Contains Nonbinding Recommendations

Instructions for Completing Form FDA 3480: OMB No. 0910-0495
Department of Health and Human Services
Food and Drug Administration

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

I. Using Form FDA 3480 with FCNs, PNCs and FMFs

- Form FDA 3480 is intended to help you assemble and transmit 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. For access to these guidances, see the Internet Resources in Part VII 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

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. Entering Information on the Form and Attaching Information

(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.

    - 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 (Cntrl+"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.

- Attaching information to the form. For each item on the Form that requests information to be attached, either:

    - Check the box indicating you have included a document in the submission responsive to the item and enter the Attachment Number(s) (Att. #'s) in the List of Attachments (Part VI of Form 3480) in the row(s) where the responsive document name(s) is listed, or

    - Check the box indicating you are referencing the information from other FDA files, and enter the name of the FDA file referenced, e.g., "PNC 099999"

- Designating non-disclosable (confidential) information on the form. You should designate information you enter on the form you consider trade secret, confidential commercial, or otherwise non-disclosable to the public under the Freedom of Information Act. We recommend you place the confidential information in brackets in the text field 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."

III. Preparing and Transmitting Your Submission

- To prepare your submission in electronic format, you should download a FCN foldering structure, and place your completed form and attachment files in the applicable folders (see Appendix 15 in Internet Resource #1 in Part VII of these instructions for a link to the downloadable foldering structure).

- To transmit your submission (*submission by one of the electronic means is recommended; first two choices below*):

    - You may upload the completed FCN foldering structure to the Electronic Submission Gateway (ESG). For information on using the ESG, see Internet Resource #2 in Part VII of these instructions

    - You may send a single copy of the submission in electronic format 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 the form and that we will use to 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.

III. 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.

- 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 Reference 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 Part 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);
    - 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 Part 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, see attachment 3)"

  You should still enter the CAS registry, 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.

- 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/in² 0.011 mg/in² 0.021 mg/in²	0.015 mg/in²
			40°C analysis after 24 hours	0.015 mg/in² 0.014 mg/in² 0.022 mg/in²	0.017 mg/in²
			40°C analysis after 96 hours	0.017 mg/in² 0.017 mg/in² 0.023 mg/in²	0.019 mg/in²
			100°C analysis after 240 hours	0.020 mg/in² 0.021 mg/in² 0.023 mg/in²	0.021 mg/in²

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.
- 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 Part 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 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 Part 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.

F. Part VI: List of Attachments.

- For electronic submissions:
  - Click on "Insert" to insert the name of a file from a directory on your local hard drive, and "Clear" to remove the name. 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 your submission). Alternatively, type or paste the filename (name files according to the File Naming Conventions in Appendix 12 of Reference 1, including the 3 character extension (e.g., .pdf, .mol). For information about downloading and organizing the attachments in your electronic submission please refer to Appendix 15.
  - 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	DesignationOfNondisclosableInformation_HPNHin Polypropylene_ACME_2007-10-12.pdf	Administrative
2	MigrationStudy_HPNH_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

(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 (*Chemical Name 1*)	Safety/*Chemical Name 1*
Safety study reports, data of a given *study type*, for a given substance (*Chemical Name 1*)	Safety/*Chemical Name 1*/Studies/*Study Type*
Published safety studies/information on a given substance	Safety/*Chemical Name 1*/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/Conf. Envr. Info

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

VIII. Public Burden Statement

Public reporting burden for this collection of information is estimated to average xx hours 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, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, 5100 Paint Branch Parkway (HFS-200), College Park, MD 20740-3835. 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.