GRMA Certification Procedure

PJRFSI offers certification services to companies seeking independent validation of their NSF/ANSI Standard for Current Good Manufacturing Practices (Dietary Supplements, Over the Counter Drugs (OTC) and Cosmetics) and the GRMA Certification Program. This procedure details from start to finish the life cycle of the GRMA certification process.

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2. Definitions

2.1 GRMA Global Standard – Current Good Manufacturing Practices based product safety and quality management system certification program published and licensed by the NSF/ANSI (GRMA).

2.2 Organization - The organization seeking GRMA certification. Until a contract for certification services is signed with PJRFSI, the Operation is initially referred to as an Applicant.

2.3 Scope of Certification – a description of the certification sought by the Operation which will be covered in the audit program and detailed in the certification certificate. The scope includes: the name and address of the site-specific facility(s) covered; the particular NSF/ANSI 455 Standard and Revision. The scope of certification also specifies exclusions, if any, which must be agreed and approved by PJRFSI in advance of the certification audit.

2.4 Site - A single physical address or facility that will be audited and granted a certificate, either individually or as part of a multiple site scheme as allowed by GRMA.

2.5 Certificate- A certificate and associated documents affirming that the GRMA certification system operated by the Operation has, as a result of the documented assessment procedure conducted by PJRFSI, been found to be in accordance with the applicable GRMA Certificate Program and NSF/ANSI 455 Standard and the scope of certification sought by the Operation.

2.6 Auditor – an employee or contractor of PJRFSI who has been qualified by PJRFSI and registered in the GRMA Directory as a GRMA Auditor and is therefore qualified to conduct GRMA certification

audits.

2.7 Pre-assessment - An informal and optional onsite evaluation carried out by a PJRFSI auditor to assess the Operation's overall GRMA certification system and to determine the Operation's readiness for a GRMA certification audit.

2.8 Certification Audit – an onsite audit of the Operation's overall GRMA certification system and facility conducted by a PJRFSI auditor.

2.9 Monitoring Audit– conducted to assess progress against corrective actions and to verify completion of corrective actions and to verify completion of corrective actions. PJRFSI will determine if this will be an in person or virtual/desk audit based on the number and severity of the noncompliance. Monitoring audits are required for any company who receives a grade of C. PJRFSI also requires a monitoring audit for companies who have not closed out previous minor nonconformances regardless of their grade.

2.10 Surveillance Audit – conducted in years 2 and 3 of the certification cycle by a PJRFSI auditor to assess the continued effectiveness of the Operation's GRMA system for continued certification.

2.11 Recertification Audit – conducted in year 4 of the certification cycle conducted by a PJRFSI auditor to assess the continued effectiveness of the Operation's GRMA system in its entirety and to serve as the basis for re-qualifying the Operation for continued certification.

2.12 Technical Reviewer– individuals who are competent to review audit results and render certification recommendations.

2.13 Designee – a PJRFSI employee who is designated and trained to complete specific procedural functions on behalf of another PJRFSI position. Throughout this SOP-1GRMA procedure, functions which may be completed by a designee will include the following references: "[position] or designee…" or "[position]/designee…"

2.14 GRMA Logo - The GRMA Logo, as issued and authorized for use by a certified Operation, to publicize that the Operation has proven its compliance with the specified GRMA NSF/ANSI 455 Standard and scope of certification.

2.15 GRMA Database – an online searchable directory of certificated companies, GRMA approved certification bodies, and delegates who have successfully completed the GRMA third party auditor training course. The database is a user-specific, web-based storage system of certificate and audit data which may be accessed, with varying levels of permissions, by Operations, retailers/customers, and certification bodies.

3. Request for Certification

3.1 The Applicant initiates the application for certification process via a written or verbal request.

3.2 In response, a PJRFSI Project/Sales Manager or the Food Safety Sales Coordinator or designee provides the Applicant with the FS-1grma – GRMA Certification Questionnaire/Client Application.

3.3 Duly Authorized representatives of the Applicant must complete and sign the Questionnaire/Application to provide PJRFSI with sufficient information required for providing a quote.

3.4 Upon receipt of the signed application, PJRFSIs Food Safety Sales Coordinator or designee trained in GRMA quoting procedures conducts an application review to ensure that:

a. certification requirements are clearly defined, documented, and understood;
b. any differences in understanding between PJRFSI and the Applicant are resolved; and

c. PJRFSI has the technical resource and competencies to perform the certification services sought by the applicant, and if not, PJRFSIs Food Safety Sales Coordinator or designee in consultation with the Food Safety Program Accreditation Manager will reject the application.

The record of this review is the Food Safety Sales Coordinator or designee's signature at the bottom of the FS-1 Food Safety Certification Questionnaire/Client Application and a completed F-207 – Food Safety Quote Approval and Audit Duration Justification Checklist.

For GRMA application review the record of this review is the Food Safety Sales Coordinator or designee's signature at the bottom of the completed F-207 Food Safety Quote Approval and Audit Duration Justification Checklist.

3.5 Based on the information furnished by the Applicant and the input from the application review process, the Food Safety Sales Coordinator or designee completes an F-207 which is a record of: the determination of scope including exclusions; the justification for quoted audit days; and the overall quote approval.

3.5.1 The scope of certification is determined using the latest GRMA guidance regarding, as applicable, audit scope, exclusions, extensions, and auditing of multiple sites. The scope and exclusions, if any must be approved by GRMA Technical Specialist or designee and documented on F-102grma GRMA Scope Approval Form in advance of the Certification Audit.

3.5.2 The required number of audit days is determined using the latest NSF/ANSI 455 GRMA audit duration. A certification audit is generally completed in two days (Dietary Supplements & Cosmetics) and three days (OTC), but shall be more or less depending upon the size of the facility and the complexity of the product categories and technologies. The audit is based on a manufacturer with up to five product categories, and up to three technologies conducted in single facility. The base case assumes that water is a raw material ingredient, and that one or more materials or products require micro quality testing.

3.5.3 The audit duration and resource requirement shall be adjusted based on knowledge of the manufacturer and its operation, regulatory history, and focus of the audit. Larger facilities with multiple buildings, more than five product categories, and more than three technologies may require additional audit time, or multiple auditors, or both

3.5.4 A monitoring audit shall be conducted to assess progress against corrective actions and to verify completion of corrective actions. The duration of the audit is determined by the PJRFSI, based on the number and severity of the nonconformances and the related corrective actions.

3.5.5 Deviations from the audit duration guidance are justified on the F-207. [Due to factors which might only be revealed once the Auditor is onsite, the Auditor may request a deviation in the actual audit time from the quoted audit time. In this case, the Auditor always contacts PJRFSIs Food Safety Program Accreditation Manager or designee for pre-approval and the Auditor justifies the deviation on the GRMA audit report.

3.5.6 PJRFSI may conduct GRMA audits combined with other certification system audits or audit elements, as long as all program rules are met and the integrity of any one component of the combined audit is not compromised. PJRFSI does not, however, conduct any consulting or training in combination with GRMA audit activity. Details of combined audits are specified on the audit report.

3.6 A pre-assessment is optional but encouraged, particularly those seeking initial certification to the applicable standard.

3.7 Transfers are handled in accordance with @Section 12 below.

3.8 Based on the information from the application review (FS-1grma) and quote approval process (F-207), the Food Safety Sales Coordinator or designee completes a quotation in the form of a Certification Agreement (FS-3grma) to cover the costs of the proposed audit activity [pre-assessment, certification audit, monitoring audit, and/or recertification audit(s) as applicable] and any associated fees.

3.9 A PJRFSI Project/Sales Manager or designee provides the Applicant with a duly authorized copy of the Certification Agreement (FS-3grma) and the Terms and Conditions (FS-3tc). (In some cases, the Certification Agreement and Terms and Conditions are forwarded directly to the Applicant by PJRFSIs Sales Coordinator or the Food Safety Program Coordinator/designee.) The Applicant then signs and returns a copy of the Certification Agreement bearing an original signature.

3.10 Signatures by both parties indicate mutual agreement of Certification Agreement including the scope of certification and any exclusions, the certification costs, and the associated Terms and Conditions. After the Certification Agreement is signed, amendments, agreed upon by both parties, may be made as necessary. However, once the certification audit has begun, the scope of the certification shall not be altered.

3.11 Receipt of the signed Certification Agreement and the first installment payment from the Operation is taken by PJRFSI as an instruction to proceed in accordance with the GRMA Certification Agreement and the Terms and Conditions. The Food Safety Program Coordinator or designee sends the Applicant, hereafter referred to as the Operation:

3.1. a summarized version of the Certification Procedure (SOP-01grma);
3.2. other guidance documents describing the audit process, as appropriate; and
3.3. a list of documents/information required from the Operation, as necessary, in preparation for the audit.

3.12 The Food Safety Program Coordinator or designee is responsible for monitoring and verifying the progress of the Operation's certification program including but not limited to audit/certification status, and timeline/due date performance for both Operation and Certification Body (PJRFSI) activities. To support these monitoring and verification activities, the Food Safety Program Coordinator or designee utilizes: the PFCgrma-TL GRMA Audit Status and Timeline Monitoring Guidance; PJRFSIs database; PJView; and the GRMA Database.

3.13 If the requirements for certification change at any time and need retroactive implementation, PJRFSIs Food Safety Program Accreditation Manager or designee will ensure that the Operation is notified as soon as possible by the most appropriate means and that the new requirements are followed/implemented at the next onsite audit activity or sooner if necessary.

4. Scheduling Audits

4.1 Once the signed Certification Agreement (FS-3grma) is received, the Food Safety Program Accreditation Manager or designee assigns a GRMA registered auditor to the audit after verifying that:

a. The Auditor is registered in the GRMA Database as qualified to audit all standards in the Operation's scope of certification;
b. The Auditor has had no prior relationship with the Operation which would present a conflict of interest. The Auditor will confirm this by signing a Certification Personnel Statement of Availability (F-71fs65) before completing the audit.
c. The Auditor has not undertaken three (3) consecutive audits at the same site on more consecutive occasions than permitted per of the GRMA Standards. Follow-up or monitoring audits conducted to verify corrective actions are not included in the count of consecutive audits.

4.2 The Operation is assigned to Food Safety Audit Program Coordinator (Scheduler) who will contact the Operation's Management Representative to schedule dates for the auditing activities. The Scheduler then coordinates the desired dates with the availability of the assigned Auditor pre-

selected by the Food Safety Program Accreditation Manager or designee. Often, this process takes several contacts between the Operation and the Auditor before dates for the auditing activities are mutually agreed upon.

4.3 The Scheduler sends the Scheduled Audit Form to the auditor when the dates are confirmed and entered into PJview.

4.4 The Scheduler then sends the Operation an Audit Scheduling Acknowledgement form (F-163fsi) or equivalent document for the Operation to sign and return by fax which indicates:

a. Operation's acceptance of the proposed audit dates and time;
b. Operation's acceptance of the proposed audit team whose background information is available upon request. The Operation has the right to object in writing to the appointment of any particular auditor or technical expert providing the objection is valid, i.e. employee of a competitor, personal differences, etc.
c. Operation's confirmation that all processes/procedures/activities will be ready by the proposed audit date.

4.5 The Scheduler then creates an Auditor Assignment Form (F-27fsi) and forwards it to the Auditor(s) after approval by relevant Customer Service Personnel.

4.6 Prior to the start of the onsite audit the Operation must have completed an Internal Audit and Management Review Meeting as according to the GRMA GMP Standard.

5 The Certification Audit (Initial Certification and Recertification Audits)

5.1 GRMA Auditors utilize the latest issue of the relevant GRMA Certification Program and NSF/ANSI 455 Standard to conduct GRMA audits but will not add additional standards or criteria. PJRFSI may seek additional guidance/interpretation from GRMA and/or Accreditation Bodies as needed.

5.2 PJRFSI undertakes the Certification Audit to verify the effectiveness of the Operation's GRMA System in its entirety to establish and ensure:

a. the effective interaction between all elements of the GRMA System; and
b. that the Operation has demonstrated a commitment to maintaining the effectiveness of the GRMA System and to meeting regulatory and customer requirements.

5.3 The Auditor is responsible for completing the Audit Workbook (WB-GRMA) and creating an Audit Plan using the F-184fs65-A Audit Plan Templates, which will be forwarded to the Operation at least one week in advance of the audit.

5.4 The Operation's senior management personnel, who have the appropriate authority to ensure that corrective actions will be implemented in response to any non-conformities found, are expected to attend the opening and closing meetings for all audit activity. In particular, the most senior operations manager onsite or their nominated deputy shall be available at the audit and attend the opening and closing meetings. All of the Operation's personnel are expected to fully assist the Auditor at all times.

5.5 At the time of the audit, the Operation is expected to have been in operation for at least three (3) months. For planned audits, the Operation shall ensure at the time of the audit that the production program includes all products and processes covered by the scope of the certification. When a significant production process cannot be observed during the audit, PJRFSI may elect to conduct a separate audit at a later time in order to audit that process.

5.6 The site shall supply the CB with background information at least one week prior to the site visit to ensure the auditor(s) is prepared to conduct an efficient audit. The information requested by the CB shall include, but is not limited to:

— organization chart;
— site plan;
— process flow diagram;
— list of products and technologies included in the scope of the audit;
— typical shift / schedule patterns;
— standard operating procedure index / table of contents;
— regulatory inspection history (past five years); and
— site regulatory registration.

5.7 The onsite audit consists of the following seven (7) stages:

1. Opening meeting to confirm the scope and process of the audit. The Auditor will utilize the Opening Meeting Agenda found in the Auditor Workbook (WB-GRMA).
2. Document review including a review of the documentation supporting each stage of the operation and GMPs.
3. Traceability challenge including a vertical audit of associated records of production.
4. Facility Tour and Inspection: to review the practical implementation of the systems and personnel interviews and observations of product changeover procedures.
5. Review of production facility inspection to verify and conduct further documentation checks.
6. Final review of findings by the auditor in preparation for the closing meeting.
7. Closing meeting to review audit findings with the Operation management personnel.

5.8 The Auditor should audit the Operation's processes where they occur. Audit evidence gathered through interviews should be verified by acquiring supporting information from independent sources, such as observations, records, and results of existing measurements. The names, job titles, and working shifts of those interviewed are to be recorded. The Auditor must record copious notes of conformity and nonconformity, including the nature and severity of any nonconformity. These notes serve as the basis for the audit report and will be submitted to PJRFSI with the audit package. Should objective evidence exist to support writing a nonconformity, the following format is used:

a. Citation of the requirement(s) not being met
b. Statement of nonconformity
c. Objective evidence observed that supports the statement of nonconformity

5.8. For multiple day audits, the Auditor must hold a daily wrap-up meeting with the PJRFSI audit team and the Operation's key personnel to discuss a summary of the findings of that day.

5.9. On the last day of the audit, the Auditor will hold a closing meeting using the Closing Meeting Agenda. During this meeting, the Auditor reviews the audit findings, including the non-conformities, with the Operation's senior management personnel. When discussing the findings, the Auditor should never comment on the likely outcome of the certification process.

5.10. At the close of the audit or within one working day of the last day of the audit, the Auditor provides the Operation with a written summary of the non-conformities discussed at the closing meeting.

6 The Use of Information Communication Technology (ICT) in the Audit Process

6.1 When GRMA issues a Temporary Audit Guidance Policy or in situations where travel by a CB to a specific location is restricted or unreasonable for either the Auditee or PJRFSI (that is, safety reasons, travel restriction, and similar), GRMA does allows the use of Information Communication Technology in the cGMP Manufacturing certification(s) audit to perform part or all of the audit virtually. ICT is the use of technology for gathering, storing, retrieving, processing, analyzing and transmitting information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others.

6.2 Prior to the virtual audit, PJRFSI determines the feasibility of using ICT methods with the site by sending the FS-228grma to the site to fill out and return. After a risk assessment is performed and approved by

the Food Safety Program Accreditation Manager or Designee then it is uploaded to the GRMAuditsphere.

6.3 The virtual audit button is marked in PJview and the remote activities will be designated on the F-27 Auditor Assignment Form. PJRFSI will assign GoToMeeting as the ICT platform or the Food Safety Program Accreditation Manager or designee approves the use of a client's preferred secure platform.

6.4 The Auditor will witness the production of the product(s), in entirety, live. Previously prepared recordings are not allowed. Videos of the Auditees' production processes will not be preserved for inclusion in the records or audit report, but the Auditor may reference their personal observations as audit evidence within the audit report.

6.5 If dead zone(s) are identified during the audit or pre-audit, PJRFSI will allow for the manufacturer to take a reasonable amount of time to fix the dead zone(s). Manufacturers will communicate their plan or provide a project update to PJRFSI within 2 weeks from identifying the dead zone(s). In limited situations, PJRFSI may determine if a recording is appropriate (such as access to a clean room environment, small dead zone). The time stamp of the video will be verified by the Auditor and noted in the report. Additionally, the Auditor will have the ability to seek additional verification of the video.

6.6 If a critical non-conformity and/or the number and level of non-conformities identified at the remote audit would result in the failure to achieve a certificate a new audit shall be completed onsite.

6.7 If the auditor is not able to complete the audit 100% virtually and/or an effective virtual audit cannot be conducted to the scope of the audit, then the audit should be terminated, and Headquarters notified. This must be documented in the WB-GRMA under the Virtual Audit report page. Upon notification, the Food Safety Accreditation Manager or designee will require all or part of the audit to be conducted onsite depending on the effectiveness of the virtual audit conducted.

6.8 If the auditor is able to complete the audit 100% virtually then the auditor a full audit report is completed along with the virtual audit page in WB-GRMA. The final audit report is then submitted to GRMA to review and 100% virtual/remote certification is issued.

7 Nonconformities and Corrective Actions

7.1 PJRFSI defines the following three levels of nonconformities:

a. Critical nonconformity - a nonconformance or condition which has produced, or may lead to a significant risk of an unsafe or hazardous product which may be harmful and puts the consumer at risk of serious injury or death.
b. Major nonconformity - a nonconformance other than critical that results in failure in one or more of the quality subsystems; or a combination of "minor" nonconformances, none of which on their own may be major, but which may together represent a major nonconformance and shall be explained and reported as such.
c. Minor nonconformity - a nonconformance where an element of GMP has not been fully met or does not adversely affect the performance, reliability, or use of a product; but on the basis of objective evidence does not meet the definition of a major nonconformance. Multiple minor nonconformances when considered collectively shall raise the category to a major nonconformance

7.2 Once the Auditor has made an observation during the audit, the Operation, if possible, may take corrective action during the audit. However, the Auditor's rating must reflect the condition or status prior to the Operation's corrective actions.

7.3 Regardless of the severity of findings, the Auditor is expected to complete the audit except when extreme circumstances would not allow him/her to do so.

7.4 The number and type of nonconformities found during an audit determine, according to GRMA guidelines: the grade achieved, whether certification will be granted, and the resulting audit

frequency. The findings, as well as the full audit report, are always subjected to a full technical review by PJRFSIs Technical Reviewer. If the technical review process results in any change in the findings, the Operation will be notified.

7.5 If during the course of the audit, the Auditor identifies findings which would result in non-certification:
a. a critical nonconformity; and/or
b. a combination of nonconformities whereby their number and type exceed the limits for certification as allowed by GRMA;

The auditor will contact PJRFSIs Food Safety Accreditation Manager/Technical Specialist or designee to discuss the findings and verify their severity. If findings are confirmed which would result in non-certification, PJRFSIs Food Safety Program Accreditation Manager or designee immediately suspends certification for a certified Operation.

A new certification audit is required when a facility scores a grade of D. This shall be a full certification assessment. For sites with critical nonconformances, an audit may be scheduled after close-out of the corrective actions, and the facility has demonstrated objective evidence to verify the completeness and effectiveness of the corrective action(s).

7.6 In the event of a failure to achieve or maintain certification, Operations, where required by their customers, must notify their customers of the circumstances and the Operation's intended corrective actions.

7.7 No certificate shall be issued until the Operation has corrected all major and minor nonconformities permanently or via a temporary solution as accepted by the Food Safety Accreditation Manager/Technical Specialist or designee.

7.8 For any nonconformity identified, the Operation must:
a. take corrective action to remedy the immediate issue; and
b. undertake a root cause analysis of the nonconformity; and
c. develop a corrective action plan and timeline to address the root cause.

7.9 The Operation must submit a corrective action plan for all nonconformities to the Auditor for approval within ten (10) business days after the receipt of the complete audit report. For an A or B grade, minor nonconformances a corrective action plan shall be submitted and accepted as closed. Corrective action against major nonconformances shall be closed with objective evidence to demonstrate the corrective action is in place and effective, before consideration for certification.

7.10 A monitoring audit is a required follow-up audit for a facility scoring a grade C and is optional for companies who have repeat minor nonconformance(s). A certification decision is made based on the objective evidence, or a determination is made as to whether the facility needs to be re-audited for compliance. For companies who achieve certification following the monitoring audit, the next full audit cycle shall be 12 months from date of the certification audit. For companies who receive initial certification nine or more months after the initial certification, the audit cycle may be extended to 18 months after the initial certification audit.

7.11 Any required onsite or virtual monitoring audit will primarily review the effectiveness of the corrective action taken for nonconformities. However, if new nonconformities are identified during the course of the revisit, these nonconformities must also be satisfactorily resolved before a certificate can be issued.

7.12 PJRFSI must notify the GRMA of any changes in an Operation's certified status and amends the Operation's record on the GRMA Directory accordingly.

8. Audit Reporting and the Certification Decision

8.1 The Auditor documents the results of the audit using the latest version of the GRMA Audit Report and following the latest GRMA guidelines for audit reporting. The report shall be written in English. The

report shall be translated to another language as appropriate for an additional fee.

8.2 Within ten (10) business days from the last day of the audit, the Auditor submits the preliminary audit report, audit notes, auditor working documents and PJRFSIs Food Safety Program Audit Support Assistant or designee to forward to a Technical Reviewer for a preliminary technical and grammatical review.

8.3 PJRFSIs Technical Reviewers are required to sign the F-71fs65 – Certification Personnel Statement of Availability prior to beginning a review of an audit report or package in order to confirm that they are impartial and free from any conflict of interest. Note: The Auditor who carried out the evaluation may not serve as the Technical Reviewer.

8.4 The PJRFSI Technical Reviewer conducts a preliminary technical and grammatical review of the audit package and documents the review on the Audit Report Review Form (F-67fs65-A), or an equivalent format. If needed the report is returned to the Auditor for clarification or revision. A record of reviews is maintained using the Audit Package Review Form (F-67fs65). The technical review process is to be completed within fifteen (15) business days.

By 30 business days from the last day of the audit, the Food Safety Audit Support Assistant sends the Operation the complete audit report including the grade. The Operation then has ten (10) business days to submit the corrective action plan for Minors and evidence of corrective actions for Majors with the auditor. After the auditor accepts the corrective action plan and any applicable evidence and closes the non-conformities, it is sent for Technical Review and Certificate Decision.

8.5 The Technical Reviewer has an additional ten (10) business days to complete the final technical review and documents the certification decision on the Audit Report Review Form (F-67fs65-A).

8.6 In cases where the Technical Reviewer rejects the package, s/he or the Food Safety Program Audit Support Assistant or designee is responsible for contacting the Auditor or Operation for resolution. As appropriate, the Technical Reviewer or other competent designee is responsible for providing any clarification or any additional training to the Auditor.

8.7 Certification of cGMP compliance is awarded to Operations who achieve the minimum compliance audit rating or greater with no outstanding non-conformities, meaning all nonconformities have been closed and verified by PJRFSI by onsite visit or by other appropriate means. However, regardless of the audit and/or certification outcome, PJRFSI will upload all audit reports to the GRMA Database.

8.8 Certification decision will be taken by PJRFSI's GRMA technical reviewer. If Certification is granted, PJRFSIs Food Safety Program Coordinator or designee notifies PJRFSIs Food Safety Program Assistant.

8.9 The Certificate Department creates a draft certificate conforming to GRMA requirements and obtains approval of the certificate from the Operation.

8.10 By 30 business days following the certification decision, PJRFSIs Food Safety Program Assistant or designee issues the certificate. Delivery of the Certificate and other documents may be delayed until all outstanding invoices have been paid by the Operation.

8.11 Ongoing Audit Frequency and Maintenance of Certification

i. In order to maintain Certification, an Operation is required to:
ii. attain the minimum compliance audit rating or greater; and
iii. ensure all nonconformities are corrected within specified timeframes.

8.12 Surveillance and Recertification audit due dates are based on the first day of the initial audit. All audits are due within the 12 months from the last audit.

8.13 Audits may be undertaken earlier than the due date in order to reset audit dates to allow combined audits with another program or to include a product produced at a different season. In these cases:

a. The audit report will detail the reasons why an audit has been brought forward.
b. The audit due date and certificate issuance/expiry will be “reset” based on the new audit date.

9 Conditions for Suspending or Withdrawing Certification

9.1 PJRFSI is responsible for initiating the suspension and withdrawal of the GRMA Certificate. PJRFSI suspends the GRMA Certificate where:

a. Critical nonconformities are detected at an audit; or
b. the Operation fails to have a required audit conducted according to their audit frequency except as justifiably allowed.
c. failure of the client to comply with PJRFSI’s terms and conditions and/or program rules
d. failure to full financial commitments (i.e. nonpayment of fees)
e. non-compliance to certification protocol
f. pending complaint investigation
g. major change to the site or its activities that require action
h. a site visit raises doubt to the validity for the current certificate
i. pending appropriate corrective action following an investigation into product recall and/or product withdraw
j. failure to notify PJRFSI of significant changes to the company see @Section 10.1

9.3 Where the Operation’s GRMA Certificate is suspended, PJRFSI’s Food Safety Program Accreditation Manager or designee immediately amends the Operation’s details on the GRMA database to a “suspended” status indicating the reason for the suspension and the date of effect. The Food Safety Program Accreditation Manager or designee will inform the Operation in writing and sent by certified mail, that their certificate has been suspended, the reasons for doing so and action required from the Operation including timescale in order to lift the certification.

9.4 Where PJRFSI has suspended an Operation’s GRMA Certificate , for the duration of the suspension, the Operation:

a. shall not represent itself as holding a GRMA Certificate ;
b. shall not use any goods, products, packaging, stationery, or other items that contain a GRMA Logo that may indicate the Operation holds a GRMA Certificate ;
c. shall notify any customers as required.

9.5 A certificate may be withdrawn by PJRFSI for the following reasons:
a. evidence that the site no longer complies with the cGMP requirements for dietary supplement, OTC, or cosmetic manufacture;
b. failure to implement adequate corrective actions within appropriate timelines;
c. evidence of falsification of records; and
d. persistent misuse of the Mark.

9.6 Where the Operation’s Certificate is withdrawn, PJRFSIs Food Safety Program Accreditation Manager or designee as appropriate immediately amends the Operation’s details on the GRMA Database to a “withdrawn” status indicating the reason for the withdrawal and the date of effect; and in writing;
a. informs the Operation that the GRMA Certificate has been withdrawn, the reason for such action, the date of effect, and in writing sent by certified mail;
b. instructs the Operation to return the Certificate ;
c. instructs the Operation to return any electronic copies of the GRMA Logo and comply accordingly with the GRMA Logo Guidelines;

9.7 PJRFSI’s Food Safety Program Accreditation Manager or designee shall require the client to
a. withdraw any claim that imply that the site has been certificated;

b. cease to advertise or use any certification mark issued by PJRFSI;
c. cease using the GRMA logo within 48 hours of certificate withdrawal or as agreed with GRMA.

10 Operation Requirement to Notify PJRFSI of Special Situations

10.1 The Operation is required to notify PJRFSI in writing and in a timely manner about any significant change(s), actual or intended, which include but are not limited to:
a. changes in legal or commercial status including changes in name;
b. changes in ownership;
c. changes in key managerial, decision-making or technical staff;
d. changes in the number of employees;
e. changes in location and/or number of sites;
f. damage to the site, e.g., damage by fire or natural disaster such as a flood;
g. changes to the physical building(s) and/or processing operations and equipment;
h. changes to the scope of certification (including expansion or reduction) in terms of products, processes, and/or facilities;
i. changes in the Operation's GRMA cGMP system or factors influencing the Operation's GRMA cGMP System; and
j. a /product safety incident as described in @10.2.

10.2 If at any time based on available information, the Operation becomes aware that concerns about actual or suspected threats to food/product safety exist which could require intervention to protect consumers' interests, Operation must notify PJRFSI immediately. Upon identification that a food/product safety event requires public notification (such as a Class I or Class II recall), the Operation shall, within 3 workings days of identifying the event, notify Perry Johnson Registrars Food Safety, Inc's Food Safety Program Accreditation Manager in writing and by phone call:

a. Business hours M-F, 9-5 EST: 248-358-3388
After hours and weekends: 248-648-0216
b. Email: foodsafety@pjrfsi.com;

10.3 Following notification of a food/product safety event by the Operation, PJRFSI will notify GRMA and any Accreditation Bodies, as necessary, within a further forty-eight (48) hours of any action PJRFSI intends to take to ensure the integrity of the certification.

10.4 When a certified Operation relocates its business premises, the Operation's Certificate is no longer valid until a successful Recertification Audit of the new premises as conducted.

10.5 A certified Operation must notify PJRFSI of any change in ownership with thirty (30) days of the effective change. When a certified Operation's ownership changes but key staff responsible for the GRMA System have been retained, PJRFSI confirms the continued effectiveness of the GRMA System within sixty (60) days of the change of ownership by means of a site audit and upon confirmation. This allows the Operation to retain the existing audit frequency status and certification number. If significant changes in key personnel have occurred with the change in ownership, PJRFSI shall complete a full Facility Audit and the Operation's audit frequency status will be based on this new audit activity.

10.6 PJRFSI reserves the right to conduct special audits during the course of the certification period, and as needed in response to changes/incidents as described above. Where such changes may affect the conformity of the product(s) and/or the Operation's GRMA cGMP System, PJRFSIs Food Safety Program Accreditation Manager or designee as appropriate determines whether the announced changes require further investigation and schedules a special audit as necessary.

10.7 The Operation must not promote products, processes, and/or facilities/sites which have not been covered in the scope of certification as audited and approved by PJRFSI. Unauthorized promotion will result in the withdrawal of the Certificate .

10.8 Where Operation fails to notify PJRFSI of any of the above changes, PJRFSI may accordingly suspend or withdraw, as deemed appropriate, the Certificate and reserves the right to retroactively invalidate the Certificate effective as of the date the change occurred.

10.9 If the site's recertification audit is due but the site is inaccessible due to COVID-19 restrictions, PJRFSI will conduct a risk assessment to determine the risk to product safety and the site's GRMA certification by extending the certificate. The Scheduler sends the site the FS-228 to fill out and send back. A two-hour risk assessment is then scheduled with an approved GRMA auditor. The auditor documents the information from the risk assessment information and conversation with the site on the FS-229.

10.10 PJRFSI will reissue the certificate with the extended expiration date and send an electronic copy of the certificate to the client. The Food Safety Program Coordinator or designee uploads the revised certificate and GRMA Risk Assessment Report Template to the GRMA Database The recertification audit can be conduct anytime during the extension period.

11 Promotion of GRMA Certification by Operation

When providing copies of any certification documents (certificates and audit reports) to interested parties, Operations shall reproduce those documents in their entirety or otherwise seek permission in writing from PJRFSI. Any additional requirements issued by PJRFSI regarding use of certification marks and promotion of certification. The proprietary names and logos of GRMA, any applicable accreditation bodies, and PJRFSI shall not be used by the Operation in any manner which could be misconstrued or defamatory to the respective parties and/or parties' brands. Any misuse of these proprietary names or logos by a certified Operation or an Operation seeking certification shall be reported to the interested parties and responded to with appropriate actions by PJRFSI.

12 Conditions for Change of Certification Body (Transfers)

12.1 A Certified Operation shall ensure it has a certification body appointed at all times. A Certified Operation may elect to cease being a client of a certification body (Former Certifier) and to have PJRFSI, as a New Certifier, undertake audits of its GRMA System.

12.2 Where a Certified Operation elects to transfer its Certificate to PJRFSI, PJRFSIs Food Safety Program Accreditation Manager or designee as appropriate undertakes a pre-transfer review of the Operation's Certification and completes the F-144fsi Transfer of Certification Body Checklist to:

a. confirm the Certificate is current, valid, and relates to the GRMA System so Certified;
b. confirm Certification under Former Certifier is not suspended or under threat of suspension or withdrawal.
c. confirm that the Operation submitted and corrective action plan and has submitted evidence of corrective action for all Major non-conformities issued by the Former Certifier;
d. review the Operation's Audit history (where the Operation can demonstrate such history to the satisfaction of PJRFSI by way of copies of Audit reports completed by any Former Certifier) and the impact of any outstanding Nonconformities.

12.3 Where a decision is made to proceed with Certification, PJRFSI:
a. Food Safety Program Accreditation Manager or designee signs off on the completed F-144fsi.
b. PJRFSI conducts the required audit which was described by the Former Certification Body within timelines consistent with the GRMA program audit frequency and certification requirements; and
c. issues a new Certificate under PJRFSI.

13 Disputes and Appeals

Disputes and appeals are handled in accordance with PJRFSIs Dispute/Appeal Procedure (SOP-10), which is available upon request.

14 Confidentiality

PJRFSI, including all auditors, administrative staff, Technical Reviewer, Impartiality Committee, and any other employee or contractor, ensures that all records, data, and information received during the execution of any audit activity remain confidential and the property of the Operation. Only with the Operation's authorization will PJRFSI release audit data to any entity other than GRMA except when mandated by law, statute, or the regulations of accreditation bodies. In the event that disclosure of such information is required by law or statute or accreditation body regulations, PJRFSI will disclose the information as required and inform the Operation of such disclosure in writing in a timely fashion.