

Contains Nonbinding Recommendations

Instructions for Completing Form FDA 3665
OMB No. 0910-0704 Expiration Date: 02/28/2015
Department of Health and Human Services
Food and Drug Administration
Final Consultation for Food Derived from a New Plant Variety
(Biotechnology Final Consultation)

- I. General Instructions**
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I. General Instructions

- Form FDA 3665 is intended to help you assemble and transmit a Biotechnology Final Consultation to FDA.
- Completion of this form can expedite processing of your submission, but does not constitute a complete submission. Your completed submission should include the items listed in Part VI of Form 3665.
- To prepare your submission in electronic format, you should download a Biotechnology Final Consultation foldering structure, then 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 submission:
 - You may upload the completed Biotechnology Final Consultation 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 on paper (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. When sending paper submissions, please include all printed barcode pages with your completed form.
- Additional information about Biotechnology Final Consultations 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 new submission, or is an amendment or supplement to a previously established Biotechnology Notification File (BNF);

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- Whether you have determined that all files provided in an electronic transmission are free of computer viruses;
- The date of your most recent meeting (if any) with FDA before transmitting a new submission; 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 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 submission;
- The contact person within any partnership, corporation, association, or other legal entity; and
- Any agent or attorney who is authorized to act on behalf of the person who is responsible for the submission. If the agent or attorney is the preferred contact person, 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 title of your submission;
- The format of your submission (i.e., paper, electronic, or electronic with a paper signature page);
- The mode of delivery 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 provided 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 –Information About the Food and the New Plant Variety From Which It Is Derived

In Part IV, you:

- Tell us the name of the food (i.e., the common name of the plant) derived from the new plant variety (e.g., corn, not corn meal and oil);
- Describe the various applications or uses of food derived from the new plant variety, including animal feed uses;
- Tell us the common name and scientific name (genus and species) of the new plant variety;

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- Tell us the distinctive designation and/or unique identifier used to identify the transformation event; and
- Describe the purpose or intended technical effect of the modification, and a expected effect on the composition or characteristic properties of the food.

5. Part V –Identity of New Substances in the New Plant Variety

In Part V, you provide information about any new substances (proteins and other metabolic products) made in the new plant variety including the name and function of the new substance. You may also include any registry designations.

6. Part VI – Summary of Safety and Nutritional Assessment

In Part VI, you are prompted to attach your safety and nutritional assessment and tell us if there is additional information for us to consider in evaluating your submission.

7. 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.

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. Select the folder location (indicating the folder in the standard foldering structure in which you placed the document) from the pull down menu. 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 Biotechnology Final Consultations.
2. [Electronic Submission Gateway](#).