

*Contains Nonbinding Recommendations*

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

**Amendment to an Existing Food Contact Notification (FCN),  
Pre-Notification Consultation (PNC), or  
Food Master File (Concerning a Food Contact Substance) (FMF)**

- I. General Instructions**
- II. Specific Instructions for Certain Items on the Form**
- III. Folder Location: Quick Reference**
- IV. FDA Internet Resources**
- V. Public Burden Statement**

**I. General Instructions**

- Form FDA 3480-A is intended to serve as a standard organizing tool for use when transmitting an *amendment* to an existing FCN, PNC, or FMF concerning a food contact substance (FCS) to FDA. You should use Form FDA 3480-A each time you transmit such an amendment to a given submission.
- Guidance on preparing and transmitting an amendment to a FCN, PNC, or FMF for a FCS is available in Parts III and V of Internet Resource #1, listed in Section IV of these instructions, below.
- For information on working with PDF Form 3480-A (entering information, designating confidential information) see Section II of Instructions for Completing Form 3480 (Appendix 3a of Internet Resource #1.)
- To prepare your amendment in electronic format, you should download a new FCN foldering structure (do not re-submit documents previously submitted), and place your completed form and attachment files in the appropriate folders (see Part V and Appendix 15 of Internet Resource #1, below, for guidance and 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 folder structure with included documents to the Electronic Submission Gateway (ESG). For information on using the ESG, see Internet Resource #2 in Section IV, below, of these instructions.

## ***Contains Nonbinding Recommendations***

- You may send a single copy of the completed FCN folder structure with included documents on physical media to (e.g., CD-ROM, DVD): 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. If only submitted in paper format, you should either submit five copies of the amendment to a FCN, PNC or FMF (each including all attachments and a signed copy of Form FDA 3480-A), or consult with FDA regarding the number of paper copies to send. NOTE: Printing the form generates one or more pages of (large) bar coded information added at the end of the form; these represent the data you entered on Form 3480-A that we will electronically capture as index data for your amendment. If you are sending your submission in paper format only, please include all printed barcode pages with your completed form.

## **II. Specific Instructions for Certain Items on the Form**

- 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 submit the documents in electronic format (via FDA ESG or by physical media), this date should match the date that you would place in the first part of the filename of each document accompanying the Form, as described under Item 8 below.
- 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: FCN/PNC/FMF Number. Check the appropriate box for FCN, PNC, or FMF, and enter the FDA assigned reference number for the FDA file to which the information is to be added. Use leading zeros to make six digits, for example: 009999
- Item 4:
  - 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.
- Item 5: Provide information about the person submitting the amendment and attorney or agent acting on behalf of that person.
- Item 6: Briefly describe the information you have submitted. If your submission is in response to an FDA request, check the applicable box and enter the date (YYYY-MM-DD) when FDA made the request (e.g., by letter, e-mail, phone call, or meeting). If the amendment, or part of the amendment, is not in response to an FDA request, explain the purpose of the amendment, e.g., to provide an update on an ongoing toxicological study or correction to a calculation.

### *Contains Nonbinding Recommendations*

- Item 7: an authorized official or agent signs and dates the form and provides his/her title.
- Item 8: 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 attachment 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 Reference 1, including the 3 character extension (e.g., .pdf, .mol).
    - NOTE: Documents you list are not actually “attached” in any way to Form 3480-A; you must place the documents in the appropriate folders in the FCN foldering structure according to Part V of Internet Resource #1 and Section III: 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:

|  |                   |
|--|-------------------|
| 2007-12-07_ResponsesToFDA2007-11-20chemistryquestions(impurities, migration) | Chemistry         |
| 2007-12-07_MigrationStudy_revised chromatograms.pdf                          | Chemistry/Studies |
| 2007-12-07_RevisedEA_HPNIHInPolypropylene.pdf                                | Environmental     |

- For paper submissions:
  - List the title of each document included with Form FDA 3480-A.
  - Enter the volume number and inclusive page numbers of each document, as applicable.

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

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

| <b>If the file is or contains:</b>  | <b>Place the file in the folder:</b> |
|---|--------------------------------------|
| Form 3480-A, administrative, regulatory information, designation of nondisclosable information, redacted copies | Administrative                       |

|   |  |
|---|--|
| Responses to a series of chemistry questions, introductions to newly submitted chemistry data                                   | Chemistry  |
| FCS identity, specifications, use, manufacture, impurities, technical effect  | Chemistry  |
| Migration, stability or other chemistry study data, data clarifications   | Chemistry/Studies  |
| Published chemistry information   | Chemistry/References                                       |
| Responses to a series of Safety/Toxicology questions, introductions to newly submitted data/info                                | Safety   |
| 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 Name 1</i> )                      | Safety/ <i>Chemical Name 1</i> /Studies/ <i>Study Type</i> |
| Published safety studies/information on a given substance ( <i>Chemical Name 1</i> )  | Safety/ <i>Chemical Name 1</i> /References                 |
| Responses to a series of environmental questions, introductions to newly submitted environmental data/information               | Environmental  |
| EA, Revised EA  | Environmental  |
| Environmental study reports & data  | Environmental/Studies                                      |
| Published environmental studies/information   | Environmental/References                                   |
| Confidential information referenced in the EA   | Environmental/Conf. Envr. Info                             |

#### **IV. 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](#)

#### **V. 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.