NHPCB Product Application Pathway #2 Eligibility Form

Date: June 13th, 2023

Overview

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

On successful completion and acceptance of the eligibility form, you will be receiving a link to the application portal. Please feel free to reach out to us with any questions as you complete this form (applications@certifiedhomeopathic.org). Note, this form only needs to be completed and accepted once, and is not needed before additional pathway #2 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 Manufacturer is submitting a separate registration application or is in the process of applying.

- ☐ That the Brand Owner (if different than 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

- ☐ Multiple Active Ingredients
- ☐ The Active Ingredients in the Product are Potentized (not a mother tincture)
- ☐ The Active Ingredients are 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
- ☐ A description of the source materials is consistent with the HPUS monograph
- ☐ Can Provide the Purpose of All Inactive Ingredients
- ☐ All Inactive Ingredients Have Been Approved by the FDA for Usage as Inactive Ingredients
- ☐ The Active Ingredient in the Product is Potentized According to HPUS Standards
- ☐ 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

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 Certified Homeopathic Seal 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 Drugs

- Can Provide the Certificate of Analysis (C of A) for the Last Batch of the Finished Product

- 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

- Can provide Laboratory Assay Testing Data for the Incoming Materials for the Homeopathic Drugs 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 HPUS Product Specific Non-conformances(s) and the Rationale for the Non-conformances, Where Applicable

Criterion Six- Product Safety

- The Dosing Instructions are in Accordance with Appendix A of the Pathway #2

Standards. NHPCB-Standards-Pathway_2-2023-05-02.pdf (certifiedhomeopathic.org)

- 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 Product, 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 Direct to Consumer 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, Contraindications, Cautions and Warnings for all Targeted Sub Populations.
- If Any of the Homeopathic Ingredients are Listed in Appendix C of the Pathway #2 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). NHPCB-Standards-Pathway_2-2023-05-02.pdf (certifiedhomeopathic.org)
- The Minimum Potencies of All Homeopathic Ingredients for Which You are Applying is At or Above the First Permissible Attenuation (FPA) as Established by the HPUS

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, If There Are Clinical Indications Provide a listing All of These
- For All Listed Indications, You Are Able to Provide Materia Medica and Repertory Justifications That The Ingredient is Effective for the Indication

- ☐ You Can Provide a screenshot of the NDC Filing on Daily Med.

- ☐ For All Listed Indications, You Can Provide Evidence That Every Homeopathic Drug Has Been Justified for At Least One Clinical 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 #2 Application Fee (https://certifiedhomeopathic.org/wp-content/uploads/2023/05/NHPCB-Fee-Sheet.pdf).