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APPLICATION FOR THIRD PARTY CERTIFICATION BODY ACCREDITATION UNDER THE FOOD & DRUG ADMINISTRATION (FDA) FOOD SAFETY MODERNIZATION ACT (FSMA)

For IAS Accredited Organizations, please list Accreditation No.: _____

New accreditation

For new accreditation request, a copy of the applicant's management system documentation must be submitted with a completed and signed application for assessing the compliance with (i) IAS Accreditation Criteria for Third-party Certification Bodies AC782; (ii) ISO/IEC 17021-1 or ISO/IEC 17065; (iii) other relevant ISO/IEC 17021 series of standards (if ISO/IEC 17021-1 option is followed); and (iv) other related regulatory/specification requirements (complete entire application)

Annual Renewal

(For renewal, complete entire application)

Scope Extension

(For scope extension, complete fill out entire application)

Company Name Change

1. NAME OF APPLICANT/ACCREDITED CERTIFICATION BODY (CB NAME) _____
 (exactly as it should appear on IAS listing)

2. HEADQUARTERS ADDRESS _____
 Address (exactly as it should appear on IAS listing) _____ City _____
 _____ State/Province _____ Zip/Postal Code _____ Country (if other than U.S.A.) _____

3. MAILING ADDRESS _____
 Address _____ City _____
 _____ State/Province _____ Zip/Postal Code _____ Country (if other than U.S.A.) _____

4. TELEPHONE NO. _____ FAX No. _____

5. E-MAIL ADDRESS _____ WEB ADDRESS _____

6. Name and title of certification body's technical representative _____
 Name _____ Title _____

Address of technical representative _____

Phone number _____ Fax number _____ E-mail _____

7. For new or transfer applicants, within the past five years have any of your accreditations been revoked, withdrawn, placed on suspension, and/or removed from listing? If "yes" please explain on a separate page. No Yes

8. For Annual Renewals, please answer the three questions below. If you answer "yes" to any of the questions, please explain on a separate sheet and/or include appropriate supporting documentation.

a. Since the last time your company applied for IAS accreditation, have there been any changes in ownership or in key management, technical, or quality assurance personnel? No Yes

b. Since the last time your company applied for IAS accreditation, have there been any major changes in the documented management system? No Yes

c. Are you aware of any complaints, from your company's clients or others, about the services covered by this application? No Yes

By signing, the applicant agrees that all the information presented in the above application is true and correct, and to abide by the CONDITIONS FOR APPLICATION listed on page 2.

 Authorized Signature for Applicant

 Name of Signer (type or print)

 Title and Date

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CONDITIONS FOR APPLICATION

- a. As a condition of the accreditation, the applicant acknowledges that the International Accreditation Service, Inc. (IAS), staff or authorized representative(s) may conduct unannounced assessments of the facilities of the applicant, or other facilities where the applying agency conducts certification activities under this application, to verify compliance with the listing and applicable rules of procedure.
- b. Within 30 days of mailing of written demand by IAS, applicant shall reimburse IAS for all expenses related to accreditation. Reimbursable expenses include, but are not limited to, travel expenses and staff time.
- c. A certification body/agency accreditation does not imply any guarantee or warranty, express or implied and including but not limited to any warranty of merchantability or fitness for any particular purpose, of any services inspected or certified by the applicant, or any guarantee or warranty of any nature by IAS concerning any certification activity conducted by the applicant. Applicant agrees that it shall have no cause of action or claim against IAS, International Code Council (ICC), or any of their affiliates, parent, or brother or sister corporations or their Successors-in-Interest or assigns, or the officers, directors, members and employees thereof (collectively, the "Indemnitees"), arising in any manner from any denial of this application or from any accreditation given pursuant to this application, whether or not such accreditation is or is not subject to any conditions. Applicant agrees to hold the Indemnitees harmless, and to protect, defend and indemnify them, with respect to any claim, liability, demand, action, judgment, proceeding, costs, damages and expenses (including attorneys' fees) whether for personal injury, wrongful death, property damage, or any type of injury or damage whatsoever, arising from: (i) the application and accreditation; (ii) any certification services of any nature provided by the applicant; (iii) the use of any service of any nature offered by the applicant, or the use or operation by any person of any product inspected or certified by the applicant, whether related to the matters set forth in the first sentence of this paragraph or otherwise; or (iv) the reference to or reliance upon, actual or asserted, any certification or approval given by the applicant or any inspection services rendered by the applicant including but not limited to the results of any certification or inspections conducted by the applicant. California law shall apply to the interpretation hereof. If any part or portion of this paragraph, or any application thereof to particular facts, should be determined invalid, the provisions hereof shall be severable so as to achieve for the Indemnitees the maximum legal application. If this application relates to a branch certification agency listing or a renewal of an existing accreditation, the provisions of this paragraph shall apply from the date of the first granting of the branch certification body listing, whether upon application or without application by applicant or a predecessor and regardless of: (i) intervening modifications of said listing or modifications pursuant to any application for renewal; (ii) any prior change in the number assigned to the listing; (iii) any prior change in ownership rights in or rights to said listing, or any branch certification body listing, whether one or more, since the granting of said first branch certification body listing.
- d. By signing this application, the applicant is giving IAS prior consent to perform any reporting or notification necessary to fulfill its obligations under the FDA Rules for this accreditation program.
- e. In consideration of the processing of this application, the applicant agrees to abide and be bound by any conditions attached to any listing or renewal thereof issued pursuant to this application, or any later amendment of said listing or renewal, the Rules of Procedure for Third-Party Certification Body Accreditation, which by this reference are made a part hereof, the Accreditation Criteria for Third-Party Certification Bodies, which by this reference is made a part hereof, and any additions, deletions, or changes to such Rules or Accreditation Criteria hereafter adopted. In agreeing to abide and be bound by the Rules of Procedure and the Accreditation Criteria for Third-Party Certification Bodies, applicant understands that the failure to do so may result in the revocation, suspension or modification of accreditation issued pursuant thereto in accordance with the terms of the Rules of Procedure.

Authorized Signature for Applicant _____

Name of applicant/accredited Certification Body _____

Date _____

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9. Instructions for new application or scope extensions.

9.1 Instructions: To provide a proposed scope of accreditation in the table below, please review and where requested, mark the relevant the SCOPE APPENDICES in this application:

Table: Proposed Scope of Accreditation

- New applicants and scope extension requests: List the proposed scope of accreditation being sought in the table below.
- Transfer applicants: If currently accredited by another accreditation body and requesting a transfer, please attach your current certificate and scope of accreditation.

(Note: Applicants seeking transfer from another accreditation body must have a valid accreditation otherwise must apply as a new applicant)

Accreditation Standard used	Category	IAS Scope codes <i>Note: Please see Appendix A below for a list of the applicable IAS Categories/Scopes.</i>	Total number of organizations certified in each Category <i>(mandatory to complete)</i>
Example of proposed scope of accreditation			
ISO/IEC 17021-1:2011	Human Food Category 1	➤ Scope: CFR 21, Chapter I, Subchapter B, parts 108, 110, 113, 114,	1 (pilot)

10. Number of auditors and staff (include full time/other):

Head Office			Branch Location		
Auditors	Staff	Scope	Auditors	Staff	Category/Scope

11. Number of Organizations and Certifications granted

Date certification granted	Name of certified organization	Category and Scope

12. Countries into which accredited certificates are issued.

Country Name	# of Certificates Issued in Specified Country	Categories of certificates issued
1. Mexico	1	e.g. Category 2, 5. 6 (Human Food), Category 2 (Animal Food)
2.		
3.		
For additional countries please attach separate sheet.		

13. Countries where the CAB has personnel that perform any key certification activities (e.g., assignment of auditors, issuance of certificates).

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Country Name	# of Remote Personnel Active in Specified Country	Type of Activities Performed
1.		
2.		
3.		
For additional countries please attach separate sheet.		

14. Supplemental Information

Instructions: New Applications – This form must be fully completed.
Annual Renewals – Either indicate no change, or provide current information (*Note: Renewals are annual certificate/administrative activity not reassessment activity*).
Scope Extensions – Only include the NEW scope items requested for addition to your existing accredited scope.

Program Information	Response
Provide the month and year that your organization began offering these certification services (this information may be identical to Question 10).	
List any existing accreditations held by your company that apply to the disciplines for which accreditation with IAS is being sought [please attach the certificate(s) of accreditation].	
Description of the liability insurance held (if this information is available elsewhere, please provide the documentation for review).	
List any additional standards and/or regulations that must be complied with in the industry for which you are seeking IAS accreditation.	
How is information about your certifications issued or made available (examples: published directory, on-line data base). If this information is available elsewhere, please provide the documentation or copy of the current published directory or a link to the on-line data base.	
Identify the physical locations from which services are provided (examples include, but are not limited to: branch locations, laboratory facilities, inspection offices, and joint venture/partner locations). If there are several offices, this information may be submitted in tabular form as an attachment. This information must also identify what services are provided by each location. Note: Additional application must be completed for any "key activity" locations.	
Provide a list of organizations to which key activities are outsourced. The information provided should also describe what specific activities are outsourced to each organization identified.	
Key Personnel (not including Auditors)	

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How many personnel are employed by the applicant/accredited/transfer organization?	Discipline	Full Time	Part Time	Contract
	Managerial/Professional:			
	Technical/Auditing:			
	Quality:			
	Administrative:			
Total Number of Personnel:				
Technical Resources Provide a brief description of the key technical resources of the organization, such as testing laboratories or inspection services. The description should include educational backgrounds, experience, professional licenses, certifications, and training of the personnel that support the technical resource(s).				
<p>Attach the following documents when submitting this application (not required for renewals):</p> <ul style="list-style-type: none"> • Management system documentation, e.g., system manual, operating procedures, work instructions, etc. • Organizational chart identifying the key positions • Example of the certificates issued to clients with certification Mark(s) currently used by each discipline • CVs, resumes, or other similar information that describes the educational background, experience, licenses, registrations, certifications, or other documentation that substantiates qualifications of individuals in key positions <ul style="list-style-type: none"> ➤ <u>For applicants and transfers:</u> List of auditors including scope of auditing for these individuals. ➤ <u>For extensions:</u> Resumes of proposed internal/external auditors for the scope of extension requested. 				

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Appendix A

Accreditation Scopes

This list of scopes of accreditation below is based on the current scopes listed in this Program.
Please indicate in the right column the category for which accreditation is desired.

(For Scope Extension, please only include the NEW scope items requested for addition to your existing accredited scope.)

Type of food	Category Number	Category Title	Food products/processes included	Scopes mapped to FDA regulations (As applicable, this is not an exhaustive list)*	Tick as appropriate
A. Food for Humans	1	Low acid and Acidified foods	a) Thermally processed low-acid foods packaged in hermetically sealed containers b) Acidified foods	CFR 21, Chapter I, Subchapter B, parts 108, 110, 113, 114, 117, 145, 155	
	2	Baby (Infant and Junior) Food Products Including Infant Formula	a) Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications b) Infant Formula	CFR 21, Chapter I, Subchapter B, parts 105, 106, 107, 108, 110, 113, 114, 117	
	3	Dairy products	a) Milk and cream b) Cheeses and related cheese products c) Frozen desserts (except water ices) d) Irradiation in the production, processing and handling of food	CFR 21, Chapter I, Subchapter B, parts 110, 131, 133, 135, 179, 117, 108, 113, 114	
	4	Dietary supplements and food for special dietary use	a) Foods for special Dietary Use b) Dietary supplements that present a significant or unreasonable risk c) Dietary supplements - new dietary ingredients d) Irradiation in the production, processing and handling of food	CFR 21, Chapter I, Subchapter B, parts 105, 110, 119, 179, 190, 111, 117	
	5	Fisheries/Seafood products	a) Fish and Fishery products b) Fish and shellfish	CFR 21, Chapter I, Subchapter B, parts 110, 123, 161, 112, 121, 108, 113, 114, 117	
	6	Fresh produce or Fresh fruits and vegetable	a) Fresh Fruits b) Fresh vegetables	CFR 21, Chapter I, Subchapter B, parts 112, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rules) for covered produce under this rule.	
	7	Processed Fruit and Fruit products	a) Canned fruits b) Fruit pies	CFR 21, Chapter I, Subchapter B, parts	

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			c) Fruit butters, jellies, preserves, and related products d) Irradiation in the production, processing and handling of food	110, 145, 150, 152, 179, 108, 113, 114, 117, 120.	
8	Fruit or Vegetable juices, other beverages including water		a) Canned fruit juices b) Vegetable juices c) Beverages d) Processing and bottling of bottled drinking water e) Irradiation in the production, processing and handling of food	CFR 21, Chapter I, Subchapter B, parts 110, 146, 156, 165, 179, 129, 108, 113, 114, 117, 120.	
9	Vegetable and Vegetable products		a) Canned vegetables b) Frozen vegetables c) Irradiation in the production, processing and handling of food	CFR 21, Chapter I, Subchapter B, parts 110, 155, 158, 108, 113, 114, 117, 179	
10	Shell Egg and egg products		a) Shell eggs b) Eggs and egg products c) Irradiation in the production, processing and handling of food	CFR 21, Chapter I, Subchapter B, parts 115, 118, 160, 117, 65 FR 76092 (shell eggs), 179	
11	Starch products		a) Bakery products b) Cereal flours and related products c) Macaroni and noodle products	CFR 21, Chapter I, Subchapter B, parts 110, 136, 137, 139, 108, 113, 114, 117	
12	Food Additives (Direct and Indirect)		a) Food additives b) Food additives permitted for direct addition to food for human consumption c) Secondary direct food additives permitted in food for human consumption d) Indirect food additives: General e) Indirect food additives: Adhesives and components of coatings f) Indirect food additives: Paper and paperboard components g) Indirect food additives: Polymers h) Indirect food additives: Adjuvants, production aids, and sanitizers i) Food additives permitted in food or in contact with food on an interim basis pending additional study j) Sweeteners and table syrups k) Food dressing and flavorings	CFR 21, Chapter I, Subchapter B, parts 110, 170, 172, 173, 174, 175, 176, 177, 178, 179, 180, 168, 169, 109, 117	

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			l) Irradiation in the production, processing and handling of food m) Unavoidable contaminants in food for human consumption and food-packaging material		
	13	Nuts and Edible Seed Products	a) Cacao products b) Tree nut and peanut products	CFR 21, Chapter I, Subchapter B, parts 110, 112, 163, 164, 117	
	14	Food Ingredients and (food) substances	a) Prior-sanctioned food ingredients b) Substances generally recognized as safe c) Direct food substances affirmed as generally recognized as safe d) Indirect food substances affirmed as generally recognized as safe e) Substances prohibited from use in human foods f) Irradiation in the production, processing and handling of food g) Unavoidable contaminants in food for human consumption and food-packaging material	CFR 21, Chapter I, Subchapter B, parts 110, 181, 182, 184, 186, 189, 109, 117, 179	
	15	Fats and Oils	Margarine	CFR 21, Chapter I, Subchapter B, parts 166, 110, 117, 108, 113, 114	
Type of food B. Animal Food	Category Number	Category Title	Food products/processes included	Scopes mapped to FDA regulations (As applicable, this is not an exhaustive list)*	
	I	Low Acid Canned Food	a) Thermally processed low-acid foods packaged in hermetically sealed containers	CFR 21, Chapter I, Subchapter E, part 108, 113, 507, 509, 556, 570, 573, 579, 582, 584, 589.	

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	II	Animal Food	a) <i>Animal food</i> means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients	CFR 21, Chapter I, Subchapter E, part 507, 509, 556, 570, 573, 579, 582, 584, 589	
	III	Medicated Feed	(a) A medicated feed, in addition to providing nutrients, is a vehicle for the administration of a drug, or drugs, to animals.	CFR 21, Chapter I, Subchapter E, 225, 507, 556, 509, 570, 573, 579, 582, 584, 589	