NHPCB
Applications Manual

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Introduction

About this Manual

The NHPCB Application Manual, is designed to be used by members of the Application Review Committee as they review applications. In addition, it is available to others to help them understand the processes and flow of the application process.

This manual was initially written by the National Homeopathic Product Certification Board (NHPCB) Applications Committee in 2023. It has gone through subsequent revisions since its inception. The current version date for the manual and date of publication is listed on the title page.

If you have suggested changes to this manual, please submit the suggested change to the NHPCB Applications Committee and the suggestion will be considered with the next updated version of the manual.

The manual is designed as a supplement and resource for reviewers and accompanies the initial and periodic training for ARC members, as well as the NHPCB Seal Applications Review Committee Manual. See Appendix D of this manual for definition of terms used.

Latest Versions

Reviewers are reminded to use only the latest approved version of the NHPCB standards. Note the version date to determine the most recent approved version.

In addition, please only use the most recent version of this manual. The manual goes through periodic revisions and version dates are updated accordingly. It is the responsibility of the Applications Committee to ensure that the date and version of this manual are updated and the most recent version will be posted to the website.

Application Process Overview

This document describes the NHPCB Seal application processes and flow. This includes the following applications:

- Pathway #1 Product Application
- Pathway #2 Product Application
- Brand Owner Application
- Manufacturer Application

A completed application with the required fee is submitted to the NHPCB Seal Application Review Committee (ARC). The application is accepted if it is determined complete by the NHPCB Executive Director/NHPCB Executive Director Assistant. The ARC reviews and determines if the application meets the NHPCB standards. If the product application is approved, the NHPCB Executive Director posts status of

submission on the website in the NHPCB Seal Database. If the brand owner or manufacturer application is approved, the NHPCB Executive Director posts status of submission on the website in the Company Registration Database. The Seal is granted for a period of three years and company registration for a period of one year. We estimate a 3-month process for completion of each of the Initial Applications.

Application Process Principles

The NHPCB has agreed to abide by the following conformity assessment principles (https://www.standardsportal.org/usa_en/conformity_assessment/conformity_assessment.aspx):

- Conformity assessment requirements and procedures are open and transparent to all applicants and provide them with equal treatment.
- All parties desiring to have their products, processes, services or personnel assessed for compliance with relevant requirements are allowed to submit an application and have their applications accepted and processed in a reasonable time.
- Conformity assessments are competently conducted and based on appropriate standards requirements and procedures. Conformity assessment requirements and procedures are based on national guides and standards to the extent feasible.
- The NHPCB demonstrates its competency to conduct conformity assessment activities using accepted standards and requirements for conformity assessment, either through formal recognition or accreditation activities or by maintaining adequate records and documentation that are available for public review.
- The characteristics of homeopathic products and the associated risks of homeopathic products drive the conformity assessment requirements and procedures.
- Information on all conformity assessment requirements and procedures for obtaining conformity assessments are publicly available. Information on costs and processing times are available at any time to all applicants.
- Conformity assessment procedures are completed promptly and efficiently. Accurate and timely information on the status of ongoing conformity assessments are provided to applicants on request.
- Information requirements are limited to what is necessary to assess conformity and determine fees. Protective measures are taken so that confidential or proprietary information is not communicated to any person or organization not having legal right to such information.
- All applicants who apply for conformity assessment are treated equally with respect to the imposition of any fees charged. When fees are imposed, they are comparable for all applicants, taking into account communication, transportation and other costs arising from differences between location of facilities of the applicants and the conformity assessment bodies. Fees are not imposed in a manner that restricts marketplace competition or creates unnecessary obstacles to trade.

- The location, timing and sample selection process for the conformity assessment work are chosen in a manner that enables competent conformity assessment and minimizes inconvenience and costs to applicants.
- When requirements and procedures change, stakeholders are notified expeditiously.
- Transition periods allow applicants adequate time to make necessary changes. However, the transition period takes into account any significant risks to health, safety or the environment associated with noncompliance of the product to the new requirements.
- The NHPCB has effective procedures for reviewing complaints, and such procedures are open to all stakeholders. Organizations take appropriate corrective action whenever they justify a complaint
- As appropriate, the NHPCB takes reasonable surveillance procedures to ensure continued product conformity and protection of their mark.

Review Process-Initial Product Applications

Note: These processes apply to both Pathway #1 and Pathway #2 Applications.

Initial Product Application Requirements

An applicant who wishes to achieve the NHPCB Seal for their product, must:

- Complete the NHPCB Product Application Eligibility Form officially indicating the applicant's interest in pursuing the NHPCB Seal process;
- Successfully complete the appropriate pathway NHPCB Product Application;
- Ensure that the NHPCB Manufacturer Application is successfully completed;
- Successfully complete the NHPCB Brand Owner Application, if the Brand Owner is different than the manufacturer for the product;
- Submit payment of the Application fee.

Who May Apply?

Applicants may be either of the following:

- Brand Owners of homeopathic products
- Manufacturers of homeopathic products, if also the Brand Owner;

Eligibility

The ARC will accept Initial Applications only from brand owners, manufacturers or retailers that fall within its scope. Based on information provided in the Initial Application, the ARC may decide to not accept the application if, for any reason, they determine that the nature or scope of the application does not comply with its standards. If the ARC decides to not accept the Initial Application, a written explanation outlining the reason for not accepting the Application will be provided to the applicant. An applicant who submits an application for the NHPCB Seal must have been manufacturing/selling the homeopathic product for a period of at least one year.

Expected Timeline

The expected timeline for an ARC decision on the initial application, once the initial application is complete, is three months. This may vary somewhat if additional information is requested.

Letter of Attestation

The applicant must complete the Initial Application and have an authorized representative from the institution's governance structure sign the attestation indicating the accuracy and completeness of its submission and its intent to abide by the NHPCB Seal standards, and policies and procedures should the NHPCB Seal be granted.

Application Support

The applicant may reach out to the NHPCB Executive Director (or Executive Director Assistant) at any time with questions about the application process.

Application Withdrawal

An applicant may withdraw its initial application at any time before a final decision is made by the ARC. In the event that an applicant withdraws its initial application, the applicant will be refunded as follows:

- Full Refund if the application is not completed;
- Half the application fee, once the application is completed.

The applicant must wait at least six months before reapplying.

Product Application Decisions

The application decision is based on verification of the product(s) meeting the standards through the application process and supporting documentation. The decision is made based on the preponderance of the evidence.

Key questions for the committee to consider are the following in their decision:

- Is the product a genuine homeopathic product?
- Is it safe to use?
- Was the product prepared according to the standards of the homeopathic industry and CGMP?
- If claims are made for the product, can they be justified according to traditional homeopathic practice (eg. Repertory and Materia Medica)?

The ARC makes one of the following determinations based on the application:

- Granting of Initial Seal;
- Request for Further Information;
- Denial of Seal.

The decision should be made by consensus whenever possible. However, a majority opinion is acceptable. Final votes should be carefully documented in the minutes along with the rationale for any dissenting opinions.

The ARC takes an administrative or procedural action when it requires further information in order to make a decision regarding granting the NHPCB Seal. The Application Review Committee may postpone a decision and request a supplemental information report when it has determined that there is insufficient information to substantiate that the applicant is in compliance with one or more of its standards.

The ARC may act to extend the eligibility determination phase for a period not to exceed six months from the time the committee first reviews the complete eligibility packet if they determine that the delay is necessary to provide the institution/program sufficient time to submit a supplemental information report pursuant to their request.

The ARC may act to terminate the eligibility application if, after the eligibility determination phase has been extended for up to six months, it is still not possible to conduct an appropriate review of the application and arrive at a decision due to the applicant failing to provide sufficient information upon which to base a decision. If within six months following the termination of the application the applicant's circumstances change so as to enable the committee to conduct a complete review, it may at its discretion allow resubmission or revision of any reports on which the review would be based, without paying an additional fee.

The ARC may reject the Initial Application if it determines that the applicant is substantially out of compliance with the NHPCB standards. Whenever the ARC rejects an Initial Application, it states the specific reasons for rejection in the action letter from the Executive Director, it sends to the applicant. In the event that an Initial Application is rejected, the applicant must wait at least six months before submitting a new Initial Application.

If a decision is made to reject an Initial Application, the applicant may formally appeal the decision in accordance with the NHPCB Appeals Policy (see NHPCB Seal Appeals Process below). In the event of a Final rejection decision, the applicant may submit a new Initial Application with the review fee after a six-month period.

It is also the responsibility of the Executive Director/Executive Director Assistant to ensure that the NHPCB fees have been paid and received by the NHPCB, before granting the Seal. This is done as part of the completeness review process.

Vote to Grant the Seal

A vote to grant the Seal should be documented in the minutes of the ARC meeting. The Executive Director/Executive Director Assistant then sends a letter to the applicant informing them of the decision within 7 business days, along with the Seal Marketing Packet (see Seal Acceptance Letter and Seal Marketing Packet). It is also the responsibility of the Executive Director/Executive Director Assistant to upload the accepted product to the Seal Database on the NHPCB website. Lastly, it is the responsibility of the Executive Director/Executive Director Assistant to add the accepted product to the review/renewal cycle (renewal application for the Seal is every three years).

Asking for Additional Information

During the initial review process, the Executive Director/Executive Director Assistant may ask the applicant for additional information if the initial application is incomplete. Generally a time frame of fifteen business days is requested for this information.

Once the formal application review process begins, the Application Review Committee may also request additional information if they determine that this information is needed for them to be able to make a final determination. Generally a time frame of fifteen business days is requested for this information. This request is sent to the Applicant by the Executive Director/Executive Director Assistant.

Denial of the Seal

A vote to deny the Seal should be documented in the minutes of the ARC meeting. The Executive Director/Executive Director Assistant then sends a letter to the applicant informing them of the decision within 7 business days, using the Seal Denial Template Letter. The letter should carefully explain the rationale of the denial. In this letter the applicant is informed of the right to appeal (see the Applications Manual for further details on the appeal process).

Granting of Seal

The seal for a product is only granted when the following are successfully completed:

- Product Application
- Manufacturer Registration
- Brand Owner Registration (if Brand Owner is Different than Manufacturer)
- Application Fees Submitted.

Request From Applicant for Withdrawal of the Seal

An applicant may request the removal of the NHPCB Seal at any time. The NHPCB will comply with such a request and delete the Seal from its approved database. If the NHPCB Seal is withdrawn or the applicant determines to withdraw the NHPCB Seal, the applicant must remove the Seal from its products and remove any publicity/marketing related to the Seal, within 30 days of this action.

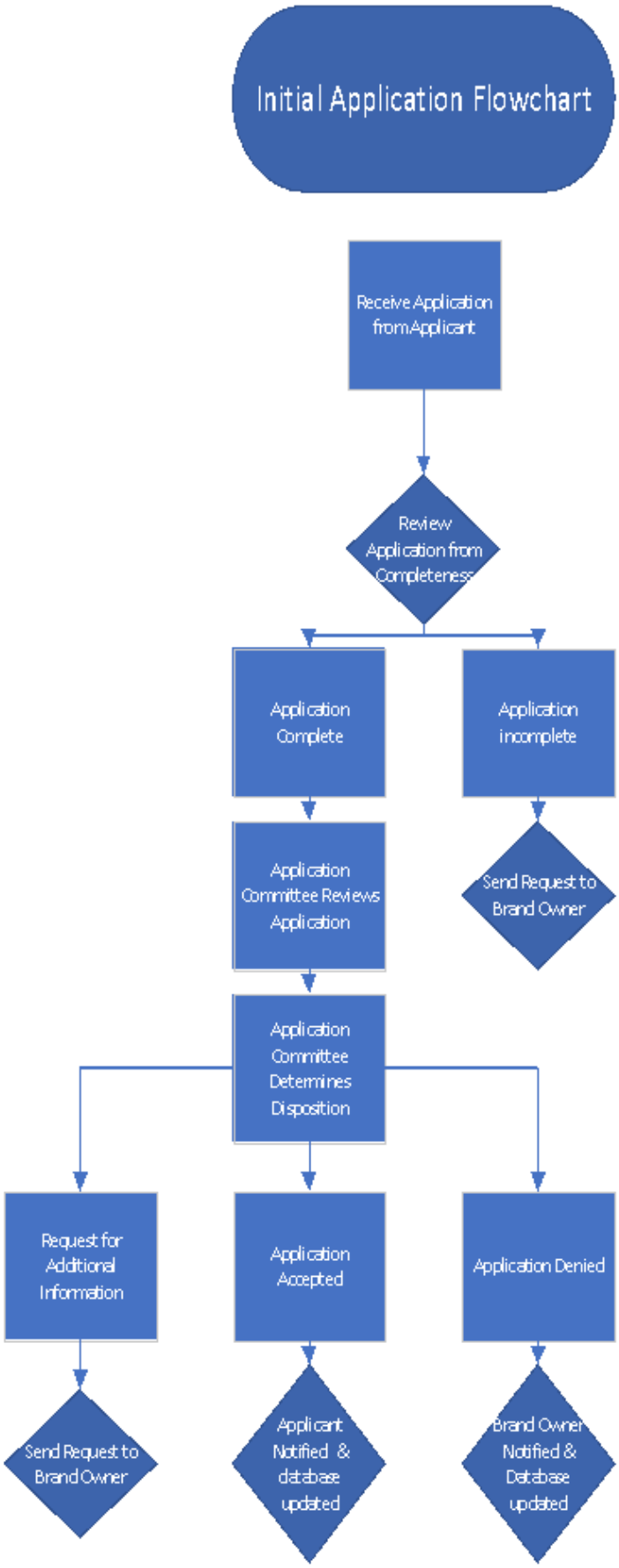
Note, however, that should the manufacturer decide to appeal the NHPCB/s withdrawal of the Seal, the NHPCB Seal automatically remains in effect until the expiration of the period within which the manufacturer may file a letter of appeal, or until the completion of the appeals process, whichever shall later occur. The NHPCB shall publicize the withdrawal of the label in its NHPCB Seal database.

NHPCB Withdrawal of the Seal

Grounds for withdrawing the NHPCB Seal after it has been granted include the following:

- Deficiencies identified in the renewal process that are required to be corrected within a specified period are not corrected within that period;
- The applicant has engaged in illegal conduct or is misrepresenting itself or presenting false information to the public;
- The applicant fails to provide fully and accurately all pertinent information and materials requested by the Application Committee;
- The applicant fails to submit a renewal application or pay the renewal fee;
- The applicant fails to notify the NHPCB of substantive change affecting the product;
- The applicant's organization ceases to exist or is no longer functional;
- The applicant's organization has a pending or final action brought by a Federal/State/Provincial agency to suspend, revoke, withdraw, or terminate the institution's legal authority to operate or manufacture the NHPCB Seal product;

Note, however, that should the brand owner/manufacturer decide to appeal the NHPCB/s withdrawal of the Seal, the NHPCB Seal automatically remains in effect until the expiration of the period within which the manufacturer may file a letter of appeal, or until the completion of the appeals process, whichever shall later occur. The NHPCB shall publicize the withdrawal of the Seal in its NHPCB Seal database.


Initial Application Flowchart
Receive Application from Applicant
Review Application from Completeness
Application Complete
Application incomplete
Application Committee Reviews Application
Send Request to Brand Owner
Application Committee Determines Disposition
Request for Additional Information
Application Accepted
Application Denied
Send Request to Brand Owner
Applicant Notified & database updated
Brand Owner Notified & Database updated

Review Process-Initial Brand Owner Application

Note: The Brand Owner application is only required if the Brand Owner and the Manufacturer of the homeopathic product are different.

Brand Owner Application Requirements

An applicant who wishes to register as an approved NHPCB company must complete the following:

- NHPCB Brand Owner Application Eligibility Form;
- NHPCB Brand Owner Application;
- Submit payment of the Brand Owner Application fee.

Who May Apply?

Applicants may be either of the following:

- Brand Owners of homeopathic products
- Manufacturers of homeopathic products, if also the Brand Owner;

Eligibility

The ARC will accept Initial Applications only from brand owners, manufacturers or retailers that fall within its scope. Based on information provided in the Initial Application, the ARC may decide to not accept the application if, for any reason, they determine that the nature or scope of the application does not comply with its standards. If the ARC decides to not accept the Initial Application, a written explanation outlining the reason for not accepting the Application will be provided to the applicant. An applicant who submits an application for Brand Owner registration must have been selling the homeopathic product for a period of at least one year.

Expected Timeline

The expected timeline for an ARC decision on the initial application, once the initial application is complete, is three months. This may vary somewhat if additional information is requested.

Letter of Attestation

The applicant must complete the Initial Application and have an authorized representative from the institution's governance structure sign the attestation indicating the accuracy and completeness of its submission.

Application Support

The applicant may reach out to the NHPCB Executive Director (or Executive Director Assistant) at any time with questions about the application process.

Application Withdrawal

An applicant may withdraw its Initial Application at any time before a final decision is made by the ARC. In the event that an applicant withdraws its Initial Application, the applicant will be refunded as follows:

- Full Refund if the application is not completed;
- Half the application fee, once the application is completed.

The applicant must wait at least six months before reapplying.

Application Decisions

The application decision is based on verification of the company's meeting the NHPCB Standards through the application process and supporting documentation. The decision is made based on the preponderance of the evidence.

The ARC makes one of the following determinations based on the application:

- Granting of Registration;
- Request for Further Information;
- Denial of Registration.

The ARC takes an administrative or procedural action when it requires further information in order to make a decision regarding granting registration. The Application Review Committee may postpone a decision and request a supplemental information report when it has determined that there is insufficient information to substantiate that the applicant is in compliance with one or more of its standards.

The ARC may act to extend the eligibility determination phase for a period not to exceed six months from the time the committee first reviews the complete eligibility packet if they determine that the delay is necessary to provide the institution/program sufficient time to submit a supplemental information report pursuant to their request.

The ARC may act to terminate the eligibility application if, after the eligibility determination phase has been extended for up to six months, it is still not possible to conduct an appropriate review of the application and arrive at a decision due to the applicant failing to provide sufficient information upon which to base a decision. If within six months following the termination of the application the applicant's circumstances change so as to enable the committee to conduct a complete review, it may at its discretion allow resubmission or revision of any reports on which the review would be based, without paying an additional fee.

The ARC may reject the Initial Application if it determines that the applicant is substantially out of compliance with the NHPCB standards. Whenever the ARC rejects an Initial Application, it states the specific reasons for rejection in the action letter from the Executive Director, it sends to the applicant. In the event that an Initial Application is rejected, the applicant must wait at least six months before submitting a new Initial Application.

If a decision is made to reject an Initial Application, the applicant may formally appeal the decision in accordance with the NHPCB Appeals Policy. In the event of a Final rejection decision, the applicant may submit a new Initial Application with the review fee after a six-month period.

Substantive Change

Applicants that have been granted NHPCB registration are required to notify the NHPCB for certain institutional and programmatic changes that the NHPCB categorizes as "substantive changes." For further information, refer to the Substantive Change Policy and the Substantive Change section of this manual.

Request From Applicant for Withdrawal of Registration

An applicant may request the removal of the NHPCB registration at any time. The NHPCB will comply with such a request and delete the registration from its approved database. If the NHPCB registration is withdrawn or the applicant determines to withdraw the registration, the applicant must remove the Seal from its products and remove any publicity/marketing related to the Seal, within 30 days of this action.

Note, however, that should the applicant decide to appeal the NHPCB's withdrawal of the Seal, the NHPCB Seal automatically remains in effect until the expiration of the period within which the manufacturer may file a letter of appeal, or until the completion of the appeals process, whichever shall later occur. The NHPCB shall publicize the withdrawal of the label in its NHPCB database.

NHPCB Withdrawal of Registration

Grounds for withdrawing the NHPCB registration after it has been granted include the following:

- Deficiencies identified in the renewal process that are required to be corrected within a specified period are not corrected within that period;
- The applicant has engaged in illegal conduct or is misrepresenting itself or presenting false information to the public;
- The applicant fails to provide fully and accurately all pertinent information and materials requested by the Application Committee;
- The applicant fails to submit a renewal application or pay the renewal fee;
- The applicant fails to notify the NHPCB of substantive change affecting the product;

- The applicant’s organization ceases to exist or is no longer functional;
- The applicant’s organization has a pending or final action brought by a Federal/State/Provincial agency to suspend, revoke, withdraw, or terminate the institution's legal authority to operate or manufacture the NHPCB Seal product.

Note, however, that should the brand owner/manufacturer decide to appeal the NHPCB/s withdrawal of the registration, the NHPCB registration automatically remains in effect until the expiration of the period within which the manufacturer may file a letter of appeal, or until the completion of the appeals process, whichever shall later occur. The NHPCB shall publicize the withdrawal of the registration in its NHPCB registration database.

Review Process-Initial Manufacturer Application

Manufacturer Application Requirements for Registration

An applicant who wishes to register as an approved NHPCB company must complete the following:

- NHPCB Manufacturer Application Eligibility Form;
- NHPCB Manufacturer Application;
- Submit payment of the Manufactuer Application fee.

Who May Apply?

Applicants may be either of the following:

- Brand Owners and Manufacturer of homeopathic products;
- Manufacturers of homeopathic products.

Eligibility

The ARC will accept Initial Applications only from brand owners and manufacturers that fall within its scope. Based on information provided in the Initial Application, the ARC may decide to not accept the application if, for any reason, they determine that the nature or scope of the application does not comply with its standards. If the ARC decides to not accept the Initial Application, a written explanation outlining the reason for not accepting the Application will be provided to the applicant. An applicant who submits an application for Manufacturer registration must have been manufacturing homeopathic products for a period of at least three years.

Expected Timeline

The expected timeline for an ARC decision on the initial application, once the initial application is complete, is three months. This may vary somewhat if additional information is requested.

Letter of Attestation

The applicant must complete the Initial Application and have an authorized representative from the institution's governance structure sign the attestation indicating the accuracy and completeness of its submission.

Application Support

The applicant may reach out to the NHPCB Executive Director (or Executive Director Assistant) at any time with questions about the application process.

Application Withdrawal

An applicant may withdraw its Initial Application at any time before a final decision is made by the ARC. In the event that an applicant withdraws its Initial application, the applicant will be refunded as follows:

- Full Refund if the application is not completed;
- Half the application fee, once the application is completed.

The applicant must wait at least six months before reapplying.

Application Decisions

The application decision is based on verification of the company's meeting the standards through the application process and supporting documentation. The decision is made based on the preponderance of the evidence.

The ARC makes one of the following determinations based on the application:

- Granting of Registration;
- Request for Further Information;
- Denial of Registration.

The ARC takes an administrative or procedural action when it requires further information in order to make a decision regarding granting registration. The Application Review Committee may postpone a decision and request a supplemental information report when it has determined that there is insufficient information to substantiate that the applicant is in compliance with one or more of its standards.

The ARC may act to extend the eligibility determination phase for a period not to exceed six months from the time the committee first reviews the complete eligibility packet if they determine that the delay is necessary to provide the institution/program sufficient time to submit a supplemental information report pursuant to their request.

The ARC may act to terminate the eligibility application if, after the eligibility determination phase has been extended for up to six months, it is still not possible to conduct an appropriate review of the application and arrive at a decision due to the applicant failing to provide sufficient information upon which to base a decision. If within six months following the termination of the application the applicant's circumstances change so as to enable the committee to conduct a complete review, it may at its discretion allow resubmission or revision of any reports on which the review would be based, without paying an additional fee.

The ARC may reject the Initial Application if it determines that the applicant is substantially out of compliance with the NHPCB standards. Whenever the ARC rejects

an Initial Application, it states the specific reasons for rejection in the action letter from the Executive Director, it sends to the applicant. In the event that an Initial Application is rejected, the applicant must wait at least six months before submitting a new Initial Application.

If a decision is made to reject an Initial Application, the applicant may formally appeal the decision in accordance with the NHPCB Appeals Policy. In the event of a Final rejection decision, the applicant may submit a new Initial Application with the review fee after a six-month period.

Request From Applicant for Withdrawal of Registration

An applicant may request the removal of the NHPCB registration at any time. The NHPCB will comply with such a request and delete the registration from its approved database. If the NHPCB registration is withdrawn or the applicant determines to withdraw the registration, the applicant must remove the Seal from its products and remove any publicity/marketing related to the Seal, within 30 days of this action.

Note, however, that should the applicant decide to appeal the NHPCB's withdrawal of the Seal, the NHPCB Seal automatically remains in effect until the expiration of the period within which the manufacturer may file a letter of appeal, or until the completion of the appeals process, whichever shall later occur. The NHPCB shall publicize the withdrawal of the label in it's NHPCB database.

NHPCB Withdrawal of Registration

Grounds for withdrawing the NHPCB registration after it has been granted include the following:

- Deficiencies identified in the renewal process that are required to be corrected within a specified period are not corrected within that period;
- The applicant has engaged in illegal conduct or is misrepresenting itself or presenting false information to the public;
- The applicant fails to provide fully and accurately all pertinent information and materials requested by the Application Committee;
- The applicant fails to submit a renewal application or pay the renewal fee;
- The applicant fails to notify the NHPCB of substantive change affecting the product;
- The applicant's organization ceases to exist or is no longer functional;
- The applicant's organization has a pending or final action brought by a Federal/State/Provincial agency to suspend, revoke, withdraw, or terminate the institution's legal authority to operate or manufacture the NHPCB Seal product.

Note, however, that should the brand owner/manufacturer decide to appeal the NHPCB/s withdrawal of the registration, the NHPCB registration automatically remains in effect until the expiration of the period within which the manufacturer may file a letter of appeal, or until the completion of the appeals process, whichever shall later occur.

The NHPCB shall publicize the withdrawal of the registration in its NHPCB registration database.

Review Process-Product Application Renewal

Note: These processes apply to both Pathway #1 and Pathway #2 Renewal Applications.

Product Renewal Application Requirements

An applicant who wishes to renew the NHPCB Seal for their product, must:

- Successfully complete the appropriate pathway NHPCB Product Renewal Application;
- Ensure that the annual NHPCB Manufacturer Renewal Application is successfully completed;
- Successfully complete the annual NHPCB Brand Owner Renewal Application, if the Brand Owner is different than the manufacturer for the product;
- Submit payment of the Product Renewal Application fee.

Who May Apply?

Applicants may be either of the following:

- Brand Owners of homeopathic products
- Manufacturers of homeopathic products, if also the Brand Owner;
- Retailers of homeopathic products;

Eligibility

The ARC will accept renewal applications only from brand owners, manufacturers or retailers that have previously been granted the seal for their product. The renewal period is every three years. Three months prior to the renewal date, the company will be notified of the upcoming renewal for their specific product.

Expected Timeline

The expected timeline for an ARC decision on the renewal application, once the renewal application is complete, is six weeks. This may vary somewhat if additional information is requested.

Letter of Attestation

The applicant must complete the Initial Application and have an authorized representative from the institution's governance structure sign the attestation indicating the accuracy and completeness of its submission and its intent to abide by the NHPCB Seal standards, and policies and procedures should the NHPCB Seal be granted.

Application Support

The applicant may reach out to the NHPCB Executive Director (or Executive Director Assistant) at any time with questions about the application process.

Application Withdrawal

An applicant may withdraw its Renewal Application at any time before a final decision is made by the ARC. In the event that an applicant withdraws its renewal application, the applicant will be refunded as follows:

- Full Refund if the application is not completed;
- Half the application fee, once the application is completed.

The applicant must wait at least six months before reapplying.

The NHPCB will comply with such a request and delete the Seal from its approved database. If the NHPCB Seal is withdrawn or the applicant determines to withdraw the NHPCB Seal, the applicant must remove the Seal from its products and remove any publicity/marketing related to the Seal, within 30 days of this action.

Application Decisions

The application decision is based on verification of the product continuing to meet the standards through the renewal process and supporting documentation. The decision is made based on the preponderance of the evidence.

The ARC makes one of the following determinations based on the application:

- Granting of Seal Renewal;
- Request for Further Information;
- Denial of Renewal.

The ARC takes an administrative or procedural action when it requires further information in order to make a decision regarding granting Seal renewal. The Application Review Committee may postpone a decision and request a supplemental information report when it has determined that there is insufficient information to substantiate that the applicant is in compliance with one or more of its standards.

The ARC may reject the Initial Application if it determines that the applicant is substantially out of compliance with the NHPCB standards. Whenever the ARC rejects an Initial Application, it states the specific reasons for rejection in the action letter from the Executive Director, it sends to the applicant. In the event that an Initial Application is rejected, the applicant may resubmit a new application when they are ready with an additional fee.

If a decision is made to reject an Initial Application, the applicant may formally appeal the decision in accordance with the NHPCB Appeals Policy. In the event of a Final

rejection decision, the applicant may submit a new Initial Application with the review fee after a six-month period.

NHPCB Withdrawal of the Seal

Grounds for withdrawing the NHPCB Seal after it has been granted include the following:

- Deficiencies identified in the renewal process that are required to be corrected within a specified period are not corrected within that period;
- The applicant has engaged in illegal conduct or is misrepresenting itself or presenting false information to the public;
- The applicant fails to provide fully and accurately all pertinent information and materials requested by the Application Committee;
- The applicant fails to submit a renewal application or pay the renewal fee;
- The applicant fails to notify the NHPCB of substantive change affecting the product;
- The applicant's organization ceases to exist or is no longer functional;
- The applicant's organization has a pending or final action brought by a Federal/State/Provincial agency to suspend, revoke, withdraw, or terminate the institution's legal authority to operate or manufacture the NHPCB Seal product.

Note, however, that should the brand owner/manufacturer decide to appeal the NHPCB/s withdrawal of the Seal, the NHPCB Seal automatically remains in effect until the expiration of the period within which the manufacturer may file a letter of appeal, or until the completion of the appeals process, whichever shall later occur. The NHPCB shall publicize the withdrawal of the label in its NHPCB Seal database.

Review Process-Brand Owner Registration Renewal

Product Renewal Application Requirements

An applicant who wishes to renew their NHPCB corporate registration, must:

- Successfully complete the appropriate pathway NHPCB Brand Owner Renewal Application;
- Ensure that the annual NHPCB Manufacturer Renewal Application is successfully completed;
- Submit payment of the Brand Owner Renewal Application fee.

Who May Apply?

Applicants may be either of the following:

- Brand Owners of homeopathic products
- Manufacturers of homeopathic products, if also the Brand Owner;

Eligibility

The ARC will accept renewal applications only from brand owners, manufacturers or retailers that have previously been granted Brand Owner registration. The renewal period is every year. Three months prior to the renewal date, the company will be notified of the upcoming renewal for their registration.

Expected Timeline

The expected timeline for an ARC decision on the renewal application, once the renewal application is complete, is six weeks. This may vary somewhat if additional information is requested.

Letter of Attestation

The applicant must complete the Initial Application and have an authorized representative from the institution's governance structure sign the attestation indicating the accuracy and completeness of its submission and its intent to abide by the NHPCB Seal standards, and policies and procedures should the NHPCB Seal be granted.

Application Support

The applicant may reach out to the NHPCB Executive Director (or Executive Director Assistant) at any time with questions about the application process.

Application Withdrawal

An applicant may withdraw its Renewal Application at any time before a final decision is made by the ARC. In the event that an applicant withdraws its renewal application, the applicant will be refunded as follows:

- Full Refund if the application is not completed;
- Half the application fee, once the application is completed.

The applicant must wait at least six months before reapplying.

Application Decisions

The application decision is based on verification of the company continuing to meet the standards through the renewal process and supporting documentation. The decision is made based on the preponderance of the evidence.

The ARC makes one of the following determinations based on the application:

- Granting of continued registration;
- Request for Further Information;
- Denial of registration.

The ARC takes an administrative or procedural action when it requires further information in order to make a decision regarding granting registration renewal. The Application Review Committee may postpone a decision and request a supplemental information report when it has determined that there is insufficient information to substantiate that the applicant is in compliance with one or more of its standards.

The ARC may reject the Renewal Application if it determines that the applicant is substantially out of compliance with the NHPCB standards. Whenever the ARC rejects a Renewal Application, it states the specific reasons for rejection in the action letter from the Executive Director, it sends to the applicant. In the event that a Renewal Application is rejected, the applicant must wait at least six months before submitting a new Initial Application.

If a decision is made to reject a Renewal Application, the applicant may formally appeal the decision in accordance with the NHPCB Appeals Policy. In the event of a Final rejection decision, the applicant may submit a new Initial Application with the initial application fee after a six-month period.

Request From Applicant for Withdrawal of Registration

An applicant may request the removal of the NHPCB registration at any time. The NHPCB will comply with such a request and delete the registration and the Seal on all applicant products from its approved database. If the NHPCB registration is withdrawn or the applicant determines to withdraw the NHPCB registration, the applicant must

remove the Seal from its products and remove any publicity/marketing related to the Seal, within 30 days of this action.

NHPCB Withdrawal of the Registration

Grounds for withdrawing the NHPCB Registration after it has been granted include the following:

- Deficiencies identified in the renewal process that are required to be corrected within a specified period are not corrected within that period;
- The applicant has engaged in illegal conduct or is misrepresenting itself or presenting false information to the public;
- The applicant fails to provide fully and accurately all pertinent information and materials requested by the Application Committee;
- The applicant fails to submit a renewal application or pay the renewal fee;
- The applicant fails to notify the NHPCB of substantive change affecting the product;
- The applicant's organization ceases to exist or is no longer functional;
- The applicant's organization has a pending or final action brought by a Federal/State/Provincial agency to suspend, revoke, withdraw, or terminate the institution's legal authority to operate or manufacture the NHPCB Seal product.

Note, however, that should the brand owner/manufacturer decide to appeal the NHPCB/s withdrawal of the Seal, the NHPCB Seal automatically remains in effect until the expiration of the period within which the manufacturer may file a letter of appeal, or until the completion of the appeals process, whichever shall later occur. The NHPCB shall publicize the withdrawal of the label in its NHPCB Seal database.

Review Process-Manufacturer Registration Renewal

Manufacturer Renewal Application Requirements

An applicant who wishes to renew their NHPCB corporate registration, must:

- Successfully complete the appropriate NHPCB Manufacturer Renewal Application;
- Submit payment of the Manufacturer Renewal Application fee.

Who May Apply?

Applicants may be either of the following:

- Manufacturers of homeopathic products

Eligibility

The ARC will accept renewal applications only from manufacturers that have previously been granted Manufacturer registration. The renewal period is every year. Three months prior to the renewal date, the company will be notified of the upcoming renewal for their registration.

Expected Timeline

The expected timeline for an ARC decision on the renewal application, once the renewal application is complete, is six weeks. This may vary somewhat if additional information is requested.

Letter of Attestation

The applicant must complete the Initial Application and have an authorized representative from the institution's governance structure sign the attestation indicating the accuracy and completeness of its submission and its intent to abide by the NHPCB Seal standards, and policies and procedures should the NHPCB Seal be granted.

Application Support

The applicant may reach out to the NHPCB Executive Director (or Executive Director Assistant) at any time with questions about the application process.

Application Withdrawal

An applicant may withdraw its Renewal Application at any time before a final decision is made by the ARC. In the event that an applicant withdraws its renewal application, the applicant will be refunded as follows:

- Full Refund if the application is not completed;
- Half the application fee, once the application is completed.

The applicant must wait at least six months before reapplying.

Application Decisions

The application decision is based on verification of the company continuing to meet the standards through the renewal process and supporting documentation. The decision is made based on the preponderance of the evidence.

The ARC makes one of the following determinations based on the application:

- Granting of continued registration;
- Request for Further Information;
- Denial of continued registration.

The ARC takes an administrative or procedural action when it requires further information in order to make a decision regarding granting registration renewal. The Application Review Committee may postpone a decision and request a supplemental information report when it has determined that there is insufficient information to substantiate that the applicant is in compliance with one or more of its standards.

The ARC may reject the Renewal Application if it determines that the applicant is substantially out of compliance with the NHPCB standards. Whenever the ARC rejects a Renewal Application, it states the specific reasons for rejection in the action letter from the Executive Director, it sends to the applicant. In the event that a Renewal Application is rejected, the applicant must wait at least six months before submitting a new Initial Application.

If a decision is made to reject a Renewal Application, the applicant may formally appeal the decision in accordance with the NHPCB Appeals Policy. In the event of a Final rejection decision, the applicant may submit a new Initial Application with the initial application fee after a six-month period.

Request From Applicant for Withdrawal of Registration

An applicant may request the removal of the NHPCB registration at any time. The NHPCB will comply with such a request and delete the registration and the Seal on all applicant products from its approved database. If the NHPCB registration is withdrawn or the applicant determines to withdraw the NHPCB registration, the applicant must remove the Seal from its products and remove any publicity/marketing related to the Seal, within 30 days of this action.

NHPCB Withdrawal of the Registration

Grounds for withdrawing the NHPCB Registration after it has been granted include the following:

- Deficiencies identified in the renewal process that are required to be corrected within a specified period are not corrected within that period;
- The applicant has engaged in illegal conduct or is misrepresenting itself or presenting false information to the public;
- The applicant fails to provide fully and accurately all pertinent information and materials requested by the Application Committee;
- The applicant fails to submit a renewal application or pay the renewal fee;
- The applicant fails to notify the NHPCB of substantive change affecting the product;
- The applicant's organization ceases to exist or is no longer functional;
- The applicant's organization has a pending or final action brought by a Federal/State/Provincial agency to suspend, revoke, withdraw, or terminate the institution's legal authority to operate or manufacture the NHPCB Seal product.

Note, however, that should the brand owner/manufacturer decide to appeal the NHPCB/s withdrawal of the Seal, the NHPCB Seal automatically remains in effect until the expiration of the period within which the manufacturer may file a letter of appeal, or until the completion of the appeals process, whichever shall later occur. The NHPCB shall publicize the withdrawal of the label in it's NHPCB Seal database.

Substantive Change Application Processes

What is Substantive Change?

Once the NHPCB Seal has been granted, the applicant is required to apply for approval to implement certain types of significant changes that affect the product, labeling or manufacturing, referred to as “substantive changes.” Substantive changes are those changes that have the potential to significantly impact the ability of the manufacturer to maintain compliance with NHPCB standards. These changes require prior notice by the applicant and advanced approval within 60 days of implementation. Notification is through the Substantive Change Application. Changes that are more minor do not require a substantive change application and are handled during the normal process of renewal.

If the applicant is unclear whether a specific change is considered substantive, it should consult the NHPCB staff. The following represent examples of substantive changes related to the NHPCB Seal that require usage of the Substantive Change Application Form:

1. Legal actions or regulatory actions from the FDA that may adversely impact the homeopathic product, which includes any FDA Warning Letters with an accompanying Official Action Indicated (OAI) from the FDA or Class I or Class II Recalls;
2. Legal actions or regulatory actions from the FTC that may adversely impact the homeopathic product which include warning letters;
3. A significant change in the manufacturing of the product; (Note: Periodic, minor modifications to manufacturing do not constitute a substantive change);
4. A change in the active ingredient (s) of the product;
5. A change in the vehicle or route of administration not already approved by the NHPCB Seal;
6. Any change that may adversely affect the safety or purity of the product (eg. Serious Adverse Event reporting);
7. Changes in clinical indications as marketed for the product.

Expected Timeline

The expected timeline for an ARC decision on the substantive change application, once the application is complete, is eight weeks. This may vary somewhat if additional information is requested.

Substantive Change Decisions

The ARC makes one of the following determinations based on the application:

- Granting of substantive change;

- Request for Further Information;
- Denial of substantive change.

The ARC takes an administrative or procedural action when it requires further information in order to make a decision regarding granting registration renewal. The Application Review Committee may postpone a decision and request a supplemental information report when it has determined that there is insufficient information to substantiate that the applicant is in compliance with one or more of its standards.

The ARC may reject the Substantive Change Application if it determines that the applicant is substantially out of compliance with the NHPCB standards. Whenever the ARC rejects a Substantive Change Application, it states the specific reasons for rejection in the action letter from the Executive Director, it sends to the applicant.

If a decision is made to reject a Substantive Change Application, the applicant may formally appeal the decision in accordance with the NHPCB Appeals Policy.

The NHPCB may, for good reason, require the applicant to postpone implementation of the change pending NHPCB action if, for example, insufficient information was furnished or because insufficient applicant evaluation has taken place. Should the applicant initiate or implement a substantive change without first obtaining approval, the NHPCB may require the program to suspend its approved status.

Letter of Attestation

The applicant must complete the Substantive Change Application and have an authorized representative from the institution's governance structure sign the attestation indicating the accuracy and completeness of its submission.

Application Support

The applicant may reach out to the NHPCB Executive Director (or Executive Director Assistant) at any time with questions about the application process.

Application Withdrawal

An applicant may withdraw its Substantive Change Application at any time before a final decision is made by the ARC. In the event that an applicant withdraws its Substantive Change application, the applicant will be refunded as follows:

- Full Refund if the application is not completed;
- Half the application fee, once the application is completed.

Application Review Committee (ARC)

Introduction

Purpose

The purpose of the Application Review Committee (ARC) is to validate whether an application meets the NHPCB Standards.

Application Submittal

Once initial eligibility is determined, applications are submitted electronically and reviewed electronically through the application portal (Armature).

Application Review Committee List

A pool of approved committee members is selected and vetted by the NHPCB Strategic Committee. This list is maintained and updated by the NHPCB Strategic Committee. All committee members sign a confidentiality agreement. See also the Confidentiality Section of this document for further details.

Role of ARC Team Leader

The ARC Team Leader's responsibility is to support the ARC Committee members through training, consultation and connecting the ARC members to the larger organization. The ARC Committee can feel free to reach out to the ARC Team Leader at any time for information about processes and needed support. The ARC Team Leader may choose to join an Applications Review Committee team review meeting as a non-voting member from time to time. Their role there is primarily one of support.

Asking for Further Information-Consultant

The committee may choose to ask a consultant for specific information that pertains to the application. On doing so, the application should not be shared, but only the information pertinent to the question. Every effort should be made to redact any confidential information. Consultants must be from the Approved ARC Consultant List. The ARC Team Leader should give approval before contacting the ARC Consultant.

If the committee decides to ask for additional information from a consultant, the Executive Director/Executive Director Assistant contacts the consultant with this request. The committee then reconvenes to discuss once the information is obtained to make a final determination.

Consultants provide expertise in the following areas:

- Manufacturing
- Safety (including Minimum Safe Dilutions)
- Materia Medica and Repertory

- HPCUS
- Complex Formulations

Importance of Only Reviewing to Validate Standards

Review of the application should only be to determine whether the application meets the NHPCB standards. This is important to ensure consistency in the review process. If you find issues that arise during the application process that are not covered in the Standards and of concern, please ask the Executive Director/Executive Director Assistant to add this to a list of compiled potential changes for the next version of the standards.

Preponderance of Evidence

Determinations are made based on a preponderance of evidence provided by the applicant. It is the applicant's responsibility to provide sufficient evidence to demonstrate that the product or organization meets the NHPCB Standards.

Initial Product Application Review

Initial Application ARC Team

The Initial Product Application Review Committee (ARC) consists of four members who serve as follows:

- Executive Director: Convenes committee; serves as secretary; non-voting member
- Two Physician Members; voting members
- Public Member; voting member
- One of the three voting Application Review Committee members serves as Lead Reviewer for an application.

Review for Completeness

Once the initial application is submitted, an initial review of the application for completeness is done by the Executive Director (or Executive Director Assistant). This should take no more than 30 days. If information is missing, the Executive Director works with the applicant to ensure that all data fields are appropriately completed. This includes a review to ensure that the appropriate fee has been paid.

Assembling the Application Review Committee (ARC)

Once this process is complete, the Executive Director then assembles the Application Review Committee. This consists in four members: Physician #1 (voting member; member of AIH), Physician #2 (voting member; member of AIH), Public (voting member) and Executive Director/Executive Director Assistant (non-voting member). The Executive Director/Executive Director Assistant also assigns a chair for the committee. Physician members and public members are selected by the Executive Director/Executive Director Assistant from a list of approved members who have been determined to be qualified to review applications for the specific pathway and have completed the initial applicant training.

Application Review Process-Independent Review

Once the application review committee has been selected, each member is assigned specific fields of the application to review. Some fields are reviewed by all members and others are only reviewed by specific members. Expected average time to complete this review for product applications is as follows:

- Pathway #1 Product Applications: One Hour
- Pathway #2 Product Applications: 75 Minutes

Application Review Process-Team Review

Once the independent review is completed, the Application Review Committee meets as a group to discuss. The chair of the committee arranges this. This is generally done

through a Zoom format. All four members are present at this meeting to review and discuss the application. The Executive Director/Assistant Executive Director keeps minutes at this meeting.

Expected average time to complete this review can be found in the Applications Review Committee Manual. For product applications, this is typically one hour.

The application decision is based on verification of the product's meeting of the standards through the application process and supporting documentation. The decision is made based on the preponderance of the evidence.

Key questions for the committee to consider are the following in their decision:

- Is the product a genuine homeopathic product?
- Is it safe to use?
- Was the product prepared according to the standards of the homeopathic industry and CGMP?
- If claims are made for the product, can they be justified according to traditional homeopathic practice (eg. Repertory and Materia Medica)?

The ARC makes one of the following determinations based on the application:

- Granting of Initial Seal;
- Request for Further Information;
- Denial of Seal.

The decision should be made by consensus whenever possible. However, a majority opinion is acceptable. Final votes should be carefully documented in the minutes along with the rationale for any dissenting opinions.

It is the responsibility of the Executive Director/Executive Director Assistant to carry out the decisions of the committee. If a consensus cannot be reached, the majority opinion is carried forward and the dissenting voting is documented in the minutes.

The Committee Chair for an application takes the lead on the application, organizing the discussion and response from the committee.

Granting the Seal

If the Seal is granted, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner using the approved notification letter. The applicant is sent an NHPCB Seal packet describing the appropriate usage of the Seal, including marketing instructions and labeling instructions.

Asking for Further Information-Applicant

If the committee decides to ask for additional information from the applicant, the Executive Director/Executive Director Assistant contacts the applicant with this request.

The request will always contain a suitable time frame for the applicant to respond. The committee then reconvenes to discuss once the information is obtained to make a final determination.

Denying the Seal

If the Seal is denied, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner. The letter includes not only the determination but also the rationale for the determination that was made. The rationale should also have been clearly documented in the minutes of the meeting. The applicant does have the option of Appeal.

Timeline

The expected timeline from when the initial application is complete to when the ARC Committee makes its final determination is three months. The committee should strive whenever possible to adhere to this timeline. If a significant deviation from this timeline is necessary please notify the ARC Team Leader.

Initial Brand Owner Application Review

Initial Application ARC Team

The Initial Brand Owner Application Review Committee (ARC) consists in three members who serve as follows:

- Executive Director: Convenes committee; serves as secretary; non-voting member
- One Physician Member; voting member
- Public Member; voting member
- One of the two voting Application Review Committee members serves as Lead Reviewer for the application.

Review for Completeness

Once the initial application is submitted, an initial review of the application for completeness is done by the Executive Director (or Executive Director Assistant). This should take no more than 15 days. If information is missing, the Executive Director works with the applicant to ensure that all data fields are appropriately completed. This includes a review to ensure that the appropriate fee has been paid.

Assembling the Application Review Committee (ARC)

Once this process is complete, the Executive Director then assembles the Application Review Committee. This consists of three members: Physician (voting member; member of AIH), Public (voting member) and Executive Director/Executive Director Assistant (non-voting member). The Executive Director/Executive Director Assistant also assigns a chair for the committee. The physician member and public member are selected by the Executive Director/Executive Director Assistant from a list of approved members who have been determined to be qualified to review applications for the specific pathway and have completed the initial applicant training.

Application Review Process-Independent Review

Once the application review committee has been selected, each member is assigned specific fields of the application to review. Some fields are reviewed by all members and others are only reviewed by specific members. Expected average time to complete this review for product applications is one hour.

Application Review Process-Team Review

Once the independent review is completed, the Application Review Committee meets as a group to discuss. This is generally done through a Zoom format. All three members are present at this meeting to review and discuss the application. The Executive Director/Assistant Executive Director keeps minutes at this meeting.

Expected average time to complete this review can be found in the Applications Review Committee Manual. For product applications, this is typically 45 minutes.

The committee works to make decisions by consensus. Determinations include one of the following:

- Granting of Initial Seal;
- Request for Further Information;
- Denial of Seal.

It is the responsibility of the Executive Director/Executive Director Assistant to carry out the decisions of the committee. If a consensus cannot be reached, the majority opinion is carried forward and the dissenting voting is documented in the minutes.

The Committee Chair for an application takes the lead on the application, organizing the discussion and response from the committee.

Granting Registration

If registration is granted, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner using the approved notification letter. The applicant is sent a registration packet describing the appropriate usage of registration.

Asking for Further Information-Applicant

If the committee decides to ask for additional information from the applicant, the Executive Director/Executive Director Assistant contacts the applicant with this request. The request will always contain a suitable time frame for the applicant to respond. The committee then reconvenes to discuss once the information is obtained to make a final determination.

Denying Registration

If the registration is denied, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner. The letter includes not only the determination but also the rationale for the determination that was made. The rationale should also have been clearly documented in the minutes of the meeting. The applicant does have the option of Appeal. Note that the applicant may not proceed with product applications until registration has been granted.

Timeline

The expected timeline from when the initial application is complete to when the ARC Committee makes its final determination is six weeks. The committee should strive whenever possible to adhere to this timeline. If a significant deviation from this timeline is necessary please notify the ARC Team Leader.

Initial Manufacturer Application Review

Initial Application ARC Team

The Initial Manufacturer Application Review Committee (ARC) consists in three members who serve as follows:

- Executive Director: Convenes committee; serves as secretary; non-voting member
- Two Physician Members; voting members
- Public Member; voting member
- One of the two voting Application Review Committee members serves as Lead Reviewer for the application.

Review for Completeness

Once the initial application is submitted, an initial review of the application for completeness is done by the Executive Director (or Executive Director Assistant). This should take no more than 30 days. If information is missing, the Executive Director works with the applicant to ensure that all data fields are appropriately completed. This includes a review to ensure that the appropriate fee has been paid.

Assembling the Application Review Committee (ARC)

Once this process is complete, the Executive Director then assembles the Application Review Committee. This consists of four members: Physician #1 (voting member; member of AIH), Physician #2 (voting member; member of AIH), Public (voting member) and Executive Director/Executive Director Assistant (non-voting member). The Executive Director/Executive Director Assistant also assigns a chair for the committee.The physician member and public member are selected by the Executive Director/Executive Director Assistant from a list of approved members who have been determined to be qualified to review applications for the specific pathway and have completed the initial applicant training.

Application Review Process-Independent Review

Once the application review committee has been selected, each member is assigned specific fields of the application to review. Some fields are reviewed by all members and others are only reviewed by specific members. Expected average time to complete this review for product applications is 90 minutes.

Application Review Process-Team Review

Once the independent review is completed, the Application Review Committee meets as a group to discuss. This is generally done through a Zoom format. All four members are present at this meeting to review and discuss the application. The Executive Director/Assistant Executive Director keeps minutes at this meeting.

Expected average time to complete this review can be found in the Applications Review Committee Manual. For product applications, this is typically 60 minutes.

The committee works to make decisions by consensus. Determinations include one of the following:

- Granting of Initial Seal;
- Request for Further Information;
- Denial of Seal.

It is the responsibility of the Executive Director/Executive Director Assistant to carry out the decisions of the committee. If a consensus cannot be reached, the majority opinion is carried forward and the dissenting voting is documented in the minutes.

The Committee Chair for an application takes the lead on the application, organizing the discussion and response from the committee.

Granting Registration

If registration is granted, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner using the approved notification letter. The applicant is sent a registration packet describing the appropriate usage of registration.

Asking for Further Information-Applicant

If the committee decides to ask for additional information from the applicant, the Executive Director/Executive Director Assistant contacts the applicant with this request. The request will always contain a suitable time frame for the applicant to respond. The committee then reconvenes to discuss once the information is obtained to make a final determination.

Denying Registration

If the registration is denied, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner. The letter includes not only the determination but also the rationale for the determination that was made. The rationale should also have been clearly documented in the minutes of the meeting. The applicant does have the option of Appeal. Note that the applicant may not proceed with product applications until registration has been granted.

Timeline

The expected timeline from when the initial application is complete to when the ARC Committee makes its final determination is eight weeks. The committee should strive whenever possible to adhere to this timeline. If a significant deviation from this timeline is necessary please notify the ARC Team Leader.

Substantive Change Application Review

Substantive Change Application ARC Team

The Substantive Change Application Review Committee (ARC) consists in four members who serve as follows:

- Executive Director: Convenes committee; serves as secretary; non-voting member
- Two Physician Members; voting members
- Public Member; voting member
- One of the two voting Application Review Committee members serves as Lead Reviewer for the application.

Review for Completeness

Once the initial application is submitted, an initial review of the application for completeness is done by the Executive Director (or Executive Director Assistant). This should take no more than 30 days. If information is missing, the Executive Director works with the applicant to ensure that all data fields are appropriately completed. This includes a review to ensure that the appropriate fee was paid.

Assembling the Application Review Committee (ARC)

Once this process is complete, the Executive Director then assembles the Application Review Committee. This consists in four members: Physician #1 (voting member; member of AIH), Physician #2 (voting member; member of AIH), Public (voting member) and Executive Director/Executive Director Assistant (non-voting member). The Executive Director/Executive Director Assistant also assigns a chair for the committee.The physician member and public member are selected by the Executive Director/Executive Director Assistant from a list of approved members who have been determined to be qualified to review applications for the specific pathway. Also physician members and public members have completed the initial applicant training.

Application Review Process-Independent Review

Once the application review committee has been selected, each member is assigned a specific field of the application to review. Expected average time to complete this review for product applications is 30 minutes.

Application Review Process-Team Review

Once the independent review is completed, the Application Review Committee meets as a group to discuss. This is generally done through a Zoom format. All four members are present at this meeting to review and discuss the application. The Executive Director/Assistant Executive Director keeps minutes at this meeting.

Product Application Renewal

A reminder that the renewal application is due will be sent out at both six months and one month before this is due. A final reminder will be sent out on the day that the renewal application is due. Late renewal applications will be charged a late fee. Applicants have two months to submit after the application is due or they will lose the NHPCB Seal.

The NHPCB Seal is good for the period of three years. The applicant must submit a renewal application every three years for the NHPCB Seal to continue to be granted.

Product Application Renewal ARC Team

The Product Application Renewal Review Committee (ARC) consists in three members who serve as follows:

- Executive Director: Convenes committee; serves as secretary; non-voting member
- Physician Member; voting member
- Public Member; voting member
- One of the two voting Application Review Committee members serves as Lead Reviewer for an application.

Review for Completeness

Once the initial application is submitted, an initial review of the application for completeness is done by the Executive Director (or Executive Director Assistant). This should take no more than 15 days. If information is missing, the Executive Director works with the applicant to ensure that all data fields are appropriately completed.

Assembling the Application Review Committee (ARC)

Once this process is complete, the Executive Director then assembles the Application Review Committee. This consists in three members: Physician #1 (voting member; member of AIH),Public (voting member) and Executive Director/Executive Director Assistant (non-voting member). The Executive Director/Executive Director Assistant also assigns a chair for the committee. The physician member and public member are selected by the Executive Director/Executive Director Assistant from a list of approved members who have been determined to be qualified to review applications for the specific pathway and have completed the initial applicant training.

Application Review Process-Independent Review

Once the application review committee has been selected, each member is assigned specific fields of the application to review. Some fields are reviewed by all members

and others are only reviewed by specific members. Expected average time to complete this review for product applications is as follows:

- Pathway #1 Product Applications: 45 minutes
- Pathway #2 Product Applications: 60 Minutes

Application Review Process-Team Review

Once the independent review is completed, the Application Review Committee meets as a group to discuss. This is generally done through a Zoom format. All four members are present at this meeting to review and discuss the application. The Executive Director/Assistant Executive Director keeps minutes at this meeting.

Expected average time to complete this review is typically 45 minutes.

The committee works to make decisions by consensus. Determinations include one of the following:

- Renewal of the Seal;
- Request for Further Information;
- Denial Renewal of Seal.

It is the responsibility of the Executive Director/Executive Director Assistant to carry out the decisions of the committee. If a consensus cannot be reached, the majority opinion is carried forward and the dissenting voting is documented in the minutes.

The Lead Reviewer for an application takes the lead on the application, organizing the discussion and response from the committee.

Renewal of the Seal

If the Seal is renewed, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner using the approved notification letter.

Asking for Further Information-Applicant

If the committee decides to ask for additional information from the applicant, the Executive Director/Executive Director Assistant contacts the applicant with this request. The request will always contain a suitable time frame for the applicant to respond. The committee then reconvenes to discuss once the information is obtained to make a final determination.

Denying Renewal of the Seal

If renewal is denied, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner. The letter includes not only the determination but also the rationale for the determination that was made. The rationale

should also have been clearly documented in the minutes of the meeting. The applicant does have the option of Appeal.

Timeline

The expected timeline from when the initial application is complete to when the ARC Committee makes its final determination is eight weeks. The committee should strive whenever possible to adhere to this timeline. If a significant deviation from this timeline is necessary please notify the ARC Team Leader.

Brand Owner Application Renewal

A reminder that the renewal application is due will be sent out at both three months and one month before this is due. A final reminder will be sent out on the day that the renewal application is due. Late renewal applications will be charged a late fee. Applicants have two months to submit after the application is due or they will lose the NHPCB registration.

The NHPCB registration is good for a period of one year.

Product Application Renewal ARC Team

The Product Application Renewal Review Committee (ARC) consists in three members who serve as follows:

- Executive Director: Convenes committee; serves as secretary; non-voting member
- Physician Member; voting member
- Public Member; voting member
- One of the two voting Application Review Committee members serves as Lead Reviewer for an application.

Review for Completeness

Once the initial application is submitted, an initial review of the application for completeness is done by the Executive Director (or Executive Director Assistant). This should take no more than 15 days. If information is missing, the Executive Director works with the applicant to ensure that all data fields are appropriately completed.

Assembling the Application Review Committee (ARC)

Once this process is complete, the Executive Director then assembles the Application Review Committee. This consists of three members: Physician (voting member; member of AIH), Public (voting member) and Executive Director/Executive Director Assistant (non-voting member). The Executive Director/Executive Director Assistant also assigns a chair for the committee.The physician member and public member are selected by the Executive Director/Executive Director Assistant from a list of approved members who have been determined to be qualified to review applications for the specific pathway. Also physician members and public members have completed the initial applicant training.

Application Review Process-Independent Review

Once the application review committee has been selected, each member is assigned a specific field of the application to review. Some fields are reviewed by all members and others are only reviewed by specific members. Expected average time to complete this review for product applications is as follows:

- Pathway #1 Product Applications: 45 minutes
- Pathway #2 Product Applications: 60 Minutes

Application Review Process-Team Review

Once the independent review is completed, the Application Review Committee meets as a group to discuss. This is generally done through a Zoom format. All four members are present at this meeting to review and discuss the application. The Executive Director/Assistant Executive Director keeps minutes at this meeting.

Expected average time to complete this review is typically 45 minutes.

The committee works to make decisions by consensus. Determinations include one of the following:

- Renewal of the Registration;
- Request for Further Information;
- Denial of Renewal Registration

It is the responsibility of the Executive Director/Executive Director Assistant to carry out the decisions of the committee. If a consensus cannot be reached, the majority opinion is carried forward and the dissenting voting is documented in the minutes.

The Committee Chair for an application takes the lead on the application, organizing the discussion and response from the committee.

Renewal of Registration

If registration is renewed, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner using the approved notification letter.

Asking for Further Information-Applicant

If the committee decides to ask for additional information from the applicant, the Executive Director/Executive Director Assistant contacts the applicant with this request. The request will always contain a suitable time frame for the applicant to respond. The committee then reconvenes to discuss once the information is obtained to make a final determination.

Denying Renewal of Registration

If renewal is denied, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner. The letter includes not only the determination but also the rationale for the determination that was made. The rationale should also have been clearly documented in the minutes of the meeting. The applicant does have the option of Appeal.

Timeline

The expected timeline from when the initial application is complete to when the ARC Committee makes its final determination is eight weeks. The committee should strive whenever possible to adhere to this timeline. If a significant deviation from this timeline is necessary please notify the ARC Team Leader.

Manufacturer Application Renewal

A reminder that the renewal application is due will be sent out at both three months and one month before this is due. A final reminder will be sent out on the day that the renewal application is due. Late renewal applications will be charged a late fee. Applicants have two months to submit after the application is due or they will lose the NHPCB registration.

The NHPCB registration is good for a period of one year. .

Product Application Renewal ARC Team

The Product Application Renewal Review Committee (ARC) consists in three members who serve as follows:

- Executive Director: Convenes committee; serves as secretary; non-voting member
- Physician Member; voting member
- Public Member; voting member
- One of the two voting Application Review Committee members serves as Lead Reviewer for an application.

Review for Completeness

Once the initial application is submitted, an initial review of the application for completeness is done by the Executive Director (or Executive Director Assistant). This should take no more than 30 days. If information is missing, the Executive Director works with the applicant to ensure that all data fields are appropriately completed.

Assembling the Application Review Committee (ARC)

Once this process is complete, the Executive Director then assembles the Application Review Committee. This consists of three members: Physician (voting member; member of AIH), Public (voting member) and Executive Director/Executive Director Assistant (non-voting member). The physician member and public member are selected by the Executive Director/Executive Director Assistant from a list of approved members who have been determined to be qualified to review applications for the specific pathway and have completed the initial applicant training.

Application Review Process-Independent Review

Once the application review committee has been selected, each member is assigned specific fields of the application to review. Some fields are reviewed by all members and others are only reviewed by specific members. Expected average time to complete this review for product applications is as follows:

- Pathway #1 Product Applications: 60 minutes
- Pathway #2 Product Applications: 90 Minutes

Application Review Process-Team Review

Once the independent review is completed, the Application Review Committee meets as a group to discuss. This is generally done through a Zoom format. All four members are present at this meeting to review and discuss the application. The Executive Director/Assistant Executive Director keeps minutes at this meeting.

Expected average time to complete this review is typically 60 minutes.

The committee works to make decisions by consensus. Determinations include one of the following:

- Renewal of the Registration;
- Request for Further Information;
- Denial of Renewal Registration

It is the responsibility of the Executive Director/Executive Director Assistant to carry out the decisions of the committee. If a consensus cannot be reached, the majority opinion is carried forward and the dissenting voting is documented in the minutes.

The Committee Chair for an application takes the lead on the application, organizing the discussion and response from the committee.

Renewal of Registration

If registration is renewed, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner using the approved notification letter.

Asking for Further Information-Applicant

If the committee decides to ask for additional information from the applicant, the Executive Director/Executive Director Assistant contacts the applicant with this request. The request will always contain a suitable time frame for the applicant to respond. The committee then reconvenes to discuss once the information is obtained to make a final determination.

Denying Renewal of Registration

If renewal is denied, it is the responsibility of the Executive Director/Executive Director Assistant to notify the applicant in a timely manner. The letter includes not only the determination but also the rationale for the determination that was made. The rationale should also have been clearly documented in the minutes of the meeting. The applicant does have the option of Appeal.

Timeline

The expected timeline from when the initial application is complete to when the ARC Committee makes its final determination is 12 weeks. The committee should strive

whenever possible to adhere to this timeline. If a significant deviation from this timeline is necessary please notify the ARC Team Leader.

NHPCB Seal Appeals Process

Overview

The NHPCB affords due process to applicants by allowing manufacturers affected by certain adverse actions (see below) to appeal the NHPCB Seal's action to an independent Appeal Board. Within fifteen business days of such action, the Executive Director of the NHPCB sends a notice by certified mail to the applicant, with the notice copied to the manufacturer's owner. The notice states the adverse action and describes with particularity the basis of the action; included with the notice is a copy of this Policy on Appeals. A manufacturer that wishes to file a letter of appeal to an adverse action must do so within 30 days of having received notice of the action from the NHPCB.

The applicant may be represented by legal counsel throughout the appeal process; however, an appeal is not a formal judicial process and the attendant procedures and rules of a formal judicial process do not apply.

The candidacy status of an NHPCB Seal application automatically remains in effect until the completion of the appeals process.

Appeal of Denials

An applicant may appeal any of the following denials within 30 days of having received notice of the action from the NHPCB Seal Executive Director:

• The denial of an application; or

• The denial of the renewal.

Grounds for Appeal

It is the responsibility of the Steering Commitee to substantiate one or more of the following as the basis for appeal:

1. There were errors or omissions in carrying out prescribed procedures on the part of the ARC;

2. There was demonstrable bias or prejudice on the part of one or more members of the ARC that significantly affected the decision;

3. The evidence before the ARC at the time of the decision was materially in error; and/or;

4. The decision of the ARC was not adequately supported by the facts before it at the time, or it was contrary to the substantial weight of evidence before the committee.

Letter of Appeal

In its letter of appeal, the applicant must set forth in detail the grounds for the appeal, stating with specificity the reasons why it believes those grounds exist. The applicant must indicate whether or not it wishes to present testimony and/or evidence at the hearing and may provide documentary evidence to support its position at this time. The Letter of Appeal is sent to the NHPCB Executive Director who forwards it to the NHPCB Steering Committee.

Appointment of the Appeal Board and Scheduling of the Hearing

Upon receipt of an appeal letter, the Steering Committee reviews the appeal and determines whether the appeal is denied or accepted. If the appeal is denied, the Executive Director is responsible for informing the applicant.

If accepted, the NHPCB Seal Steering Committee appoints a three-person Appeal Board that includes three members of the ARC pool that did not serve initially on the application. No member of the Appeal Board may be a member of the NHPCB Steering Committee, or otherwise have a conflict of interest.

The Executive Director, in consultation with the applicant, establishes a date, time and place for a meeting of the Appeal Board at least 21 days in advance of the meeting, and notifies in writing the parties concerned. At least five calendar days before the meeting, the applicant provides the chair of the Appeal Board with all documentary evidence and with the names and positions of any witnesses it plans to have in attendance.

In carrying out their duties, the members of the Appeal Board:

1. Select a member to serve as chair;

2. Meet at the time and place designated by the NHPCB Steering Committee;

3. Provide for a hearing if the applicant has so requested;

4. Consider the grounds for the appeal as stated by the applicant;

5. Study the evidence submitted in writing by the applicant in support of its appeal;

6. Consider all records of the ARC's decision,

7. Compare the Seal's policies and procedures with the procedures followed in arriving at the adverse action;

8. Prepare a report of the meeting of the Appeal Board, including the final decision of the Appeal Board, within ten calendar days after the meeting; and

9. Forward the record of the Appeal Board's meeting and the decision of the Appeal Board to the NHPCB Steering Committee and Applicant including a summary report of

the Appeal Board's meeting, the appeal documents filed by the program, and other statements and documents considered by the Appeal Board.

Hearing Procedures

1. If the appellant has requested an opportunity to appear, the chair of the Appeal Board presides at the hearing. The chair ensures that all participants have a reasonable opportunity to be heard and to present all relevant oral and written evidence.

2. Technical rules of evidence do not apply to the hearing, and the chair of the Appeal Board may limit the evidence to avoid undue repetition and to ensure relevance. The chair rules on all questions pertaining to the conduct of the hearing.

3. Each party—the applicant and the NHPCB—has the right to be represented by counsel or an authorized spokesperson, to examine the witnesses of the other party, and to present oral or written evidence.

4. The hearing is conducted in closed session with only necessary participants present. The Executive Direcotr records the hearing minutes; however, at the election of either party and at that party's expense, a court reporter may be hired to prepare a record of the hearing.

5. As the proceeding before the Appeal Board is appellate in nature and is therefore limited to the existing record from previous proceedings, no discovery shall be permitted for either side and no evidence not already properly in the record on appeal shall be accepted, provided that the parties may offer witnesses for the limited purpose of elucidating the meaning of evidence properly before the Appeal Board.

Decisions of the Appeal Board

The Appeal Board may issue a final decision that a denial be affirmed, reversed or modified—which decision is binding on the NHPCB. After arriving at its final decision, the Appeal Board shall remand the decision to the NHPCB for further action consistent with the decision of the Appeal Board.

Should an applicant believe that the NHPCB has not correctly carried out the final decision of the Appeal Board, the applicant may present this issue to the Appeal Board, which issue shall be appealable to the same Appeal Board; the Appeal Board in this circumstance shall retain jurisdiction for the limited purpose of determining whether its decision on remand has been correctly carried out and, if not, to provide further instruction to the Appeal Board.

Costs of an Appeal

A program's appeal letter to the Commission shall be accompanied by a deposit of $1,000 (U.S. funds). The expenses of the appeals process will be handled as follows:

1. If the Appeal Board affirms the Denial of the Commission, the appellant bears all of the expenses of the members of the Appeal Board and all of the NHPCB's expenses related to the appeal.

2. If the Appeal Board remands the matter to the NHPCB Steering Committee with the instruction that the Denial be reversed or modified, the costs of the appeal are equally borne by the appellant and the NHPCB.

3. Following the completion of the appeals process, the NHPCB Steering Committee prepares for the appellant a detailed statement of all expenses. The appellant is obligated to pay any expenses that exceed its deposit, and any unused portion of the appellant's deposit shall be refunded (approximately $200).

ARC Member Selection and Training

ARC Member Recruitment

It is the responsibility of the Strategic Committee to recruit members for the ARC and to maintain a list of approved candidates for the position. Job descriptions can be found in Appendix A for physician members and Appendix B for public members. The application can be found in Appendix C.

Selection of Application Review Set

Based on their knowledge, skills and training, selected applicants can choose one of the following options:

- Brand Owner Application Review; Manufacturer Application Review; Pathway #1 Product Application Review
- Brand Owner Application Review; Manufacturer Application Review; Pathway #2 Product Application Review
- Brand Owner Application Review; Manufacturer Application Review; Pathway #1 and Pathway #2 Product Application Review

ARC Member Orientation

The orientation for ARC Members is conducted by the ARC Team Leader.. It is their responsibility to update the orientations as needed.

The orientation will be available as a pre-recorded video. There are separate orientations which will be reviewed by ARC members depending on the Review set chosen. These include:

- General Orientation
- Orientation to Pathway #1 Initial Product Application and Renewal Review
- Orientation to Pathway #2 Initial Product Application and Renewal Review
- Orientation to Brand Owner and Manufacturer Application and Renewal Review

Once the ARC Member has completed listening to the requisite videos, they then meet with the NHPCB Executive Director and ARC Team Leader to answer any questions they may have about the application process.

Ongoing In-Service Training

It is the responsibility of the ARC Team Leader to hold periodic in-service training for all ARC Members. ARC members will be paid for this time. These meetings will provide opportunities for all ARC members to share experiences and lessons learned, as well as to provide project updates to the team.

Confidentiality

The NHPCB strictly adheres to its confidentiality policies. Any information that you receive about a company is considered strictly confidential and should not be shared outside of the ARC. This even includes other members of the project that do not sit on the ARC, with the exception of the ARC Team Leader. The conformity assessment principle on which this is based is the following (https://www.standardsportal.org/usa_en/conformity_assessment/conformity_assessment.aspx):

- Information requirements are limited to what is necessary to assess compliance and determine fees. Protective measures are taken so that confidential or proprietary information is not communicated to any person or organization not having legal right to such information;

For more information on this please see our Confidentiality Policy.

Conflicts of Interest

All Application Review Committee members must disclose immediately, verbally and in writing, any existing, potential or apparent conflict of interest with a manufacturer or retailer being reviewed before assignments are made to serve on the ARC.

A committee member may not have access to the written documents and reports submitted by the applicant, and must recuse himself/herself when reviewing the applicant's application, if:

1. they work for the brand owner or manufacturer;

2. has been a candidate for employment by the brand owner or manufacturer within the past year;

3. has been employed by the brand owner or manufacturer within the past five years;

4. is a member of the brand owner or manufacturer's governing body;

5. has a personal, business, consultative, or other interest in or relationship with the brand owner or manufacturer under review, or there are other considerations that could affect his or her objectivity;

6. has a family member who is an employee, board member, or a candidate for employment with the brand owner or manufacturer;

7. is associated with any other circumstances that could be perceived as a conflict of interest.

Please see the NHPCB Conflict of Interest Policy for further details.

Resources

The NHPCB provides a variety of resources to support the members of the Application Review Committee (ARC). These are described below. If there are additional resources that would be helpful to you in your work, please let us know.

NHPCB Strategic Committee

- Responsible for Marketing to AIH Membership to Become an ARC Professional Member;
- Responsible for Marketing to the Public to Become an ARC Public Member;
- Reviews Applications and Determines Eligibility for ARC Membership;
- Compiles and Maintains Listing of ARC Members.

Executive Director/Executive Director Assistant

- Responsible for Initial Completeness Review;
- Responsible for Choosing, Notifying and Convening ARC;
- Responsible to Ensure that All Committee Members Have Access to the Application Materials That They Need;
- Responsible to Take Minutes of All ARC Meetings;
- Responsible to Carry Out All Decisions of the ARC;
- Responsible to Answer Questions Regarding ARC Processes.

ARC Team Leader

- Responsible for All Initial Training for ARC Members;
- Responsible for Leading Periodic Training Updates for ARC Members;
- Responsible for Updating ARC Manuals;
- Responsible for Answering Questions Regarding ARC Application Review Content ;
- Responsible for Identifying and Hiring ARC Consultants.

ARC Consultants

- Responsible for Answering Specific Questions from ARC Members.

Applications Review Committee Manuals

- Manual that Guides ARC Members in Validating that an Application Meets Pathway #1 Standards
- Manual that Guides ARC Members in Validating that an Application Meets Pathway #2 Standards
- Manual that Guides ARC Members in Brand Owner Registration Process
- Manual that Guides ARC Members in Manufacturer Registration Process

Applications Manual

- Manual that Describes ARC Processes

Subscription to the HPUS

- Subscription Access to the HPUS is Available to all ARC Members

Shared Google Drive

- Resource for Communication and Document Storage for ARC Members

Letter Templates

- Seal Acceptance Letter Template
- Request for Additional Information Letter Template
- Seal Denial Letter Template

Appendix A: NHPCB ARC Physician Member Job Description

> "The highest ideal of cure is the speedy, gentle and enduring restoration of health by the most trustworthy and least harmful way."
> -Samuel Hahnemann, MD; *Organon*

NHPCB ARC Physician Member Job Description

Date: January 1st, 2023

Position: **NHPCB Applications Review Committee Physician Member**
Appointed By: NHPCB Strategic Committee
Reports to: NHPCB Executive Director

Purpose of position:

To serve as a member of the Applications Review Committee (ARC), evaluating applications as they are submitted and verifying that they meet the AIH Seal Standards.

Responsibilities:

Report as necessary to the NHPCB Executive Director.

Fill out the ARC Committee Member application.

Work closely with fellow NHPCB ARC members.

Notify the Executive Director when there is a conflict of interest with any NHPCB Seal application and recuse yourself from participating.

Review applications as forwarded to you by the Executive Director.

Participate in ARC meetings as needed.

Submit monthly billing statements to the Executive Director for reimbursement.

Qualifications:

Active member of the American Institute of Homeopathy or a physician who is a member of an organization with an MOU with the AIH.

Has a strong knowledge of homeopathic medicine

Demonstrates responsibility and accountability

Has good communication and teamwork skills

Appendix B: NHPCB ARC Public Member Job Description

> "The highest ideal of cure is the speedy, gentle and enduring restoration of health by the most trustworthy and least harmful way."
> -Samuel Hahnemann, MD; *Organon*

Rough Draft of NHPCB ARC Public Member Job Description

Date: April 5th, 2022

Position: **NHPCB Applications Review Committee Public Member**
Appointed By: ???AIH Seal Project Steering Committee vs. Applications Committee vs Strategic Committee
Reports to: AIH Seal Project Executive Director

Purpose of position:

To serve as a member of the Applications Review Committee (ARC), evaluating applications as they are submitted and verifying that they meet the AIH Seal Standards.

Responsibilities:

Report as necessary to the AIH Seal Project Executive Director.

Fill out the ARC Committee Member application.

Work closely with fellow AIH Seal ARC members.

Notify the Executive Director when there is a conflict of interest with any NHPCB application and recuse yourself from participating.

Review applications as forwarded to you by the Executive Director.

Participate in ARC meetings as needed.

Submit monthly billing statements to the Executive Director for reimbursement.

Qualifications:

Has a strong knowledge of homeopathic medicine

Demonstrates responsibility and accountability

Has good communication and teamwork skills

Appendix C: Application to Serve on the NHPCB Application Review Committee

Date: January 1st, 2023

Instructions:
This application is for those who wish to serve on the Applications Review Committee (ARC). This includes both AIH Members, physicians for which the AIH has an MOU with another organization, and Public Members.

Please fill out this application and return to:

NHPCB Executive Director
ADDRESS
EMAIL

Note that applications take up to six weeks to process. Please contact the NHPCB Executive Director with any questions about the application process or the status of your application.

I. Contact Information (All Applicants)

- Name:
- Address:
- Phone Number:
- Email:

II AIH Members Only (Skip to #III if applying as a Public Member)

- Are you an active member of the AIH or a member of a professional organization that has a signed MOU with the AIH?
- Approximately how long have you been a member of this organization?
- How many years have you been in homeopathic practice or were in practice before you retired your practice?
- Briefly describe your training in homeopathic medicine.
- List any licenses (medical or homeopathic) that you currently hold and their status.
- List any certifications that you currently hold (medical or homeopathic) and their status.
- Describe any homeopathic organizations in which you currently serve or are a member of.
- Describe any affiliations that you currently hold with the homeopathic manufacturing community.
- Attach a copy of your most recent CV/resume to this application.

III. Public Members Only (Skip to #IV if applying as an AIH Member)

- Describe your background in homeopathy.
- Describe any formal or informal training that you have had in homeopathic medicine.
- What has been your experience in volunteering with or working with non profit organizations?
- Why do you think this might be a good fit for you?
- Attach a copy of your most recent CV/resume to this application.

IV. Pathways

The AIH Label Project currently offers two pathways to achieve the AIH Label.

- **Pathway #1**: Single Ingredients/Single Potencies that are Currently Listed in the Homeopathic Pharmacopeia of the United States (HPUS)
- **Pathway #2**: Complex Formulations with Ingredients that are All Currently Listed in the Homeopathic Pharmacopeia of the United States (HPUS)

For which of the following pathways would you like to serve?

A. Pathway #1 Only
B. Pathway #2 Only
C. Both Pathway #1 and #2

If you check either B or C above, describe your background and experience with complex formulations.

V. Signature and Date

- Signature
- Date

Appendix D: Definitions

Accreditation

Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. (These tasks include sampling and testing, inspection, certification and registration.)

Certification

Procedure by which a third party gives written assurance that a product, process, service or person conforms to specified requirements.

Conformity Assessment

Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.

First, Second and Third Party

The first party is usually the supplier. The second party is usually the customer. The third party is that person or body that is recognized as being independent of the parties involved, as concerns the issue in question.

Recognition

Procedure used to provide formal notice that an accreditation body is competent to carry out specific tasks. These tasks include accreditation of testing laboratories and inspection, certification and registration bodies. A governmental recognition system is a set of one or more procedures used by a Federal agency to provide recognition.

Registration

Procedure used to give written assurance that a system conforms to specified requirements. Such systems include those established for the management of product, process or service quality and environmental performance..

Supplier's Declaration

Procedure by which a supplier gives written assurance that a product, process or service conforms to specified requirements