

AIH Seal Required Supporting Documentation for Brand Owner Application

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	Description
Document Control	<p>Provide the current master SOP list. This list should minimally include the following:</p> <ul style="list-style-type: none">• 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;• 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
FDA Inspections	<p>Provide 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 facility has not been inspected in the last three years, provide evidence that the company has requested an FDA inspection.</p>

Category	Description
	If the standing with the FDA is OAI, share any concerns, including warning letters generated by the FDA and how the manufacturer is addressing these concerns in a timely manner with appropriate documentation.
FTC Concerns	Share 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.
Letter of Attestation	Provide a letter of attestation signed by a senior officer of the company attesting to accuracy and truthfulness of the application.
Letter of Attestation (if re-packaging, re-processing or re-labelling)	Letter of Attestation from Brand Owner that facility conforms with both GMP and HPUS manufacturing guidelines for homeopathic medicines. "I attest that the building(s), practice(s), and procedure(s) used for conducting homeopathic manufacturing activities in our facility comply with the good manufacturing practices and HPUS manufacturing guidelines."
Registration	Provide evidence of the brand owner (distributor) registration as a drug establishment for a period of one year.
Social Compliance Policies	Provide the social compliance policy demonstrating ethics for both the brand owner and manufacturer in accordance with the standards.
State Licensure	Provide evidence that the facility is licensed within its state or jurisdiction in the last year.

Documentation Under Consideration for Future Version of Standards for Brand Owner Application

<u>Category</u>	<u>Description</u>
Environmental Systems	Provide proof of warehouse storage conditions including protection from direct sunlight, temperature and humidity records for the last three months.
Facilities and Equipment	Provide pest control contract and data demonstrating a pest free environment for the last three months.
Facilities and Equipment	Provide a floor plan to demonstrate that there are adequate facilities for operations.
Facilities and Equipment	<p>Answer each of the following questions:</p> <ul style="list-style-type: none"> • Is access to processing areas restricted? • Are measures present to minimize product tampering/sabotage? • Are employee background checks run on those who have access to sensitive areas, before hiring? • Are doors leading to the outside kept locked? • Are outbound trailers inspected before loading and sealing? Are these inspections documented? • Are outside premises well-lit at night? • Is there a guard service/security system present or is there any barrier device around the facility? <p>If negative response, please explain.</p>