CONTRACT MANUFACTURER PRE-APPROVAL QUESTIONNAIRE

Please complete the following information and return to _____ as soon as possible. All details provided to us will be treated as confidential and only used to support the approved Contract Manufacturer requirements of our food safety program.

ADMINISTRATIVE INFORMATION

Corporate Name: _____

Division Name: _____

Company Website: _____

Facility Address: _____

Mailing Address: _____

QUALITY CONTACT INFORMATION

Name and Title: _____

Telephone Number: _____

Fax Number: _____

Email: _____

DESCRIPTION OF PRODUCT(S) TO BE MANUFACTURED AT THIS FACILITY

(To be Filled Out by Brand Owner) - Product Name(s) and Description(s):_____

_____

(To be Filled out by Contract Manufacturer) – List of Products Produced/Production Capabilities in the Facility:

_____

_____

MANAGEMENT COMMITMENT AND RESPONSIBILITY

DO YOU HAVE:	YES	NO	N/A	ADDITIONAL INFORMATION
A written management food quality safety/policy statement?	☐	☐	☐	
An upper management organizational chart?	☐	☐	☐	
A designated Certified Food Protection Manager (CFPM)? License?	☐	☐	☐	

QUALITY AND FOOD SAFETY MANAGEMENT SYSTEM

DO YOU HAVE:	YES	NO	N/A	ADDITIONAL INFORMATION
A Quality and Food Safety Manual?	☐	☐	☐	
A written procedure for document control?	☐	☐	☐	
A written procedure for keeping and maintaining records?	☐	☐	☐	

PERSONNEL AND TRAINING

DO YOU HAVE:	YES	NO	N/A	ADDITIONAL INFORMATION
Written job descriptions for all employees?	☐	☐	☐	
A defined training program?	☐	☐	☐	
An established visitor policy?	☐	☐	☐	

INFRASTRUCTURE

DO YOU HAVE:	YES	NO	N/A	ADDITIONAL INFORMATION
A documented preventative maintenance program?	☐	☐	☐	
A documented pest control program?	☐	☐	☐	
Safety Data Sheets (SDS) for all pesticides and hazardous chemicals used or stored on site?	☐	☐	☐	
Written cleaning procedures outlining methods, equipment, and areas for cleaning?	☐	☐	☐	

PRODUCT REALIZATION

DO YOU HAVE:	YES	NO	N/A	ADDITIONAL INFORMATION
Written Standard Operating Procedures (SOPs) for the production floor that follow MDA/MDH/FDA/USDA manufacturing control Current Good Manufacturing Practices (cGMPs)?	☐	☐	☐	
A defined procedure for the release of finished products according to specifications?	☐	☐	☐	
A master list of finished product specifications?	☐	☐	☐	
Written SOPs for formulation procedures and product development processes?	☐	☐	☐	
Written SOPs for identifying and controlling non-conforming products, raw materials, ingredients and packaging?	☐	☐	☐	
Written SOPs for rework (out of specification finished products that can be reprocessed in part or total)?	☐	☐	☐	
A process/procedure for controlling and storing hazardous chemicals?	☐	☐	☐	

PURCHASING AND PROCESS CONTROLS

DO YOU HAVE:	YES	NO	N/A	ADDITIONAL INFORMATION
A defined procedure for vendor/supplier evaluation and approval?	☐	☐	☐	
Written specifications for all raw materials/ingredients?	☐	☐	☐	
Written specifications for all packaging and components?	☐	☐	☐	

VALIDATION AND VERIFICATION

DO YOU HAVE:	YES	NO	N/A	ADDITIONAL INFORMATION
A system to identify raw materials, ingredients, works in progress and finished goods?	☐	☐	☐	
A defined food defense and biosecurity plan?	☐	☐	☐	
A defined allergen control program?	☐	☐	☐	
List all allergens present in the facility	☐	☐	☐	

FOOD SAFETY PLAN

DO YOU HAVE:	YES	NO	N/A	ADDITIONAL INFORMATION
An accredited HACCP (Hazard Analysis and Critical Control Point) or similar food safety plan in place?	☐	☐	☐	
Does the plan include:	☐	☐	☐	
A defined food safety team?	☐	☐	☐	
Process flow diagrams?	☐	☐	☐	
Hazard Identification, such as HACCP?	☐	☐	☐	
Preventive controls?	☐	☐	☐	
Verification and validation activities?	☐	☐	☐	
Corrective actions?	☐	☐	☐	
Recall plan?	☐	☐	☐	

CERTIFICATIONS AND REGISTRATIONS

DO YOU HAVE:	YES	NO	N/A	ADDITIONAL INFORMATION
Safe Quality Foods (SQF) or other Third Party FSMA certification?	☐	☐	☐	Please attach example
Have you recently been audited? If so, please provide a copy of the most recent audit	☐	☐	☐	Please attach copy of audit report and any Form 483s
MDH/MDA License?	☐	☐	☐	Please attach copy of license
Organic?	☐	☐	☐	Please attach copy of certification
Non-GMO?	☐	☐	☐	Please attach copy of certification
cGMPs – Current Good Manufacturing Practices?	☐	☐	☐	Please attach example
Bioterrorism Act – Food Facility Registration?	☐	☐	☐	Please provide registration number
Additional Certifications?	☐	☐	☐	Please attach copies

CONTRACT MANUFACTURER PRE-APPROVAL QUESTIONNAIRE

This form must be completed by the Contract Manufacturer before pre-approval can be granted.

I hereby declare, to the best of my knowledge, the answers within this questionnaire are true and accurate. I understand this information will be used in the Client Contract Manufacturer Evaluation process. I understand pre-approval does not grant full approval and further actions will be taken to complete the Contract Manufacturer approval process.

FORM COMPLETED BY:

Name: _____ Phone: _____

Position: _____

Signature: _____ Date: _____

Please return the completed form to: _____

……

For internal use only:

Contract Manufacturer Pre-Approval

☐ **GRANTED** / **REJECTED** ☐

Name: _____ Position: _____

Signature: _____ Date: _____