NHPCB Brand Owner Registration Application Eligibility Form

Date: May 2nd, 2023

Overview

This form was created to help determine eligibility for the Brand Owner Registration Application. Companies that are both brand owner and manufacturer for homeopathic products, should fill out the Combined Brand Owner/Manufacturer Registration Form.

Please send this completed form to applications@certifiedhomeopathic.org. 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 that if you are a manufacturer of homeopathic products, that this requires a separate application. 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 Company (Required Field)

_____

Other Applications

Please confirm the following, if the Brand Owner is separate from the Manufacturer:

- ☐ That the Manufacturer is submitting a separate application or is in the process of applying.
- ☐ That the Brand Owner is submitting a product application or is in the process of applying.
- ☐ That the Brand Owner can provide evidence of a quality agreement with their contract manufacturer ensuring compliance with GMP.

Brand Information

Please confirm that you can provide the following:

- ☐ An excel spread sheet providing information on all homeopathic products or products with homeopathic ingredients 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 Homeopathic Active Ingredient (s)
  - Potency/Potencies (Range Acceptable)
  - Route of Administration
  - OTC vs. Prescription
  - How Long Has Product Been Sold in Years?
  - Is the active ingredient (or any of the active ingredients) found on the required BADP listing in Appendix C of the Standards?
  - Is the Product a Nosode or Does it Contain Nosodes?
  - Manufacturer of Product
  - Number of Units Sold in Last Year

Criterion Two-Legal and Regulatory Compliance

- ☐ Provide the current FDA Establishment Number unless exempt under 21 CFR 207-17 (b) (private label distributors).
- ☐ A copy from the last year of the brand owner's license to operate within their state, province, or jurisdiction, if required by the state.

- A screenshot demonstrating that the company is current for this year from the FDA Database (https://datadashboard.fda.gov/ora/fd/fser.htm), unless exempt under 21 CFR 207-17 (b) (private label distributors).

- Unless exempt under 21 CFR 207-17 (b) (private label distributors), evidence that the facility is in good standing (NAI or VAI) with FDA inspections for a period of three years. A recent letter would be acceptable or a screen shot of the recent company's standing on the FDA website. (www.datadashboard.fda.gov). If the standing with the FDA is OAI, share any FDA concerns, including warning letters generated by the FDA and how the manufacturer is addressing these concerns in a timely manner with appropriate documentation.

- 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. NHPCB Seal Standards - NHPCB (certifiedhomeopathic.org)

  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 Five-Manufacture of Homeopathic Drug

- Can provide the current master SOP list.
  It should minimally include the following:

  - Adverse events and serious adverse event handling;
  - Complaint handling system;
  - Document change;
  - Employee health and safety;
  - Incoming materials and receiving;
  - Label control;
  - 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;

Criterion Six-Product Safety

- A pdf copy 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 the application is accurate and truthful.

- [ ] A letter of attestation that the facility follows both GMP and HPUS standards (if re-packaging, re-labeling or reprocessing).

Fees

- [ ] Able to pay the annual brand owner application fee (https://certifiedhomeopathic.org/wp-content/uploads/2023/05/NHPCB-Fee-Sheet.pdf).