Contains Nonbinding Recommendations

Instructions for Completing Form FDA 3667
OMB No. 0910-0342
Department of Health and Human Services
Food and Drug Administration
Generally Recognized As Safe (GRAS) Notice

I. General Instructions

- Form FDA 3667 is intended to help you assemble and transmit a GRAS notice submission to FDA.
- Completion of this form alone does not constitute a complete GRAS notice. A complete GRAS notice also includes the items listed in Part VI of Form 3667.
- To prepare your submission in electronic format, you should download a GRAS Notice foldering structure, and place your completed form and files in the applicable folders (see Appendix 15 in Internet Resource #1 in Part III of these instructions for a link to the downloadable foldering structure).
- To transmit your GRAS notice submission:
    - You may upload the completed GRAS Notice foldering structure to the Electronic Submission Gateway (ESG). For information on using the ESG, see Internet Resource #2 in Part 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, 5100 Paint Branch Parkway, College Park, MD 20740-3835.
- Additional information about GRAS notices is available on FDA's Internet Site (see Internet Resource #1 in Part 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 GRAS notice submission is a new GRAS notice, or an amendment or supplement to a previously transmitted GRAS notice;
- Whether you have determined that all files provided in an electronic transmission are free of computer viruses;
- The date of your most recent meeting with FDA before transmitting a new GRAS notice; and
- The date of any correspondence, sent to you by FDA, relevant to an amendment or supplement you are transmitting;

2. Part II – Information About the Notifier

In Part II, you identify:

- The notifier (i.e., the individual, partnership, corporation, association or other legal entity) who is informing FDA that a particular use of a substance is exempt from the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act based on that notifier's determination that such use is GRAS;
- The contact person for the notifier within any partnership, corporation, association, or other legal entity; and
- Any agent or attorney who is authorized to act on behalf of the notifier. If the agent or attorney is the preferred contact person for the notifier, write "See agent or attorney" in the box for "Name of Contact Person" in Part II, 1a.

3. Part III - General Administrative Information

In Part III, you tell us:

- The name of the substance that is the subject of your GRAS notice 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;
- The statutory basis for your determination of GRAS status;
- 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 Part 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 – Intended Use

In Part IV, you describe the intended conditions of use of the notified substance.

5. Part V - Identity

In Part V, you provide information that identifies the notified substance. For example, there may be a chemical name and formula and a standardized registry number. Taxonomic information is appropriate for substances from biological sources, and many biological sources have scientific names as well as common names. If Part V does not capture some or all of the identity information about the notified substance, include any remaining identity information in Part VI.

6. Part VI - Other Elements In Your GRAS Notice

Part VI provides a checklist for those elements of a GRAS notice that do not get completed directly on Form 3667:

- Any additional information about identity not covered in Part V
- Method of manufacture
- Specifications for food-grade material
- Dietary exposure
- Self-limiting levels of use
- Common use in food before 1958 (if applicable)
- Comprehensive discussion of the basis for the determination of GRAS status
- Bibliography

A GRAS notice also may include other information – e.g., a document identifying information you view as trade secret or as confidential commercial or financial information.

7. Part VII – Signature

In Part VII, you complete certain statements, 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.

8. Part VIII - List of Attachments

In Part VIII, you should list all attachments you include in your submission (For information about downloading and organizing the attachments in your 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

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 GRAS notices.
2. Electronic Submission Gateway.