AIH Seal Required Supporting Documentation for Product Applications

December 1st, 2022

Manufacturer: Business entity that manufactures or processes a homeopathic product. This includes re-processing, re-packaging and re-labeling of homeopathic products.
Brand Owner: Business entity that works with homeopathic products, for the purpose of sale, who does not manufacture, re-process, re-package or re-label those products.
Brand Owner Application: Every Year
Manufacturer Application: Every Year
Product Application: Every Product Every Three Years

Note that items in red type are under consideration for a future version of the standards.

Category	Pathway #1	Pathway #2	Description
Adverse Events (Product)	X	X	Provide a description of all reported adverse events and serious adverse events for the product in the last year. Provide an analysis of how these complaints were handled, including the response to the customer.
Below Analytically Detectable Presence-BADP Testing (if appropriate)	X	X	If the ingredient (s) is/are listed on the List of Required BADP Testing Ingredients, provide documentation (Certificate of Analysis acceptable) that the substance is undetectable at the minimum potency offered. If an ingredient does not have QC Data listed in HPUS, provide a detailed description of the testing method used.
Certificate of Analysis	X	X	Provide the Certificate of Analysis (C of A) for the finished product addressing medicinal ingredient quantity & identity, manufacturing information, microbial and environmental contaminants, residual solvents and pesticides.
Certificate of Analysis	X	X	Provide the finished product specifications for the finish product.
Clinical Indication Justifications		X	Provide evidence that every homeopathic ingredient is justified for at least one clinical indication using materia medica or repertory.
Complaints	X	X	Provide any complaints, and investigation of the complaint against the product in

Category	**Pathway #1**	**Pathway #2**	**Description**
			distribution in the last two years. Please include the response to the customer.
Document Control	X	X	Provide identification testing data for the incoming material for the homeopathic ingredient in the last batch of the product.
Document Control	X	X	Provide the Finished Product Specification for the product, including analytic (microbiological) testing, for the homeopathic product.
Dosing Justification (if necessary)	X	X	If the dosing recommendations for the product are outside of the specifications found in Appendix A of the Pathway #1 and #2 Standards, provide a well-reasoned rationale.
HPUS Monograph Inclusion	X	X	Provide a screen shot of the HPUS monograph(s) demonstrating that the active homeopathic ingredient(s) found in the product is/are listed in the HPUS.
Inactive Ingredient Approval	X	X	Provide a screen shot (s) from the FDA Database of approved inactive ingredients demonstrating that each of the inactive ingredients are approved for use by the FDA.
Inimical Justifications		X	If two are more ingredients in the final product are listed on the List of Inimical Ingredients found in Appendix E of the Standards, provide a justification for inclusion.
Label and Marketing Information	X	X	Provide a copy of the product label and any additional marketing information for the product.
Letter of Attestation	X	X	Provide a letter of attestation signed by a senior officer of the company attesting to accuracy and truthfulness of the application.
Materia Medica Justifications (if appropriate)	X	X	Provide a justification of each of the clinical indications, through published homeopathic materia medica or from a homeopathic proving (see standards for specifications).
Non-Conformances	X	X	Identify and describe any noted GMP or HPCUS product specific non-conformances(s) in the last year, and the rationale for the non-conformances, where

Category	**Pathway #1**	**Pathway #2**	**Description**
			applicable. Detail the corrective action(s) taken and/or to be taken. Attach supporting documentation such as action plans with timelines for each corrective action identified.
Registration	X	X	Provide a screen shot of the NDC Filing on Daily Med.
Repertory Analysis of Indications	X	X	Provide a justification of each of the clinical indications through published homeopathic repertory (see standards for specifications).

Documentation Under Consideration for Future Version of Standards for Product Applications

Category	Pathway #1	Pathway #2	Description
Deviation	X	X	Identify and describe any noted GMP or HPUS deviation(s) and the rationale for the deviation, where applicable for the product for the last two years. Detail the corrective action(s) taken and/or to be taken. Attach supporting documentation such as action plans with timelines for each corrective action identified.