

Novel Excipient Review Pilot Program Initial Proposal Model Content Outline

FDA is providing a model content outline describing the information that should be included in initial proposals for the Novel Excipient Review Pilot Program. The cover email should identify the submission as an initial proposal. If literature is referenced, please cite using the number assigned to the source in a numbered reference list.

This program is designed to support novel excipients in drug development. For purposes of this Pilot Program, an excipient is intended to mean any ingredient intentionally added to a drug product (including biological drug products) that is not intended to exert therapeutic effects at the intended dosage, although it may improve product delivery (see FDA guidance for industry “Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients” (Excipients guidance), May 2005, p. 1 (available at <https://www.fda.gov/media/72260/download>)). Examples of excipients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents (see Excipients guidance, pp. 1–2). A novel excipient is any excipient that is not fully supported by existing safety data with respect to the currently proposed level of exposure, duration of exposure, or route of administration (see Excipients guidance, p. 1). For this program, FDA will consider novel excipients that have not been previously used in FDA-approved drug products and that do not have established use in food. Novel excipients selected for this pilot will have the potential to facilitate drug development, and a description of this should be included in the documentation provided.

1. **Submission Title:** One sentence description of the submission.
2. **Excipient:** Name(s), CASN, UNII (if available), structure, pharmaceutical function.
3. **Requesting Organization:**
 - Name of Organization: Physical Address; Phone Number; Website address
 - Primary Point of Contact: Name; Job Title; Address; Phone Number; Email
 - Alternate Point of Contact: Name; Job Title; Address; Phone Number, Email
 - Supporting or participating organizations or individuals
4. **Drug Development Need Statement:** Describe the public health and/or drug development need that the submission is intended to address, including (if applicable) the proposed benefit over currently used excipients in similar conditions of use. (100 words maximum)
5. **Conditions of Use Statement:** A statement that fully and clearly describes the way the novel excipient is intended to be used and the drug development-related purpose of the use. An understanding of the drug development related purpose is necessary before the supportive safety information can be ascertained. An example of a condition of use statement is: “Excipient A increases the solubility of hydrophobic active pharmaceutical oral formulations intended for chronic oral administration.” (150 words maximum)



6. **Supporting Data:** Provide a description of the quality and toxicology information available to support the safety of the new excipient for the proposed conditions of use. Such information should include data for topics normally addressed when evaluating the safety of a drug product. Depending on the conditions of use, this can include information on genotoxicity, general toxicity, developmental and reproductive toxicity and carcinogenicity. Pharmacokinetic/toxicokinetic data are recommended in order to correlate analysis across pharmacology and toxicology studies. Recommendations for the nonclinical information typically recommended for the safety evaluation of pharmaceutical excipients can be found in the CDER/CBER guidance on this topic.¹ If information needed to support a full package is not available, include an approximate timeframe for when such information would be ready to include, should the excipient be selected. (5 pages plus references maximum)

7. **Previous Regulatory Interactions:** Please describe any previous or concurrent interactions with FDA or other regulatory agencies (e.g., European Medicines Agency, Pharmaceuticals and Medical Devices Agency) regarding this submission. Include information about the timing and nature of the interaction and any outcomes. (1-page maximum)

¹ Guidance for Industry Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients, 2005, <https://www.fda.gov/media/72260/download>.

