Contains Nonbinding Recommendations

Instructions for Completing Form FDA 3666
OMB No. 0910-0583
Department of Health and Human Services
Food and Drug Administration
Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation)

I. General Instructions

- Form FDA 3666 (available on FDA's website at Forms | FDA) is intended to help you assemble and transmit a New Protein Consultation (NPC) 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 3666.

- 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 an NPC to be uploaded and submitted online via Form FDA3666. You may use the same COSM account for future submissions. We encourage firms to submit their NPC through COSM. Use of the portal facilitates FDA review and 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 NPC 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 NPC 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 NPCs 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 submission is a new submission, or an amendment or supplement to a previously established NPC.
- 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 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."

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 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.
- 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 attached 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.

- The date of any correspondence, sent to you by FDA, relevant to an amendment or supplement you are transmitting.

4. Part IV –Information About the New Protein

In Part IV, you:

- Tell us the name of the new protein.
- Have an option to provide any registry designations for the new protein; and
- Describe the purpose or intended technical effect of the new protein.

5. Part V –Information About Genetic Material

In Part V, you provide information about the introduced genetic material (including identity and source).

6. Part VI – Scientific Evaluation of the Food Safety of the New Protein

Part VI provides a checklist for those elements of an NPC that do not get completed directly on Form 3666:

- Whether there is a history of safe use in food or feed
- Whether you have included an assessment of the amino acid similarity between the new protein and known allergens and toxins.
- Whether you have included information about the overall stability of the protein, and the resistance of the protein to enzymatic degradation using appropriate in vitro assays; and
- Whether you included any other information, you want us to consider in evaluating your NPC.
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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.

III. 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.