the subject of the submission, including information such as the chemical name, trade name (when applicable), and Chemical Abstracts Service Registry Number (CAS Reg. No.).

8. Part VI - Other Elements In Your Submission

Part VI includes a checklist for those elements in a FAP or CAP that do not get completed directly on Form 3503. Some of these elements may be part of a FMF or CMF. These elements include:

- An Executive Summary;
- Designation of Nondisclosable Information;
- Additional Information/Incoming Correspondence (which applies only to amendments or updates to the original submission);
- As applicable, a proposed regulation, proposed tolerance, and statement regarding exemption from batch certification (for a color additive);
- Chemistry information (such as specifications and analytical methods);
- Safety information (such as a safety narrative and studies conducted in animals); and
- Environmental information (such as an environmental assessment or a claim for categorical exclusion).

9. Part VII – Signature

In Part VII, you print or type the name and title of the responsible official (or agent or attorney) who is signing the submission, and sign and date the form.

10. Part VIII - List Of Attachments

In Part VIII, you should list all attachments you include with Form 3503 as part of your submission (For information about downloading and organizing the attachments in your electronic submission please refer to Appendix 15). If you are completing the form by electronic means use the “Insert” button to browse for a file name that you want to insert in the box for “Attachment Name.” Use the “Clear” button if you want to remove or replace the “Attachment Name” you inserted. For paper submissions, you should number consecutively the pages within the attachments and enter the inclusive page numbers of each portion of the complete paper submission.

III. FDA Internet Resources

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The following resources are available on FDA's Internet site.

1. [Guidance for Industry: Providing Regulatory Submissions in Electronic or Paper format to Office of Food Additive Safety](#). This guidance document includes a list of, and hyperlinks to, guidance documents associated with the preparation of food and color additive petitions.
2. [Electronic Submission Gateway](#)