

Contains Nonbinding Recommendations

Instructions for Completing Form FDA 3480:
OMB No. 0910-0495; Expiration Date: Current expiration date available at
<https://www.reginfo.gov/public/do/PRAMain>
Department of Health and Human Services
Food and Drug Administration

Food Contact Substance Notification (FCN)
Prenotification Consultation (PNC)
Food Master File (concerning a Food Contact Substance) (FMF)

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- I. Using Form FDA 3480 with FCNs, PNCs, and FMFs**
 - Form FDA 3480 is intended to help you assemble a FCN, PNC, or FMF concerning a food contact substance (FCS) to FDA.
 - Before you complete the form, you should read the appropriate guidance (administrative, chemistry, toxicology, and environmental) for completion of a notification for a food contact substance (the guidances are Internet Resources #3-6 listed at the end of these instructions.)
 - For FCNs, a completed Form FDA 3480 *is required* as part of your submission. You must provide all applicable information requested in the Form to the extent

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that it is known or reasonably ascertainable by you. You should make reasonable estimates if you do not have actual data.

- For PNCs and FMFs concerning a FCS, a completed Form FDA 3480 is recommended but not required. Using Form FDA 3480 when you submit PNCs and FMFs for FCSs will assure uniformity with the arrangement of information submitted in FCNs. You should provide responses and data on the form only for those items relevant to the purposes of your submission.

II. Steps in Preparing Your Submission

- For submissions in electronic format, download a FCN folder structure (see Appendix 15: Links to Downloadable Foldering Structures of Internet Resources #1, listed at the end of these instructions.)
- Prepare attachment documents (documents responsive to items on Form 3480) in accordance with FDA guidances for food contact substance submissions, Internet Resources #3-6 below.
- For submissions in electronic format, place your attachment documents in the appropriate folders in the folder structure (see Internet Resource #1, Part V.B.: Food Contact Notification Submissions in Electronic Format for descriptions of the attachment documents to be placed in each folder in the FCN folder structure and the basic file-naming format.) For paper submissions, arrange the documents according to the order of items on the form.
- List your attachment documents and their folder locations (volume and page numbers for paper submissions) in the List of Attachments (Part VI of the form) as described in Section V.F. of these instructions, then proceed to filling out all relevant items on Form 3480, referencing your attachment documents or other FDA files as appropriate for each item on the form.

III. Entering Information on the Form

(Note: you should frequently save Form 3480 as you enter information because certain actions, e.g., executing a digital signature, choosing a write-in choice from a pull-down menu may be irreversible.)

- Entering information on the Form. The form is a PDF document with fillable text fields. It can be filled in using Adobe Acrobat or Acrobat Reader and possibly other PDF reading software. We recommend you enter complete information in all applicable fields that are provided on Form 3480, rather than only attaching the information. Our systems will “capture” information you enter in the fields (both for electronic and paper submissions). This enables us to use this information as searchable index information for your FCN in our database.

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- To enter information on the form, you can type the information or paste it from other sources. In Acrobat or Acrobat Reader you can change the font to underline, superscript, subscript, bold, etc., by selecting the text, right-clicking and selecting “text style”, or typing (Ctrl+”E”), or selecting the button View → Tool Bars → Properties Bar.
- Placing stamps, sticky notes, drawings or other mark-ups on the form is disabled in order to allow extended functions in Acrobat Reader. As for the form you actually submit, we request it not be saved as a version allowing these operations, nor printed as a new PDF, as this will remove needed functionality and our ability to capture the form data.
- Designating non-disclosable (confidential) information on the form. You should designate information you enter on the form that you consider trade secret, confidential commercial, or otherwise non-disclosable to the public under the Freedom of Information Act. In the text field where the confidential information is entered, we recommend you place the confidential information in brackets and precede it with “confidential:”, as:

confidential:[*your confidential information*]

- Notes. There is space for “notes” under many of the items on the form that request responsive information be attached. We recommend that you place any clarifying information here, such as: “We are incorporating by reference the manufacturing information in FMF 099999.” or “not applicable.”
- Mandatory fields. These “mandatory” fields may have a visible border highlighting them, indicating an entry of text (or a check in a box) is required (the form will not permit a signature until they are filled in); this is to help assure that FCN 3480 is completed (most fields will not be mandatory for PNCs and FMFs). Entering text in one field may cause others to become mandatory or become non-mandatory, depending on the logical interrelationships of the fields on the form. If you attempt a signature in Part V of Form 3480 with one or more mandatory fields unfilled, the form will indicate this, not allow the signature, and change the view (move the cursor) to the location on the form where entry of text is required. Note: the fact that some fields are designated as mandatory does not imply other fields are not important; for FCNs, all portions of Form 3480 relevant to your submission must be completed.

III. Transmitting Your Submission

- To transmit your submission (*submission by one of the electronic means is recommended; first two choices below*):
 - You may upload the completed FCN folder structure with included documents to the Electronic Submission Gateway (ESG). For information

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on using the ESG, see Internet Resource #2 in Section VII of these instructions.

- You may send a single copy of the completed FCN folder structure with included documents on physical media (e.g., CD-ROM, DVD) to: Notification Control Assistant, Office of Food Additive Safety, HFS-275, 5100 Paint Branch Parkway, College Park, MD 20740-3835.
- You may send the submission in paper format to the above address. You should submit five copies of a completed FCN if submitted only in paper format (each with all attachments and a signed original or copy of Form FDA 3480). For PNCs or FMFs, we recommend that you either send 5 paper copies (each with all attachments and a signed original or copy of Form FDA 3480), or consult with FDA regarding the number of paper copies to send. NOTE: Printing the form generates approximately 12 full pages of (large) bar coded information added at the end of the form; these represent the data you entered on Form 3480 that we will electronically capture as index data for your FCN. If you are sending your submission in paper format only, please include all printed barcode pages with your completed form.

IV. General Regulatory Instructions for FCNs

(These instructions appeared on page 1 of previous versions of Form 3480)

- Subject of a FCN. Only new uses of a FCS may be the subject of a notification. A “new” use is one not otherwise authorized. Only one FCS may be the subject of a particular notification, but multiple new uses of the same FCS may be combined in one notification. If you seek authorization for new uses of multiple FCSs that are food additives, you should submit a separate notification for each FCS.
- Referencing Information. Additional information regarding your FCN may be provided to FDA, by you or by a third party, in a Food Master File. You may reference this additional information in your FCN if it is submitted to FDA prior to the submission of your FCN. If information you refer to is from a third party and is not publicly available, provide a letter of authorization for such use, including the name of the authorizing official for the third party and a mailing address. Authorization is not necessary to reference publicly available information in FDA’s files.
- Complete Notification. Completion of Form FDA 3480 alone may not constitute a complete notification for a new use of an FCS. You must also submit all data and information that forms the basis of your safety determination for the use that is the subject of the notification and any data and information required by regulation.

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- Confidential Information. By submitting a notification under section 409(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)), a notifier waives any claim to confidentiality for information necessary to describe the food contact substance and the intended conditions of use that are the subject of the notification. If you are claiming any information to be confidential, you should designate the confidential information in writing, or otherwise mark the confidential information in the notification (e.g., by drawing a line around it or by following the recommendations in Section II of Internet Resource #1). You also may submit a separate redacted copy of the notification. However, FDA may disagree regarding the disclosability of information claimed confidential.
- For additional regulatory information, see “Guidance for Industry: Preparation of Food Contact Notifications: Administrative” (see Internet Resource #3 in Section VII of these instructions).

V. Specific Instructions for Certain Items on the Form (FCNs, PNCs, FMFs)

A. Part I: General Information

- Item 1: Enter the date that you transmit the submission to FDA in the format YYYY-MM-DD (e.g., 2007-12-23). If you include a cover letter, the date you enter should match the date of the cover letter.
- Item 2: You should check electronic submissions for viruses (with updated virus protection software) before transmitting them to FDA; check the box to indicate you have done this.
- Item 3:
 - a. Indicate the mode of transmission (ESG Gateway or courier/mail) and the format of your submission if you submit by courier/mail (electronic physical media or paper).
 - b. If submitted by courier/mail, describe in the space provided the type of electronic media (e.g., CD-ROM, DVDs) and the number of discs, or the number of volumes and copies for paper submissions.

B. Part II: Chemistry Information

1. General Instructions for Part II

- Summarize all pertinent information concerning the FCS that is the subject of the notification. This should include:
 - Chemical identity (Section A);
 - Manufacturing process (Section B);
 - Impurities and physical/chemical properties and specifications (Section C);
 - Intended use and intended technical effect (Section D);
 - Stability (Section E);

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- Migration Levels in food (Section F); and
 - Estimated daily intake (Section G).
- In addition to the summary information provided, your notification should include all supporting information or data. For recommendations on migration testing and presentation of the chemistry information see “*Guidance for Industry: Preparation of Premarket Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations*” (see Internet Resource #4 in Section VII of these instructions). On Form FDA 3480, we refer to this guidance as “*Chemistry Recommendations*.”
- Include sufficient supporting information and data to enable FDA to confirm values and results reported on the Form or in attachments or appendices, including the estimated daily intake(s) resulting from the intended use of the substance.

2. *Entering Chemical Information and Quantities on the Form*

Below, we provide some specific recommendations for entering information in the fields in Part II of the Form:

- For chemical names in the tables, the Chemical Abstracts Service (CAS) name, or the International Union of Pure and Applied Chemistry (IUPAC) name is acceptable. Do not use trade or code names/numbers. Many fields in the tables allow several lines of text for the entry of long chemical names. *If a chemical name will not fit in the space provided* in a text field on the form, enter terms that will identify the substance in the context of your submission and refer to the location in your submission where the complete chemical name can be found. For example, you might enter:

“(Oxidation product of FCS, see attachment 3)”

You should still enter the CAS registry number, if it exists, and other requested information in the row for the substance.

- To name non-specified total nonvolatile extractives (TNEs) or oligomers for a given polymeric FCS, enter the FCS chemical name followed, in parentheses, by (TNEs) or (oligomers), space permitting, and use the FCS CAS number.
- For CAS registry numbers, use the standard CAS format that includes hyphens, e.g., 12367-78-9. Enter “none” if no CAS number exists for the given chemical.
- For quantity fields, report values in the units specified in the table column on the Form, e.g., ppb, mg/in², and use ordinary base ten, e.g., 0.0000045. Do not use scientific notation.

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- If you exceed the available number of rows in a table, click the check box below that table; this causes a continuation page of the table to be generated.

3. Entering Information Into Table 4 in Section F.1.b – Summary of the Migration Testing

Below is an example of information entered in Table 4 in Part II, Section F.1.b:

Example: A notifier conducted a migration study to support the use of a polymer adjuvant, Adjuvant X, intended for use at a maximum level of 0.01 wt.% in LDPE. The example table below shows how the notifier might tabulate migration data obtained from sample plaques tested in 10% ethanol under conditions of use B.

Table 4: Summary of Migration Testing

TEST SAMPLE FORMULATION	MIGRANT	FOOD OR FOOD SIMULANT	TEMPERATURE AND TIME OF ANALYSIS	MIGRATION (each replicate)	AVERAGE MIGRATION (average of replicates)
LDPE containing 0.01 wt.% of Adjuvant X	Adjuvant X	10% ethanol	100°C analysis after 2 hours	0.012 mg/in ² 0.011 mg/in ² 0.021 mg/in ²	0.015 mg/in ²
			40°C analysis after 24 hours	0.015 mg/in ² 0.014 mg/in ² 0.022 mg/in ²	0.017 mg/in ²
			40°C analysis after 96 hours	0.017 mg/in ² 0.017 mg/in ² 0.023 mg/in ²	0.019 mg/in ²
			100°C analysis after 240 hours	0.020 mg/in ² 0.021 mg/in ² 0.023 mg/in ²	0.021 mg/in ²

C. Part III: Safety Information

- Provide a safety narrative, comprehensive toxicology profile(s) (CTPs), and list pertinent toxicological studies as directed on the Form.
- Include full study reports of studies that are used as the basis of the safety determination and current literature search results.

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- For more complete recommendations regarding the safety information, see *“Guidance for Industry: Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations”* (see Internet Resource #5 in Section VII of these instructions). On Form FDA 3480, we refer to this guidance as *“Toxicology Recommendations.”*

D. Part IV: Environmental Information

- Either:
 - provide a complete claim of categorical exclusion by, under item 1, checking the box(es) for the exclusion(s) you are claiming, completing the items below the exclusion, and completing items 2 and 3 if the proposed use qualifies for exclusion from the need to prepare an Environmental Assessment (EA) as defined under 21 CFR 25.32; or
 - Submit an EA.
- For more information about the environmental information in a FCN, see *“Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition”* (see Internet Resource #6 in Section VII of these instructions). On Form FDA 3480, we refer to this guidance as *“Environmental Recommendations.”*

E. Part V: Certification

In Part V, an authorized official or agent signs and dates the form and provides his/her title. For information on electronic signatures, see Internet Resource #1, Part III.G.

F. Part VI: List of Attachments.

- For electronic submissions:
 - Click on “Insert” to insert the name of a file from the directory on your local hard drive that is the FCN folder structure wherein you have placed the documents for your submission. Clicking on “Clear” will remove the name if you need to change it. This assures that the name of the file entered in the table matches the name of the file included your submission (our system will automatically check the filenames in the List of Attachments against the filenames of files actually included in the folder structure of your submission). Alternatively, type or paste the filename (name files according to the File Naming Conventions in Appendix 12 of Internet Resource #1, including the 3 character extension (e.g., .pdf, .mol).
 - NOTE: Documents you list are not actually “attached” in any way to Form 3480; you must place the documents in the appropriate folders in the FCN

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foldering structure according to Part V.B. of Internet Resource #1 and Section VI: Folder Location Quick Reference, below.

- Select the folder location (indicating the folder in the standard FCN foldering structure in which you placed the document) from the pull down menu. For example:

1	Att.1-DesignationOfNondisclosableInformation_HPNIin Polypropylene ACME 2007-10-12.pdf	Administrative
2	Att.2-MigrationStudy_HPNIH_StandardCurves,chromatograms, calculations 2007-9-24.pdf	Chemistry/Studies

- For paper submissions:
 - List the title of each document included with Form 3480.
 - Type in the volume number and inclusive page numbers of each document, as applicable.
- If a document is responsive to a given item on the Form, the attachment number adjacent to the document name should match the attachment number entered under the given item on the Form (note: not all attached documents will necessarily be responsive to items on Form 3480).

VI. Folder Location Quick Reference (based on Internet Resource #1, Part V.B.)

(Note: Chemistry, Safety, Environmental and Administrative information should not be combined in a single file)

If the file is or contains:	Place the file in the folder:
Form FDA 3480, administrative, regulatory information, designation of nondisclosable information, redacted copies	Administrative
FCS identity, specifications, use, manufacture, impurities, technical effect	Chemistry
Migration, stability or other chemistry study reports & data	Chemistry/Studies
Published chemistry information	Chemistry/References
Safety narrative	Safety
Comprehensive toxicological profile (CTP) and/or literature search information for a given substance (<i>Chemical Name 1</i>)	Safety/ <i>Chemical Name 1</i>
Safety study reports, data of a given <i>study type</i> , for a given substance (<i>Chemical</i>	Safety/ <i>Chemical Name 1</i> /Studies/ <i>Study</i>

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<i>Name 1)</i>	<i>Type</i>
Published safety studies/information on a given substance (<i>Chemical Name 1</i>)	Safety/ <i>Chemical Name 1</i> /References
EA, categorical exclusion supporting information	Environmental
Environmental study reports & data	Environmental/Studies
Published environmental studies/information	Environmental/References
Confidential information referenced in the EA	Environmental/Confidential Environmental Information

VII. FDA Internet Resources

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

1. [Guidance for Industry: Providing Regulatory Submissions in Electronic or Paper format to the Office of Food Additive Safety](#)
2. [Electronic Submission Gateway](#)
3. [Guidance for Industry: Preparation of Food Contact Notifications: Administrative](#)
4. [Guidance for Industry: Preparation of Premarket Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations](#)
5. [Guidance for Industry: Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations](#)
6. [Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition](#)