THE
NATURE’S
BOUNTY
CO.

CONTRACT MANUFACTURING
QUALITY GUIDE AND REQUIREMENTS
FOR BULK ITEMS

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About The Nature’s Bounty Co.

The Nature’s Bounty Co., together with its affiliates (collectively “Nature’s Bounty”), is the leading vertically integrated manufacturer, marketer, distributor and retailer of a broad line of high-quality, value-priced vitamins, nutritional supplements and related products in the United States, with operations worldwide. Nature’s Bounty has manufacturing facilities in Canada, the United Kingdom, and the United States and are able to produce and package capsules, tablets, powders, liquids under a number of well-known brands as well as private label brands.

Nature’s Bounty offers products marketed under a portfolio of brands, including Nature's Bounty®, Puritan's Pride®, Holland & Barrett®, Sundown®, MET-Rx®, American Health®, SISU®, Solgar®, Ester-C®, Balance Bar® and other brands. In addition, Nature’s Bounty enjoys long-standing relationships with several domestic retailers, including Wal-Mart, Costco, CVS, Sam’s Club, Walgreens, Kroger and Target.

Nature’s Bounty's principal executive offices are located at 2100 Smithtown Avenue, Ronkonkoma, NY 11779 and its website is www.naturesbountyco.com.

Introduction

This Contract Manufacturing Quality Guide and Requirements for Bulk Items document (this “Guide”) has been developed to manage Contract Manufacturing suppliers (each a “Contract Manufacturer”) engaged by Nature’s Bounty.

Contract Manufacturer must comply with the procedures and requirements described herein to maintain its position as an approved supplier, as Nature’s Bounty only conducts business with the most consistent and reliable of suppliers. If you require clarification, or have questions about our policies and procedures, please contact Nature's Bounty's Supplier Management Office (SMO) at SupplierManagement@nbty.com.

All products manufactured by Contract Manufacturer hereunder (“Products”) will be subject to Nature’s Bounty’s Supplier Compliance Guide – Version F (the “Compliance Guide”), the terms of which are hereby incorporated by reference. All references to “Materials” in the Compliance Guide refer to Products manufactured by Contract Manufacturer and delivered to Nature’s Bounty hereunder. In the event of any conflict between this Guide and the Supplier Compliance Guide, the term most favorable to Nature’s Bounty shall prevail. Any Supplier Agreement with Nature’s Bounty will supersede this Guide in the event of a conflict.

Purpose

The purpose of this Guide is to ensure that no Contract Manufacturer is authorized to manufacture any Products until Nature’s Bounty is confident that its minimum standard specifications and requirements can be met. Prior to any production and/or shipment of Product, the Contract Manufacturer must have the required documentation and the included quality systems in place.
Scope

This Guide and requirements apply to any bulk product manufactured for Nature’s Bounty by a Contract Manufacturer.

Definitions

Contract Manufacturer: Any company that is contracted to manufacture items to the specifications and requirements of Nature’s Bounty.

Quality Assurance (QA): Nature’s Bounty department responsible for the overall safety, quality and consistency of all finished commercial goods.

Control Point (CP): Any point in production that helps to ensure the safety of the end product.

Critical Control Point (CCP): Any single control point where failure has the potential to affect Consumer Product Safety.

OPRP: Operational Prerequisite Program

SCAR: Supplier Corrective Action Report; A standard document issued to Contract Manufacturers when a non-conformance is found by Nature’s Bounty, and requires a response to assure corrective actions.

SOP: Standard Operating Procedure

DQ/IQ/OQ/PQ: Design, Installation, Operation, and Production Qualification

SQQ: Nature’s Bounty’s Supplier Quality Questionnaire document

Responsibility

It is the responsibility of the Contract Manufacturer to abide by the specifications and requirements herein.
Contract Manufacturer Requirements

1. Supplier Verification/ Qualification Program

1.1 Supplier Pre-Qualification / Onboarding Process

As part of Nature’s Bounty’s Supplier Management program, which is governed by Nature’s Bounty’s Supplier Management Office (SMO), an operational arm of its NY-based Global Procurement organization, Nature’s Bounty has partnered with Global Risk Management Solutions (“GRMS”) to provide Supplier Pre-Qualification and Risk Screening services as part of our supplier onboarding process.

Upon Nature’s Bounty’s direction, all Contract Manufacturers shall register with GRMS and provide all required documentation as part of Nature’s Bounty’s Supplier Onboarding Process. Required documentation includes:

- Form W9 (or W8 for international suppliers)
- Certificate of Insurance (meeting Nature’s Bounty’s minimum coverage requirements)
- Nature’s Bounty Global Anti-Corruption & Third Party Certification (signed and dated)
- Nature’s Bounty Supplier Compliance Guide – Version F (signed and dated)
- Nature’s Bounty Supplier Quality Questionnaire (completed in full, signed and dated)

Please note that:

- As part of Nature’s Bounty’s Supplier Management program, Contract Manufacturers are required to renew their enrollment in the GRMS Supplier Pre-Qualification and Risk Screening service on an annual basis.
- There is a nominal annual enrollment fee associated with Nature’s Bounty’s Supplier Pre-Qualification and Risk Screening process managed through GRMS. Suppliers will be obligated to pay this non-refundable fee directly to GRMS at the time of initial enrollment and each subsequent annual renewal. Nature’s Bounty will not receive any compensation from GRMS as part of your enrollment/re-enrollment.
- Suppliers will be able to view the results of the Risk Screening Report and will have the opportunity to correct any information they deem to be incorrect. THIS REPORT IS NOT A PERSONAL CREDIT CHECK – PERSONAL CREDIT CHECKS ARE NOT PERFORMED.

1.2 Raw Material Qualification

All vendors/suppliers whose materials are to be used in a Nature’s Bounty product must be approved by Nature’s Bounty and/or Contract Manufacturer. Contract Manufacturer shall maintain records of Contract Manufactured Product Formula Approval and shall provide such records to Nature’s Bounty upon request. Any ingredient changes to the approved formula must be communicated to Nature’s Bounty and approved in writing prior to implementation. All Contract Manufacturer supplied materials must have raw material specifications submitted to Nature’s Bounty’s Contract Manufacturing Quality Manager for pre-approval prior to use in Nature’s Bounty Products.
1.3 **Bulk Material Qualification**

Contract Manufacturers must provide Nature’s Bounty’s Quality Assurance or Global Supplier Team the following items: Pre-shipment Product samples, a copy of process batch records, test data and analysis, upon completion of the first production run. Pre-shipment samples should be sent by overnight priority as directed by Contract Manufacturing Quality Manager. Contract Manufacturers must receive formal approval from Nature’s Bounty’s Contract Manufacturing Quality Manager prior to commercial production.

1.4 **Finished Product Qualification**

Contract Manufacturers must provide Nature’s Bounty’s Contract Manufacturing Quality Manager the following items: Pre-shipment product samples, Process batch records, test data and analysis, upon completion of the first production run. Pre-shipment samples should be sent by overnight priority as directed by Nature’s Bounty’s Contract Manufacturing Quality Manager. ‘Contract Manufactured Product Formula Approval’ shall be followed for any type of changes.

2. **Site Risk Assessments**

2.1 **Initial Assessment**

Nature’s Bounty shall perform a Site Risk Assessment prior to fully qualifying a Contract Manufacturer and before Nature’s Bounty (or a Nature’s Bounty supplier) ships any type of materials to the Contract Manufacturer. This step ensures that Contract Manufacturer is capable of and has required quality management system in place to manufacture and supply Nature’s Bounty Products.

2.2 **NBTY Site Risk Assessments**

Nature’s Bounty reserves the right to perform site risk assessments at any Contract Manufacturing site on a regularly scheduled basis or as Nature’s Bounty deems reasonably necessary. Nature’s Bounty will make reasonable efforts to inform the Contract Manufacturer of the site to be assessed and the expectation to be met.

2.3 **Third Party Audits**

Nature’s Bounty requires that all Contract Manufacturers undergo an audit from a recognized and certified third party (registrar) on a yearly basis. Nature’s Bounty recommends that your audit be based on a GFSI certification standard, though it is not required. Customers of Nature’s Bounty may request third party audit information from Contract Manufacturers. Contract Manufacturers must release their most current audit report, including findings and remediation and submit to any additional audit requirements prescribed by Nature’s Bounty customers.
Contract Manufacturer must advise Nature’s Bounty immediately of any regulatory audits or assessments by Federal, State, or local authorities and report all communicated findings.

3. **Finished Product Information Form (FPIF)**

Contract Manufacturer will be provided with a copy of the FPIF, which needs to be completely filled in and sent back to Nature’s Bounty prior to production. As per the outlined requirements in the FPIF, Contract Manufacturer shall provide information regarding the following:

- Serving Size and Package Information
- Ingredient Information
- Required Documentation (COA, GMO Statement, HACCP, and Others)
- Formula Information and Country of Origin
- Nutritional Information
- Allergen Information
- Additional Regulatory Data
- GMO Status
- Kosher and Halal when applicable

4. **Specifications**

The Contract Manufacturer must verify that the materials provided by Nature’s Bounty conform to our current specifications. Materials found to be out of specification shall be reported to Nature’s Bounty prior to their use. If Contract Manufacturing Quality Manager does not provide a deviation, the lot will be rejected and returned.

Materials procured by the Contract Manufacturer: All materials must conform to Nature’s Bounty's specifications. Material deemed to be “Out of Specification” shall be rejected and shall not be processed. A rejection log and records shall be maintained by Contract Manufacturer.

5. **Label Specifications and Formulation Compliance**

Nature’s Bounty may provide all labels to the Contract Manufacturer for packaging. This includes the labels for the finished item, folding carton, master case, and display case (if applicable).

All packaging components will have a bulk number followed by five digits (Bxxxxx) that pairs the bill of material, labels, master case, display case and inner finished carton. Contract Manufacturers are required to verify that the bulk number (i.e. Bxxxxx) matches all components. If a discrepancy is noted, Contract Manufacturer must contact Contract Manufacturing Quality Manager for verification and final disposition (use as is, reject and destroy, reject and return).
6. **Initial Trial Samples/ Non-Commercial Pilot Runs**

In certain events, Nature’s Bounty may require the Contract Manufacturer to produce Trial/Pilot samples as requested by procurement. Causes for such testing and sampling may be, but are not limited to the following:

- New Nature’s Bounty product
- New Nature’s Bounty formula
- Change in production methods
- Change in raw material
- Change in raw material supplier(s)

The need for samples or pilot runs will be communicated to Contract Manufacturer by Nature’s Bounty.

7. **First Products and Samples/ Qualification Samples**

Finished product samples must be provided to Nature’s Bounty Quality Assurance organization to ensure Products manufactured for Nature’s Bounty are within established specifications. Each Contract Manufacturer is responsible for collecting and sending twelve (12) micro samples as stated in accordance with the microbiological monitoring systems and three (3) finished product samples, one each from the beginning, middle and end of production, and evaluation information to Nature’s Bounty QA for final approval and sample retention. Nature’s Bounty’s Contract Manufacturing Quality Manager will inform Contract Manufacturer of their approval status once test results are available. Contract Manufacturer shall maintain adequate records of samples provided to Nature’s Bounty.

8. **Certification of Compliance/ Manufacturing/ Analysis**

All Contract Manufacturers must provide a hard copy of the Certificate of Analysis (CoA) and Certificate of Compliance (CoC) with all Product shipments. Both certificates must also be signed and dated by a representative from the Contract Manufacturer.

CoAs must contain the following information relating to the materials shipped:

1. Contract Manufacturer’s name and lot number
2. Expiration date
3. Manufacturing and packaging dates
4. Relevant technical data
5. Physical, chemical, and microbiological data, and required by Nature’s Bounty’s specifications
6. Nature’s Bounty supplied raw materials name and lot number

It is required that the Contract Manufacturer provide an electronic copy of all relevant certificates to CertificateUpload@NBTY.com prior to our receipt of the shipment. Detailed instructions for the uploading process can be found in the Supplier Compliance Guide.
9. **Purchase Order**

All inbound deliveries must be accompanied by a Packing List that provides the following information:

a. Nature’s Bounty Purchase Order Number
b. Nature’s Bounty Part Number
c. Unit of Measure
d. Pallet Count and Quantity Breakdown
e. Manufacturer’s Name
f. Manufacturer’s Lot Number
g. Distributor/Supplier Name (if different than manufacturer)*

*Any distributor/supplier that is used in any part of the manufacturing of a Nature’s Bounty product must be approved by Nature’s Bounty prior to receiving delivery.

10. **Regulation and Compliance**

All Contract Manufacturers must have a clearly defined and documented GMP Program. This program/policy shall comply with the U.S. Code of Federal Regulations, Title 21 part 111 and all applicable laws of the country in which you are providing services to Nature’s Bounty. The Contract Manufacturer’s GMP program must address operating procedures, raw material procurement methods, quality management systems, laboratory maintenance and procedures, and detection/investigation of quality deviations. Products must be manufactured, held, and packaged in an environment that assures the identity, strength, quality, and purity. All Products shall be prepared, packed or held under sanitary conditions. Any Product that is manufactured or packaged outside of an environment that meets or exceeds FDA regulations is legally considered adulterated and shall be rejected.

Contract Manufacturers providing bars or other food item manufacturer must comply with FDA 21 CFR part 110.

11. **Quality Control Test Methods**

To assure consistent results, Nature’s Bounty requires all Contract Manufacturers use the same sampling and test methods/procedures as those used by Nature’s Bounty’s Quality Control. These methods/procedures are proprietary to Nature’s Bounty and may not be shared with any third party. Nature’s Bounty’s methods should be followed but equivalent methods may also acceptable at Nature’s Bounty’s sole discretion. Any discrepancies between the test findings of the Contract Manufacturer and Nature’s Bounty arising from differences in methods or procedures may be cause for Product rejection.
12. **Sanitary Operations for Facilities and Control**

Each of your facilities shall have a written cleaning program and an individual clearly responsible for the Sanitation Program. Program shall include a master cleaning schedule for periodic cleaning assignments and a housekeeping schedule for daily cleaning. Frequency of cleaning shall be determined by validation and verification to prevent the potential of contamination to the product contact surfaces. Micro (product contact) and bio luminous techniques are acceptable.

Your site shall also be equipped with adequate utilities and sanitary facilities and accommodations including but not limited to water supply, plumbing, sewage disposal, toilet facilities, hand washing facilities and rubbish and offsite disposal. Flow of people, materials and waste should be smooth, not interfering with each other’s flow to ensure safety requirement.

Building, fixtures, equipment, warehouse, material and product storage areas, and other physical facilities of your plant shall be maintained in a sanitary condition that is suitable for the activity and be kept in operational condition sufficient to prevent product from becoming adulterated.

13. **Pre-Operational Cleaning, Sanitation, and Startup**

Each facility shall have a written, validated procedure of cleaning all machines involved in the manufacturing of Nature’s Bounty Products. Verification of this task being performed must be kept in a log on site as well as any results from regular testing to ensure the prevention of contamination. Each of your facilities shall also have a written procedure for controlling the risk of contagions associated with the specific materials used in manufacturing Nature’s Bounty products.

In addition to regular Pre-Operation Cleaning Procedure, any machine being changed to manufacture different product or part of a different product must test negative to an ATP swab prior to its operation. Periodic Certificate of Analysis (COA) verification will be required.

14. **Allergen Control Program**

All Contract Manufacturers must have a documented allergen control program that identifies the source, handling and addresses the segregation /storage, cleaning and packaging for all allergens in the facility. The allergen control program must address material receiving, identification, storage, manufacturing, product changeover, maintenance, and site mapping. All cleaning must reduce the risk of allergen cross-contamination, which must be documented and verified to ensure the cleaning is adequate. The allergen control program should be specific to every manufacturing site and be updated on a regular basis or when a new allergen is introduced the site.
15. Integrated Pest Management

All Contract Manufacturers must have an effective and written Integrated Pest Management (IPM) program that strategically inspects, monitors, controls and reacts to pest management needs of the facility. Program should include diagrams of stations, service reports, activity recorded (monthly), chemical compound, usage report and observations noted. Each observation should have verifiable corrective action. Trend analysis of the pest activity should be maintained and reviewed.

16. HACCP (Hazard Analysis Critical Control Point)

It is required that a HACCP system must be in place for all products and/or processes. This system shall include but is not limited to a comprehensive and documented Hazard Risk Assessment, with a process flow chart for each product made for Nature’s Bounty. Process flow charts must be approved by Nature’s Bounty and must include all Critical Control Points (CCP) and Control Points (CP or OPRP), an effective date, revision date, and a Contract Manufacturer representative approval. Nature’s Bounty reserves the right to reject materials that were made using a new or changed process flow diagram that was not approved by Nature’s Bounty Contract Manufacturing Quality Manager.

17. Foreign Material Control System

All Contract Manufacturers shall conduct a risk assessment to identify potential foreign material hazards. This assessment must include the following:

17.1 Metal Detection

A Metal Detection program shall have a written procedure detailing metal detector requirements. Sensitivity settings must be set to detect a least 1.0 non-ferrous, ferrous and 1.5 stainless steel. Metal detector challenge should be tested routinely (at least twice per run, and at the beginning and end of each lot) to verify the metal detector is functioning properly. X-ray is also valid and acceptable device. All findings and corrective actions must be documented.

Magnets, Screens, Sieves and Filters should be used to minimize the risk of foreign material contamination when identified as an opportunity to reduce downstream contamination.

17.2 Glass and Brittle Matter

A glass and brittle matter program that addresses the prohibition of non-essential items from all processing, packaging and storage areas, a written procedure for breakage and an inspection process.
17.3 Wood

A program that prevents the use of wood (pallets, tools, or otherwise) in areas where the product or raw materials are exposed.

18. Microbiological Monitoring Systems

All Contract Manufacturers require implementing microbiological sampling program for microbiologically sensitive products.

Nature’s Bounty’s minimum requirements for Microbiological testing are performed on a composite of twelve randomly selected units throughout the lot. Samples shall be labeled with the time packaged and pallet number. Once testing is complete, results recorded on the Certificate of Analysis (CoA) for Nature’s Bounty.

If microbiological testing is to be conducted by Nature’s Bounty’s laboratory, then these samples will have to be shipped to designated point of contacts provided by Nature’s Bounty Contract Manufacturing Quality Manager.

Supplier must provide a hard copy Certificate of Analysis with every shipment. All Products shipped to Nature’s Bounty must have a CoA with each physical shipment and sent electronically to Certificateupload@NBTY.com.

19. Deviation Control

All Contract Manufacturers must have a documented Deviation Control Program and standard operating policy in place. All recognized deviations (planned and unplanned) shall be well documented. Any materials with a deviation from Nature’s Bounty standards or specifications must be communicated to Nature’s Bounty and approved prior to the material’s processing. Products that need a deviation shall be identified and quarantined. If Nature’s Bounty does not approve the Product’s deviation, affected lots will be held for final product and disposition by Nature’s Bounty Quality.

20. Environmental Control

All Contract Manufacturers must have a documented environmental monitoring program designed to detect adverse drifts in microbiological conditions in a timely manner that allows for meaningful and effective corrective actions. This program must be tailored to specific facilities and conditions used in the manufacture of dietary supplements and food products. Environment must be monitored and maintained within tolerances acceptable to preserve product quality.
21. **Product Defense and Security**

All Contract Manufacturers shall have a documented Product Defense and Security Program. Employee access shall be controlled to their work area only. GMP area and processing area entrances shall have controlled access. A comprehensive visitor policy shall be in place for any areas where Product is exposed. Parking lots and similar areas should be under recorded video surveillance.

22. **Maintenance**

Contract Manufacturer should have a written preventive maintenance program, schedules, and SOP in place. Program should be based on equipment supplier recommendations and statistical analysis of equipment performance. This program shall address but is not limited to makeshift repairs that pose a risk, leakage of lubricants, weld quality, corrosion, and documented post-maintenance inspections. New equipment or existing equipment undergoing major repairs or part/equipment changes shall go through the DQ/IQ/OQ/PQ process. Adequate records shall be maintained for any changes of equipment and machinery.

23. **Internal Inspection or Auditing Program**

All Contract Manufacturers must have a planned and routine internal inspection program for auditing and inspecting their facility against 21 CFR part 111, the cGMPs for dietary Supplements. Contract Manufacturers producing food products exclusively, must be audited or inspected using 21 CFR part 110 and FSSC 22,000 standards. A Corrective and Preventative Action (CAPA) process for recognizing and addressing trends in accordance with FDA regulations is required.

24. **Training Program**

All Contract Manufacturers must have a documented training program for temporary, part-time, and full-time employees that satisfy the competency needs for performing their activities. Appropriate refresher training shall be provided annually. Training should include all aspects of cGMP and product safety and quality.

25. **Finished Good Tracker**

Each Contract Manufacturer is responsible for providing daily production tracker to Contract Manufacturing Quality Manager at a mutually agreeable frequency. This data reflects daily totals of bulk inventory, packaging components received, Nature’s Bounty supplier supplied items, finished product lots, total shipped (with location) and any non-conformances encountered.

Below is an example of format the data can be in. Contract Manufacturer can use a system generated format for convenience if the data provided is in a usable format and contains all fields shown in the example:
Nonconformance data should include and raw material, packaging components, work in process and finished Product. Nature’s Bounty must approve any disposition. Contract Manufacturer must maintain records for audit verification and quantity reconciliation.

A separate nonconformance log must be maintained by Contract Manufacturer pertaining to issues from Nature’s Bounty supplied raw materials and bulk as well as Nature’s Bounty supplier supplied raw material and packaging material. Records should be maintained for each Nature’s Bounty disposition provided against each issue.

26. Product Identification and Lot Traceability

Raw Material Program must be documented and comprehensive to ensure identification and inventory control using FIFO (First in, First Out) program for all ingredients and finished packaging material.

No substitutions are permitted without prior approval from Nature’s Bounty Contract Manufacturing Quality Manager.

A Code Dating System: All Products must be coded using a pre-approved Nature’s Bounty dating format unless otherwise designated by Nature’s Bounty. Correct, legible lot codes and expiration dates applied on the labels, inner finished cartons, case cartons, and master cases. 

- Contract Manufacturers shall adjust lot number for each packaging run of the same batch so that Nature’s Bounty can distinguish when testing is required. For example, the first packaging run would be lot # 123456 -01 and the second 123456-02 and so on.
- The Case label must include product number, lot number, expiration date (MM/YY), description, case quantity, inner packs, and unit size (count / bottle) Case container UPC must be in scanning bar code format.
27. **Raw Material Storage**

All raw materials must be stored in conditions suggested by the raw material supplier that meet their individual requirements for safe and sanitary retention. Under no circumstances will expired materials be used in the manufacturing process.

28. **Finished Good Storage and Shipping**

All Contract Manufacturers must have a documented program in place to ensure the safe handling of Nature’s Bounty Products during storage, loading and transit process. Product storage must have temperature, humidity control and mapping studies available upon request. These programs must also make provisions for handling finished Products that are in need to re-work or repacking.

Finished Products must be shipped using clean and sanitary transportation, using the recommended temperature control equipment when required. Trucks must be sealed and assigned a seal number prior to shipping. Seal numbers must be recorded and maintained by the Contract Manufacturer.

29. **Non-conformance Management**

A documented procedure must be in place to ensure that all non-conforming Products are controlled and prevented from unintentional use and shipment. Nature’s Bounty shall be notified of all non-conforming Product received, processed or packaged. A detail list shall be provided to Nature’s Bounty’s Contract Manufacturing Quality Manager on a daily production tracker provided by Contract Manufacturer. Non-conforming products posing a consumer safety risk must be physically tagged and held in a secure area.

Nature’s Bounty conducts inspections on each received shipment. Any nonconformance found by Nature’s Bounty will result in Supplier Corrective Action Report (SCAR). All finished Products, works in process, raw materials, and packaging materials that do not comply with specifications, are discontinued, out of code, expired, or infested or damaged shall go through the HOLD process to ensure that proper sampling, testing, documentation, disposition, and corrective action are completed by responsible parties. The HOLD process from initiation to notifying the Contract Manufacturer shall be completed within eight (8) business hours. All HOLD notifications must have disposition within sixty (60) days.

In the event that Nature’s Bounty receives multiple customer complaints resulting from a nonconformity attributed to the Contract Manufacturer (whether previously noted or not), a SCAR may be issued at that time.

In the event that materials are received directly from a Nature’s Bounty qualified supplier and does not meet Nature’s Bounty specifications, the Contract Manufacturer must communicate this nonconformance to Contract Manufacturing Quality Manager as soon as possible. Nature’s Bounty will follow up with the supplier and initiate a SCAR when appropriate.
30. Supplier Corrective Action Report/Response (SCAR)

All Contract Manufacturers must have a documented supplier Corrective Action Response (SCAR) and Verification program. This program must ensure that Contract Manufacturer performs root cause analysis, and provides corrective actions and preventive actions in a timely manner, which focuses on improvement and reduction or elimination of nonconformity reoccurrence. Failure to provide prompt and adequate corrective actions will impact Contract Manufacturer’s quality score card or rating.

31. Crisis Management/Product Recall and Withdrawal/Mock Recall

Crisis Management Program: All Contract Manufacturers must have a documented Crisis Management Program in place to assess potentially serious incidents, including but not limited to recalls. Program should describe the processes for identifying a crisis, opening lines of communication, withdrawing or recalling product, emergency contacts for the organization, and final disposition of effected products.

Mock recall: The Contract Manufacturer’s recall procedure shall be tested bi-annually for Nature’s Bounty products through a mock recall plan. Recall shall be performed one level up and one level down encompassing packaging, raw materials and finished products. Records shall be maintained on how long (time) the process needed to cover the amount of items (packaging, raw materials and finished products) accounted for (in percentage).
Nature’s Bounty Contacts

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References

SOQ (http://vendor.naturesbountyco.com/terms/)

GFSI: FSSC 2200 Standards (http://www.fssc22000.com/downloads/PartIversion32013.pdf)

NBTY Supplier Compliance Guide – Version F (http://vendor.naturesbountyco.com/terms/)

FAARP Guide for Allergen Control (http://farrp.unl.edu/c/document_library)

FDA Title 21 Sections 110, 111, 210, 211 (http://www.accessdata.fda.gov)

Contract Manufacturing Product Formula Approval: COGN-013

Finished Product Information Form 12. 12