DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FINAL CONSULTATION FOR FOOD DERIVED FROM A NEW PLANT VARIETY *(BIOTECHNOLOGY FINAL CONSULTATION)*

Form Approved: OMB Control No. 0910-0583;
Expiration Date: 08/31/2024 *(See page 4 for OMB Statement)*

FDA USE ONLY

BNF NUMBER

DATE OF RECEIPT

Transmit completed form and attachments electronically via the COSM online submission system *(see Instructions)*; OR Transmit completed form and attachments in paper format or in physical media to: Office of Food Chemical Safety, Dietary Supplements, and Innovation (HFS-200), Human Foods Program, Food and Drug Administration, 5001 Campus Drive, College Park, MD, 20740-3835.

PART I – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Check one)*

☐ New ☐ Amendment to BNF No. _____ ☐ Supplement to BNF No. _____

2. ☐ All electronic files included in this submission have been checked and found to be virus free. *(Check box to verify)*

3a. For New Submissions Only: Most recent presubmission consultation *(if any)* with FDA on the subject food *(yyyy/mm/dd)*: _____

3b. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? *(Check one)* ☐ Yes ☐ No If yes, enter the date of communication *(yyyy/mm/dd)*: _____

PART II – INFORMATION ABOUT THE NOTIFIER

1a. Notifier	Name of Contact Person		Position	
	Company *(if applicable)*			
	Mailing Address *(number and street)*			
City		State or Province	Zip Code/Postal Code	Country
Telephone Number		Fax Number	E-Mail Address	

1b. Agent or Attorney *(if applicable)*	Name of Contact Person		Position	
	Company *(if applicable)*			
	Mailing Address *(number and street)*			
City		State or Province	Zip Code/Postal Code	Country
Telephone Number		Fax Number	E-Mail Address	

PART III – GENERAL ADMINISTRATIVE INFORMATION

1. Title of Submission

2. Submission Format: *(Check appropriate box(es))*

☐ Electronic Submission (COSM) ☐ Electronic files on physical media with paper signature page

☐ Paper

If applicable give number and type of physical media

_____

3. For paper submissions only:

Number of volumes _____

Total number of pages _____

4. Does this submission incorporate any information in FDA's files by reference? *(Check one)*

☐ Yes *(Proceed to Item 5)* ☐ No *(Proceed to Item 6)*

5. The submission incorporates by reference information from a previous submission to FDA as indicated below *(Check all that apply)* :

☐ a) BNF No. BNF _____

☐ b) NPC No. NPC _____

☐ c) GRAS Notice No. GRN _____

☐ d) GRAS Affirmation Petition No. GRP _____

☐ e) Food Additive Petition No. FAP _____

☐ f) Food Master File No. FMF _____

☐ g) Other or Additional *(describe or enter information as above)*

6. Does the submission (including information that you are incorporating by reference) contain information that you view as trade secret or as confidential commercial or financial information?

☐ Yes *(Proceed to Item 7)* ☐ No *(Proceed to Part IV)*

7. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information *(Check all that apply)*

☐ Yes, see attached Designation of Confidential Information

☐ Yes, information is designated at the place where it occurs in the submission

☐ No

8. Have you attached a redacted copy of some or all of the submission? *(Check one)*

☐ Yes, a redacted copy of the complete submission

☐ Yes, a redacted copy of part(s) of the submission

☐ No

PART IV – INFORMATION ABOUT THE FOOD AND THE NEW PLANT VARIETY FROM WHICH IT IS DERIVED

1. Name of food derived from the new plant variety

2. Describe the various applications or uses of food derived from the new plant variety, including animal feed uses.

3. Common name of the plant variety from which the food is derived	4. Scientific designation (genus and species) of the plant variety from which the food is derived	5. Distinctive designation(s) and/or unique identifier(s) that you use to identify the applicable transformation event(s)

PART IV – INFORMATION ABOUT THE FOOD AND THE NEW PLANT VARIETY FROM WHICH IT IS DERIVED *(Continued)*

6. Describe the purpose or intended technical effect of the modification and any expected effect on the composition or characteristic properties of the food.

PART V – IDENTITY OF NEW SUBSTANCES IN THE NEW PLANT VARIETY

Provide the information below about each new substance made in the new plant variety

Name of Substance	**Registry Used** ***(e.g., CAS, IUB)***[1] ***(optional)***	**Registry No.** ***(optional)***	**Function**

Add Continuation page

[1] *Common registries used include CAS (Chemical Abstracts Service) and EC (Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB))*

PART VI – SUMMARY OF SAFETY AND NUTRITIONAL ASSESSMENT
(check list to help ensure your submission is complete - check all that apply)

1. ☐ Summary of safety and nutritional assessment attached

2a. Did you include any other information that you want FDA to consider in evaluating your Biotechnology Final Consultation?

☐ Yes ☐ No

2b. Did you include this other information in the list of attachments?

☐ Yes ☐ No

PART VII – SIGNATURE

Signature of Responsible Official, Agent, or Attorney	**Printed Name and Title**	**Date** ***(mm/dd/yyyy)***

PART VIII – LIST OF ATTACHMENTS

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
	Insert Clear	
	Insert Clear	
	Insert Clear	
	Insert Clear	
	Insert Clear	
	Insert Clear	
	Insert Clear	
	Insert Clear	
	Insert Clear	

Add Continuation Page

OMB Statement: Public reporting burden for this collection of information is estimated to average 150 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: Department of Health and Human Services,Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, Room 400, Rockville, MD 20850. (Please do NOT return the form to this address.). 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.