Appendix 11
Definitions

I. Definitions of Regulatory Submissions Addressed in This Document

Biotechnology Final Consultation – A voluntary submission to FDA, regarding food or feed derived from a new plant variety, including a new plant variety developed using recombinant DNA techniques. FDA also assigns a file number (Biotechnology Notification File No. (BNF)) to the Biotechnology Final Consultation.

Color Additive Petition (CAP) – A petition, submitted to FDA pursuant to section 721(b)(1) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 71.1, requesting listing of a color additive as suitable and safe for use in or on a food, drug, medical device, or cosmetic or for coloring the human body.

Color Master File (CMF) – A voluntary submission to FDA, regarding a color additive, outside the realm of a CAP. The reasons for submitting a CMF vary. For example, a CMF could be a repository of confidential data or information provided by "Manufacturer A" to support a regulatory submission provided by "Manufacturer B" when "Manufacturer B" does not have access to these confidential data or information. As another example, a CMF could be a repository of data or information submitted by "Manufacturer C" before "Manufacturer C" submits a CAP.

Food Additive Petition (FAP) – A petition, submitted to FDA pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 171.1, proposing the issuance of a regulation prescribing the conditions under which a food additive may be safely used.

Food Contact Notification (FCN) – A notification, submitted to FDA pursuant to section 409(h) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 170.101. An FCN is submitted at least 120 days prior to the introduction or delivery for introduction into interstate commerce of a food contact substance. An FCN notifies FDA of the identity and intended use of a food contact substance, and of the determination of the manufacturer or supplier that the intended use of the food contact substance is safe under the standard described in section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act.

Food Master File (FMF) – A voluntary submission to FDA, regarding a food substance other than a color additive, outside the realm of submissions such as FAPs, GRAS notices, FCNs, BNFs and NPCs. The reasons for submitting a FMF vary. For example, a FMF could be a repository of confidential data or information provided by "Manufacturer A" to support a regulatory submission provided by "Manufacturer B" when "Manufacturer B" does not have access to these confidential data or information. As another example, a FMF could be a repository of data or information provided by "Manufacturer C" before "Manufacturer C" submits a FAP.

GRAS notice – A voluntary submission notifying FDA of your view 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 your determination that such use is GRAS in accordance with 21 CFR 170.30.

New Protein Consultation (NPC) – A voluntary submission to FDA, regarding the early food safety evaluation of a new non-pesticidal protein produced by a new plant variety intended for food or feed use.

Pre-Notification Consultation for a Food Contact Substance (PNC) – A voluntary submission to FDA regarding a food contact substance, prior to submitting a FCN, for the purpose of consulting with FDA to facilitate preparation of a complete FCN.

II. Other Terms Used In This Document

Amendment –

1. For FAPs/CAPs: any additional information or data submitted to a petition in response to an FDA request for additional and/or clarification data in support of a filed petition.
2. For a GRAS notice, Biotechnology Final Consultation, or New Protein Consultation: any additional information submitted to a notice before FDA has responded to the notice.
3. For FCNs: any additional information submitted to an FCN.

Electronic Submission – A single transmittal of electronic files to FDA.

Redacted Copy – a copy of the regulatory submission or a document within that submission, except that it has been modified to remove information you view exempt from disclosure under the Freedom of Information Act.

Reference – any published or unpublished study or information provided in support of a regulatory submission.

Roadmap – An organized grouping of electronic folders that you can download and use to structure an electronic submission. A visual representation of the roadmap will orient the submitter and FDA to the entire submission.

Study – a compilation of information and raw data resulting from the testing of a substance.

Supplement –any data or other information submitted to a filed GRAS notice, a Biotechnology Final Consultation, or a New Protein Consultation after FDA has responded to the notice.

Update – voluntary information submitted from a petitioner to a filed petition (FAP/CAP) or to an established FMF or CMF.