NHPCB Product Application Pathway #1 Eligibility Form

Date: May 2nd, 2023

Overview

This form was created to help determine eligibility for product Pathway #1 application for the Certified Homeopathic Seal. Pathway #1 is designed for single homeopathic ingredients currently listed in the Homeopathic Pharmacopoeia of the United States (HPUS). **Please fill out the Pathway #2 Eligibility Form for complex homeopathic products.**

On successful completion and acceptance of the eligibility form, you will be receiving a link to the application portal. The NHPCB will notify the company of which products to submit once they receive the Brand Owner Registration Application.

Please feel free to reach out to us with any questions as you complete this form (application@certifiedhomeopathic.org). Note, this form only needs to be completed and accepted once and is not needed before additional pathway #1 submissions.

Your Information

A. Name of Person Filling Out Form (Required field):
_____

B. Email (Required field):
_____

C. Phone Number (Required field)
_____

D. Name of Company (Required Field)
_____

Other Applications

Please confirm the following:

- ☐ That the Brand Owner (if different than the manufacturer) is submitting a separate registration application or is in the process of applying.
- ☐ That the Manufacturer is submitting a separate registration application or is in the process of applying.

Product Information

Please confirm that the product(s) for which you will be applying meet all the following criteria (Check Boxes):

Criterion One-Identity and Nomenclature

- ☐ There is Only a Single Ingredient
- ☐ There is Only a Single Potency Included in the Product (not a homochord) (note that a single application can be used for all potencies utilized by the Brand Owner)
- ☐ The Active Ingredient in the Product is Potentized (not a mother tincture)
- ☐ The Active Ingredient is Listed in the HPUS and If Necessary Justify Any Deviation of the Latin Name or Common Name from the HPUS Monograph
- ☐ The Route of Administration is either Oral or Topical for the Product
- ☐ The Source Material is Consistent With the HPUS Monograph and If Not Can Justify any Deviations
- ☐ All Inactive Ingredients Have Been Approved by the FDA for Usage as Inactive Ingredients
- ☐ Can Provide the Purpose of All Inactive Ingredients

Criterion Two-Legal and Regulatory

- ☐ Can Provide Information on Any Product Recalls in the Last Three Years
- ☐ Can Share Any Concerns From the FTC in the Last Three Years Related to the Product and the Response of the Company.

Criterion Three-Labeling and Marketing

- ☐ Can Provide Electronic Copy of Label and Any Marketing Materials
- ☐ Product Meets HPUS Labeling Standards

Criterion Four-Identity and Purity

- Can Provide Evidence that the Homeopathic Drug Has Been Tested for Microbial Contaminants at the Raw Material Stage as Outlined in the HPUS Used in the Most Recent Batch of the Product or If Not, Adequate Justification Can Be Provided

- Can Provide Evidence that the Homeopathic Drug Has Been Tested for Microbial Contaminants at the Finished Product Stage as Outlined in the HPUS Used in the Most Recent Batch of the Product or If Not, Adequate Justification Can Be Provided

- If a Nosode, Provide Evidence That the Material Has Been Tested for Sterility at the Raw Material Stage

- Can Provide Evidence that the Homeopathic Drug Has Been Tested for Chemical Contaminants at the Raw Material Stage as Outlined in the HPUS Used in the Most Recent Batch of the Product or If Not, Adequate Justification Can Be Provided

Criterion Five-Manufacture of Homeopathic Drug

- Can Provide the Certificate of Analysis (C of A) for the Last Batch of the Finished Product Addressing Medicinal Ingredient Quantity & Identity, Manufacturing Information, Microbial and Environmental Contaminants, Residual Solvents and Pesticides.

- Can Provide any Complaints to Both the Brand Owner and Manufacturer, and Investigation of the Complaint Against the Product in Distribution in the Last Two Years, Including the Response to the Customer

- Can provide Laboratory Assay Testing Data for the Incoming Material for the Homeopathic Drug Used in the Most Recent Batch of the Product.

- Can Provide the Finished Product Specification for the Product, Including Analytic (Microbiological) Testing, for the Homeopathic Product.

- Can Identify and Describe any noted GMP or HPCUS Product Specific Non-conformances(s) and the Rationale for the Non-conformances, Along with Corrective Actions Taken, Where Applicable

Criterion Six-ProductSafety

- The Dosing Instructions are in Accordance with Appendix A of the Pathway #1 Standards and If Not, Can Provide Sufficient Evidence to Support the Safety fo the Dosing instructions

- If the Directions for Use Include Children 0-2 years of age, For a Solid Vehicle of Administration, Provide Evidence that the Directions of Use Include Instructions to Dissolve the Solid Dosage Form in a Small Amount of Water

- If Not a Topical Drug, Provide Evidence That the Directions For Use Do Not Include the Term “or as needed” As Part of the Dosage Frequency.

- If the Product Has Clinical Indications, Can Justify the Duration of Use for the Clinical Indications

- For OTC Products, Is There a Statement To the Effect of “Consult a health care practitioner if symptoms persist or worsen”.

- You Are Able to Provide Any Adverse Event and Serious Adverse Event Information on the Product for the Last Year

- Can Provide a Listing, Age Range, Dose Modifications, Cautions, Warnings or Contraindications for all Is Targeted Sub Populations.

- If the Ingredient is Listed in Appendix C of the Pathway #1 Standards (List of Required Below Analytically Detectable Presence (BADP) Testing Ingredients), Provide Evidence that BADP Testing was Performed for the Last Batch/lot of the Product Using Methods Outlined in the HPUS (QC Data).

  The Minimum Potency for Which You are Applying is At or Above the First Permissible Attenuation (FPA) as Established by the HPUS and If Not, Can Provide Sufficient Evidence to Support the Safety of the Propose Potency

Criterion Seven-Clinical Indications

- Provide a List of Any Clinical Indications

- For Direct to Consumer (OTC) Products, Indications are Consistent with Self Limiting Conditions

- For Prescription Products, does it have clinical indications and if so, provide a listing of all clinical indications

- For All Listed Indications, You Are Able to Provide Materia Medica and Repertory Justifications That The Ingredient is Effective for the Indication

General

- Can Provide a Letter of Attestation Signed by a Senior Officer of the Company Attesting to Accuracy and Truthfulness of the Application

Fees

- Able to Pay the Pathway #1 Application Fee (https://certifiedhomeopathic.org/wp-content/uploads/2023/05/NHPCB-Fee-Sheet.pdf).