Contains Nonbinding Recommendations

Instructions for Completing Form FDA 3665
OMB No. 0910-0704
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

- Form FDA 3665 (available on FDA's website at Forms | FDA) is intended to help you assemble and transmit a Biotechnology Final Consultation (also known as a Biotechnology Notification File (BNF)) 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.

- FDA developed an electronic portal (an online submission module known as COSM) for electronic submissions. COSM was specifically designed to aid firms wishing to file submissions with FDA. COSM is a web-based tool that walks users through a step-by-step process to assemble and send fully electronic submissions to the agency, thereby eliminating the need for printing and mailing of paper submissions. COSM allows safety, nutritional, and other information in a BNF to be uploaded and submitted online via Form FDA3665. You may use the same COSM account for future submissions. We encourage firms to submit their BNF through COSM. Use of the portal facilitates FDA review and also will allow submitters to obtain real-time status updates of their submission. COSM's data validation also helps prevent incomplete notifications by ensuring that all required fields are completed before the BNF is submitted. For COSM instructions and account management information, visit the COSM website at Centralized Online Submission Module (COSM) | FDA.

- To transmit your submission:
  - You may submit your BNF electronically via COSM at Online Submission; or
  - You may send the completed submission, either on paper (including the form and all attachments) or in electronic format on physical media, to: FDA Office of Food Chemical Safety, Dietary Supplements and Innovation, Innovative Foods Staff, HFS-200, 5001 Campus Drive, College Park, MD 20740-3835.

- 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);
- 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
- Whether you have provided a redacted copy of some or all 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.
- 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 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.

II. FDA Internet Resources

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

1. Biotechnology Guidance Documents & Regulatory Information (Biotechnology Guidance Documents & Regulatory Information | FDA) - This website includes a list of, and hyperlinks to, guidance documents associated with the preparation of Biotechnology Final Consultations.
2. Centralized Online Submission Module (COSM) (Centralized Online Submission Module (COSM) | FDA) - This website includes information and links to instructions for COSM.
3. Centralized Online Submission Module (COSM)-Login (Online Submission) - This is the login webpage for COSM.