NHPCB Combined Brand Owner/Manufacturer Registration Application Eligibility Form

Date: May 2nd, 2023

Overview

This form was created to help determine eligibility for the Manufacturer Registration Application. Companies that are either only brand owners or only manufacturers, should fill out separate Registration Forms.

Please send this completed form to applications@certifiedhomeopathic.com. 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.com). Note that this form only needs to be completed and accepted once to determine eligibility, and is not needed to be filled out again for annual brand owner renewal.

Your Information

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

_____

B. Email (Required field):

_____

C. Phone Number (Required field)

_____

D. Name of Brand Owner/Manufacturer (Required field)

_____

Other Applications

Please confirm the following:

- That you are submitting a product application or are in the process of applying.

Manufacturing Information

Please confirm that you can provide the following:

Criterion Two-Legal and Regulatory Compliance

- A copy from the last year of the manufacturer's license to operate within their state, province or jurisdiction, if required by the state.
- The company's current FDA Establishment Number. You may provide a screenshot demonstrating that the company is current for this year from the FDA Database. (https://datadashboard.fda.gov/ora/fd/fser.htm)
- A copy (s) of all FDA inspections for the Manufacturer for the last three years. A recent letter would be acceptable or a screenshot of the recent company's standing on the FDA website. (www.datadashboard.fda.gov). Explain any OAI, letters of concern, or warning letters generated by the FDA and how the manufacturer is addressing these concerns in a timely manner with appropriate documentation.
- If the facility has not been inspected in the last three years, evidence that the company has requested an FDA inspection.
- Any concerns from the FTC that have arisen with the brand owner or manufacturer in the last three years and the response of the company. .
- Can provide a social compliance policy consistent with the Seal Standards Criterion #2. https://certifiedhomeopathic.org/nhpcb-seal-standards/

  2.5. Ethical Standards Provide evidence of social compliance policy demonstrating that both the manufacturer and brand owner meet ethical standards. Failure to comply with ethical standards will result in removal of the Seal. This policy should minimally contain the following:
  • Honesty: Open and transparent communication

• Fairness: Fair and unbiased treatment of employees
• Responsibility: Taking responsibility for problem solving
• Respect in employee relationships: Colleagues and workers should always be respectful.
• Integrity: Do the right thing even if no one is watching
• Environmental consciousness: Employ non-polluting business practices and recycling at work.
• Respect for privacy and individuality in personal, professional and health matters.
• Commitment to constructive problem solving of workplace problems.
• Conducting one's business in accordance with legal and ethical principles.
• Commitment to providing quality products for one's customers and customer satisfaction.

Criterion Four-Identity and Purity

- A description of the most recent raw material specification handling system. An SOP would be acceptable. Methods used for identity testing should be consistent with the HPUS. If you use identity testing methods not outlined by the HPUS, provide a detailed rationale.

- A description of testing for microbial contaminants at the finished product stage as outlined in the HPUS. Or if you use identity testing methods not outlined by the HPUS, provide a detailed rationale

- A description of testing for chemical contaminants at the raw material stage as outlined in the HPUS. Or If you use chemical testing methods not outlined by the HPUS, provide a detailed rationale

Criterion Five-Manufacturing of a Homeopathic Drug

- A Master Batch Record (PBR) or its equivalent (feel free to redact any proprietary information).

- A sample Finished Product Specification for a finished product.

- A description of the complaint handling system. An SOP would be acceptable.

- The current master SOP list. This should minimally include the following:

  - Adverse events and serious adverse event handling;
  - Complaint handling system;
  - Raw material specification handling system;

- Document change;
- Employee health and safety;
- Incoming materials and receiving;
- Label control;
- Laboratory systems;
- Master cleaning procedures;
- Material management;
- Non-conformance management;
- Personnel training;
- Quality systems;
- Recall, return and salvage procedures;
- Record retention procedures;
- Security procedures;
- Self-inspection and auditing;
- Supplier management;

- Information about any outside laboratories used, including names and credentials, is it accredited and are the processes validated?

- Description of whether the Quality Department's reporting structure is independent of operations? Is QA or QC responsible for the batch records? For any negative responses provide the rationale.

- Information about any third party audits such as company name, contact information, and frequency of audits.

Criterion Six-Product Safety

- A description of how the organization handles all reported adverse events and serious adverse events. An Adverse Event SOP would be acceptable.

Brand Information

Please confirm that the brand owner can provide the following:

- An excel spread sheet providing information on all homeopathic products sold. This will be used by the NHPCB to determine which products the company should submit for product application (10% of products for companies with less than 250 products or 5% of products for companies with 250 products or more). Minimally this should include:

  - Name of Product
  - Product Active Ingredients
  - Potency/Potencies

- Route of Administration
- How Long Has Product Been Sold
- BADP Ingredients
- Is the Product a Nosode or Does it Contain Nosodes
- Is the Product a Sarcode or Does it Contain Sarcodes
- GRAS
- Manufacturer
- Number of Units Sold in Last Year

- A description of how the organization handles all reported adverse events and serious adverse events. An Adverse Event SOP would be acceptable.

- Information on all Adverse Events for homeopathic products within the last year. This information will be used in the formation of the National Adverse Event Database. Minimally this should include:

- Manufacturer (if different than Brand Owner)
- Brand Name of Product
- Potency
- Route of Administration
- Date of Event
- UDI/Lot Number
- Prescription vs. OTC
- Contact Information for Individual Reporting Event
- Was Event Also Reported to FDA?
- Type of Event
    - Adverse Event
        - Excluding Lack of Efficacy
        - Including Aggravations
        - Expected vs. Non-Expected
        - Relatedness
    - Serious Adverse Event
- Description of Adverse Event
    - Attach Case Report
    - ?Code for Diagnosis or Type of AE
- Relatedness of AE to Usage of Product
    - Very Likely
    - Likely
    - Possibly
    - Unlikely
    - Unrelated
- Result of Event
    - Recovery
    - Disability

    - Congenital Anomaly/Birth Defect
    - Hospitalization
    - Death
- Response of Company to Adverse Event
- Number of Units Sold of Product In Last Year

General

- ☐ A letter of attestation that all homeopathic products are manufactured according to GMP and HPUS standards.
- ☐ A letter of attestation signed by a senior officer of the company attesting to accuracy and truthfulness of this application.
- ☐ Evidence of either a single-user or multi-user subscription to the HPUS.

Fees

- ☐ Able to pay the manufacturer application fee (https://certifiedhomeopathic.org/wp-content/uploads/2023/05/NHPCB-Fee-Sheet.pdf).