APPLICATION FORM AND QUESTIONNAIRE FOR THE ACCREDITATION OF THIRD PARTY CERTIFICATION BODIES UNDER THE FDA – FOOD SAFETY MODERNISATION ACT (FSMA)

RESET FORM

Part A – Application Details

1. Name of Applicant *(legal entity or parent organization name)*:	**FOR OFFICIAL USE ONLY** Client Reference Number: _____
2. Applicant's Address:	**3. Contact Information** **Tel. No.:** **Fax No.:** **Website:**
4. Name of Certification Body Seeking Accreditation: *(if different from 1, above)*	**5. Address of Certification Body Seeking Accreditation:** *(if different from 2)*
6. Name & Email Address of Person in Charge of Certification Body:	**7. Name & Email Address of Person Responsible for Technical Management:** *(If there is more than one such person, please add relevant contact information as appendices)*
8. Name & Email Address of Contact Person:	**9. Name & Email Address of Financial Manager of Certification Body:**

10. Please select the appropriate accreditation request:

☑ 1st Accreditation ☑ Transfer of Accreditation ☑ Extension of Scope

11. Please select the applicable FDA Scheme(s) for which accreditation is being sought*:

☑ Third Party Programme (TPP) ☑ Foreign Supplier Verification Program (FSVP)

☑ Voluntary Qualified Importer Program (VQIP)

☑ Other (Please Specify):_____

**NB: Additional information will be required in Part B, Section B, 4.0 of this application form.*

12. Please select the supplementary certification standard for which accreditation is being sought*:

☑ ISO/IEC 17021-1:2015 ☑ ISO/IEC 17065:2012 ☑ No supplementary standard

☑ Other (Please Specify):_____

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We hereby apply for accreditation for the certification activity(ies) detailed in the attached documents.
On the granting of accreditation, we agree:

a) to abide by the applicable requirements stated in **21 CFR Subpart M** and _____ *(List all standard(s) that apply)*;
b) to abide by all the statutory requirements of the field of management systems certification for which accreditation is requested;
c) to abide by the requirements of JANAAC's accreditation programme;
d) to pay the required annual accreditation fees;
e) that accreditation may be withdrawn, suspended or reduced if we fail to comply with the foregoing, subject only to the rights of appeal set out in the relevant standard and Subpart M.

We acknowledge the fact that the application fee (paid for the initial assessment) is non-refundable

		February 20, 2025
13. Name of Authorized Personnel	**Position**	**Date**
	Company Seal:	
14. Signature of Authorized Personnel		

Except for information that the applicant makes publicly available, or when agreed in writing between JANAAC and the applicant, all other information obtained during the accreditation process will be considered proprietary and shall be regarded as confidential. If JANAAC is required by law or authorized by contractual arrangements to release confidential information, the applicant will, unless prohibited by law, be notified of the information to be provided.

If, at any point during the application or initial assessment process, there is evidence of fraudulent behaviour, or if the applicant intentionally provides false information or conceals information, JANAAC shall reject the application or terminate the assessment process.

All assessments and audits are to be conducted in person.

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Part B - Questionnaire

Section A

I. General Instructions

1. Applicants should review the relevant requirements *(please see the General Criteria for Conformity Assessment Body Accreditation–JANAAC/DOC33 on the JANAAC website or in your information package),* as well as statutory and other regulations and standards that pertain to their facilities and field of certification and the accreditation being sought. They should also ensure that these are understood and fulfilled to the best of the applicant's ability, before submitting the completed Application Form and Questionnaire for the Accreditation of Certification Bodies.
2. Responses to each question and attached listings must be clear and concise.
3. Material deemed to provide necessary additional information, e.g., promotional material, annual reports, etc. can be submitted, but must be clearly titled as appendices and referenced to specific questions on this application form and questionnaire.
4. Any question or item on this application form and questionnaire that is deemed to be "not applicable" to the applicant's facility should be indicated as such.

II. Required Documentation

Please attach the following:

1. Proof of legal status/identity of the Certification Body.
2. Copy/generic template of organization's legally enforceable client agreement for providing certification services.
3. Authorized policy(ies) and agreements outlining the organization's understanding of, commitment to and management of impartiality and confidentiality.
4. Policies/procedures related to the use of license, certificates and marks of conformity.
5. Policies/procedures related to potential conflicts of interest and threats to impartiality.
6. An authorized copy of the management system manual and/or associated documents that outline compliance to all applicable requirements as indicated in 11.and 12. of Part A.
7. Documentation outlining organizational structure, including relationship to other parts within the same legal entity, if applicable, and related details for ALL personnel (both full time and contracted) involved in the certification process (i.e., job descriptions, resumes and/or other evidence of qualification competence).
8. Evidence of qualifications and competence of all auditors and technical experts (both full time and contracted) that are engaged by the organization to conduct certification audits.
9. Copies of certificates of qualification of the head and deputy head of the Certification Body as well as any other person(s) with signatory authority (include specimen signatures).
10. Evidence of adequate provisions to cover liabilities arising from the operations of the organization, e.g., insurance.
11. Sample of (blank) certification documentation.
12. Evidence of accreditation received from any other accreditation body, if applicable.

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Section B

Answer all questions in the fields provided. Where attachments are necessary please ensure that each sheet is signed and dated by the organization/department leader, and the organization stamp/seal affixed.

I. General

1.0 Is the Certification Body a legal entity or a defined part of a legal entity?

☑ **Yes** ☐ **No**

2.0 If yes, describe the legal status and corporate ownership of the organization:

3.0 Outline all major sources of income for the Certification Body. *(i.e., service fees, corporate funding, government grants, other etc.)*

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II. Scope, Clients and Interested Parties

4.0 Indicate in the table below, the specific scope(s) which accreditation is being requested. Also, include technical competence/expertise and limits of capability where applicable. **NB: Refer Appendix 1 as a guide for selecting the applicable products/processes and FDA Regulations**.

CATEGORY *Select the relevant food categories that apply*	**FOOD PRODUCTS/PROCESS** *Describe the specific food products/processes to be covered by the scope*	**FDA REGULATIONS** *State the specific FDA regulations against which accreditation is being sought.*
Example: ☑ Seafood HACCP	Fisheries/Seafood products: a) Fish and Fishery products b) Fish and shellfish	CFR 21, Chapter I, Subchapter B, parts 123, 161, 121, 108, 113, 114, 117, 172, 174
☐ Preventive Control for Human Foods(PCHF)		
☐ Preventive Control for Animal Foods (PCAF)		
☐ Acidified Foods (AF)		
☐ Low-Acid Canned Foods (LACF)		
☐ Juice Hazard Analysis and Critical Control Point (Juice HACCP)		
☐ Seafood Hazard Analysis and Critical Control Point (Seafood HACCP)		
☑ Shell eggs		
☑ Produce Safety		
☐ Medicated Feed		
☑ Dietary Supplements		
☐ Other (*please specify*):		
☐ Other (*please specify*):		
☑ Other (*please specify*):		

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5.0 List the registered client organizations for which the certification body currently provides certification services *(add additional pages as necessary)*. State also the food products/processes and FDA Regulatory Codes applicable to the scope of certification.

CLIENT ORGANIZATION	FOOD PRODUCTS/PROCESS	FDA REGULATIONS	DATE GRANTED

6.0 Indicate the interested parties (persons or organizations), excluding clients and staff, stating their specific interest. (e.g., *government ministries, public/private entities, individuals etc.*).

7.0 Does the certification body or entities under the same organizational control, provide services other than certification?

☑ **Yes** ☐ **No**

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8.0 If yes to 7.0 briefly describe the nature of these services and the general groups who are clients of these services:

9.0 Does the certification body have established relationships with any organizations that perform internal auditing or consultancy services?

☑ **Yes** ☐ **No**

10.0 If yes to 9.0 above, give a brief description of the organization(s), services provided and the nature/extent of their relationship with the certification body. Include names/positions of the **key** operational personnel within the organization(s):

11.0 Has your organization provided certification services for any client that has received consultancy or internal audit services from any organization described in 9 and 10 above?

☑ **Yes** ☐ **No**

12.0 Has your organization provided certification services for any client that is also a certification body?

☑ **Yes** ☐ **No**

13.0 Has your organization been previously accredited by another accreditation body?

☑ **Yes** ☐ **No**

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14.0 If yes to 13.0 above, indicate:

a. The name of the body responsible for the most recent accreditation.

b. The expiry date of accreditation: _____

c. The scope for which the certification body is/was accredited

III. Personnel and Resources

15.0 Indicate:

a. Size of internal staff:_____

b. Number of auditors: _____

c. Number of contracted personnel: _____

16.0 Supported by documentation in Section A, II, 6. above, list all internal staff members for each position within the organizational with functions related to certification activities, indicating the name, respective job titles and primary responsibilities in the table below. Please also indicate in the last column by referencing the corresponding letter (i.e., a – o), individuals specifically responsible for the following functions:

a. Development and implementation of operational policies, processes and procedures
b. Supervision of the implementation of operational policies, processes and procedures
c. Ensuring impartiality

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d. Making decisions on certification
e. Supervision of finances
f. Development of management system certification schemes and services
g. Leading/conducting certification audits; audit reporting
h. Contractual arrangements
i. Provision of resources for certification activities and associated operations
j. Delegating authority to individual and committees to undertake activities on its behalf
k. Selection, training and authorizing personnel including auditors and technical experts
l. Handling appeals
m. Handling complaints
n. Establishing, implementing and maintaining the management system processes and procedures
o. Assessing and reporting on the performance of the management system

NAME OF STAFF MEMBER	JOB TITLE	MAJOR RESPONSIBILITIES	SPECIFIC FUNCTIONS *(Relative to 16.0 a. - o. above)*

17.0 Supported by documentation in Section A, II, 7. above, list all auditors, technical experts including contracted personnel that perform certification activities.

NAME	ROLE *Auditor, Technical Expert, etc.*	FDA REGULATION/ AREA OF EXPERTISE

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NAME	ROLE *Auditor, Technical Expert, etc.*	FDA REGULATION/ AREA OF EXPERTISE

18.0 Does the certification body outsource (in part or in whole) any of its certification services (e.g., to other certification bodies etc.)?

☑ **Yes** ☐ **No**

19.0 If yes to 18.0 above, identify in the table below the nature of the outsourced activities and respective suppliers/service providers for each:

OUTSOURCED ACTIVITY	SUPPLIER/ SERVICE PROVDIER

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20.0 If your application covers activities performed at more than one location (including virtual sites if applicable, branch offices, partners locations, agents, etc.), provide details in the table below: **[Clause 6.2; 8.1.2]**

No.	LOCATION/ADDRESS	CERTIFICATION ACTIVITIES PERFORMED AT LOCATION	CONTACT DETAILS

21.0 Briefly describe the security arrangements, equipment and/or facilities established to prevent loss of, or unauthorized access to client data and information?

IV. Information

22.0 Briefly describe the mechanisms through which information about the organization and its certification services is made available to the public; to certified clients.

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V. Management System Documentation

23.0 In accordance with clause 10.1 in ISO/IEC 17021-1:2015; 8.1 in ISO/IEC 17065:2012, indicate the management system option employed by your organization.

☑ **Option A** ☐ **Option B** ☐ **Not Applicable**

24.0 Has your organization established documentation for the following requirements?

*Indicate where in a management system manual or other suitable documentation, the related process/policy/procedure is referenced. The requirements cited are abstracted from 21 CFR Chapter 1, Subchapter A, Part 1, Subpart M: Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (**F**), ISO/IEC 17021-1:2015 (**M**); and ISO/IEC 17065:2012 (**P**). Not all may be applicable to your organization. The corresponding code (**F**, **M** or **P**) is assigned to each applicable requirement for guidance*.

Documents/Processes/Procedures	YES	NO	N/A	Management/Quality Manual or Other Relevant Reference
Impartiality/Confidentiality				
1. Impartiality policy; Written program for protecting against conflicts of interest **[F, M, P]**	☐	☐	☐	
2. Impartiality mechanism **[P]**	☐	☐	☐	
3. Risk assessment – treatment of threats to impartiality and mitigation measures **[M, P]**	☐	☐	☐	
4. Confidentiality Agreement **[M, P]**	☐	☐	☐	
Organizational Structure				
5. Organizational structure and duties (e.g., job descriptions) for managerial and key certification personnel **[M, P]**	☐	☐	☐	
6. Terms of reference for all committees involved in certification activities **[M, P]**	☑	☐	☐	
7. Process for control of activities conducted by branches, partnerships, agents, franchises, etc. **[M]**	☐	☐	☐	
Resources				
8. Procedure of management and monitoring of competence of certification personnel **[F, P]**	☐	☐	☐	
9. Criteria of required knowledge and skills necessary to perform audits and certification tasks **[M]**	☐	☐	☐	

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Documents/Processes/Procedures	YES	NO	N/A	Management/Quality Manual or Other Relevant Reference
10. Procedure for initial competence evaluation and monitoring of personnel involved in audit and certification activities (general) **[M]**	☐	☐	☐	
11. Procedure containing audit instructions and relevant information to auditors **[M]**	☐	☐	☐	
12. Monitoring of competence and performance of auditors (including on-site evaluation, review of audit reports and client feedback) **[M]**	☐	☐	☐	
13. Description of process for outsourcing of certification activities **[M, P]**	☐	☐	☐	
14. Contractual arrangements with auditors/experts **[M, P]**	☐	☐	☐	
15. Contractual arrangements with outsourced entities **[M, P]**	☐	☐	☐	
Information				
16. Information made publicly available/accessible with respect to the following: a. Audit processes **[M, P]**	☐	☐	☐	
b. Processes for granting, refusing, maintaining, renewing, suspending, restoring or withdrawing certification or expanding or reducing the scope of certification **[M, P]**	☐	☐	☐	
c. Management systems and/or certification scheme for which certification is offered **[M, P]**	☐	☐	☐	
d. Use of the certification body's name and certification mark or logo **[M, P]**	☐	☐	☐	
e. Handling requests for information, complaints and appeals **[M, P]**	☐	☐	☐	
f. Impartiality Policy **[M]**	☐	☐	☐	
g. Description of the rights and duties of applicants and clients **[P]**	☐	☐	☐	
h. Description CB obtains financial support and general information on the certification fees **[P]**	☐	☐	☐	
17. Provisions for supplying information on certification activities and requirements, geographical areas of operation, status of a certification and certified clients **[M]**	☐	☐	☐	
18. Directory of certified products **[P]**	☐	☐	☐	
19. Certification documents (sample) **[M, P]**	☐	☐	☐	
20. Rights and duties of certified clients **[M, P]**	☐	☐	☐	
Certification Process				
21. Application process; application review **[M, P]**	☐	☐	☐	
22. Audit programme; plan for evaluation **[M, P]**	☐	☐	☐	

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Documents/Processes/Procedures	YES	NO	N/A	Management/Quality Manual or Other Relevant Reference
23. Procedures for determining audit time **[M, P]**	☐	☐	☐	
24. Sampling programme/plan (if applicable) for multi-site audits **[M, P]**	☐	☐	☐	
25. Process for selecting and appointing the audit team **[M, P]**	☐	☐	☐	
26. Process for conducting audits/evaluations **[M, P]**	☐	☐	☐	
27. Audit Report (sample/template) **[M, P]**	☐	☐	☐	
28. Process to conduct review of audit results prior to decision **[M, P]**	☐	☐	☐	
29. Process for transfer of certification **[M, P]**	☐	☐	☐	
30. Policy for suspension, withdrawal or reduction of the scope of certification **[M, P]**	☐	☐	☐	
31. Procedure(s) for suspension, withdrawal or reduction of the scope of certification **[M, P]**	☐	☐	☐	
32. Certification documentation **[M, P]**	☐	☐	☐	
33. Directory of certified products **[M, P]**	☐	☐	☐	
34. Procedure to receive, evaluate and make decisions on appeals **[F, M, P]**	☐	☐	☐	
35. Procedure to receive, evaluate and make decisions on complaints **[M, P]**	☐	☐	☐	
36. Record retention policy **[M, P]**	☐	☐	☐	
37. Record retention procedure **[M, P]**	☐	☐	☐	
Management System				
38. Management system policies **[M, P]**	☐	☐	☐	
39. Management system objectives **[M, P]**	☐	☐	☐	
40. Management system manual or equivalent documentation **[M, P]**	☐	☐	☐	
41. Procedure for document control **[F, M, P]**	☐	☐	☐	
42. Procedure for record/data control **[F, M, P]**	☐	☐	☐	
43. Management review **[M, P]**	☐	☐	☐	
44. Internal audits **[M, P]**	☐	☐	☐	
45. Procedures for identification and management of corrective actions **[M, P]**	☐	☐	☐	
46. Preventive actions; risks **[M, P]**	☐	☐	☐	

VI. Other Requirements

25.0 Application fees (non-refundable) submitted?

☑ **Yes** ☐ **No**

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26.0 If yes, state payment method

NB: In the event that application documents are incomplete or not satisfactorily completed, the applicant will be informed of this, and is required to adequately address discrepancies in no more than twenty (20) working days after notification. Failure to comply with this delivery date will result in the application being returned for completion and re-submission.

The application will not be registered until the requisite documents are received.

Name of applicant's representative: _____

Position: _____

Signature: _____

Date: _____

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APPENDIX 1
ACCREDITATION SCOPES

The table below outlines the possible scope characterizations for applicant certification bodies. NB: This does NOT represent an exhaustive list.

Type of food	Category Title	Food products/processes included	Scopes mapped to FDA regulations (As applicable)*
A.) Food for Humans	Low acid and Acidified foods [As applicable: LACF, AF, PCHF, Seafood HACCP, Juice HACCP]*	a) Thermally processed low-acid foods packaged in hermetically sealed containers b) Acidified foods	CFR 21, Chapter I, Subchapter B, parts 108, 113, 114, 117, 121, 123, 145, 155, 172, 174
	Baby (Infant and Junior) Food Products Including Infant Formula Baby Food ([As applicable: PCHF, LACF, AF, Juice HACCP, Seafood HACCP]	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, 113, 114, 117, 120, 123
	Dairy products ([As applicable: PCHF, LACF, AF]*)	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 131, 133, 135, 179, 117, 108, 113, 114, 172, 174
	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, 119, 179, 190, 111, 117, 172, 174
	Fisheries/Seafood products ([As applicable: Seafood HACCP, LACF, AF]*)	a) Fish and Fishery products b) Fish and shellfish	CFR 21, Chapter I, Subchapter B, parts 123, 161, 121, 108, 113, 114, 117, 172, 174

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Type of food	Category Title	Food products/processes included	Scopes mapped to FDA regulations (As applicable)*
	Fresh produce or Fresh fruits and vegetable [As applicable, (Produce Safety; most fresh cut produce under PCHF]*)	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. CFR 21 Chapter I, Subchapter B Parts 112, 117, 172, 174, 175, 178
	Processed Fruit and Fruit products [As applicable: PCHF, LACF, AF]*	a) Canned fruits b) Fruit pies c) Fruit butters, jellies, preserves, and related products d) Irradiation in the production, processing and handling of food	CFR 21, Chapter I, Subchapter B, parts 117, 145, 150, 152, 172, 174, 179, 108, 113, 114, 117, 120.
	Fruit or Vegetable juices, other beverages including water [As applicable, PCHF, Juice HACCP, LACF, AF]*	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 146, 156, 165, 170, 172, 174, 179, 129, 108, 113, 114, 117, 120.
	Vegetable and Vegetable products [As applicable, PCHF, LACF, AF]*	a) Canned vegetables b) Frozen vegetables c) Irradiation in the production, processing and handling of food	CFR 21, Chapter I, Subchapter B, parts 155, 158, 108, 113, 114, 117, 170, 172, 174,179
	Shell Egg and egg products [As applicable, PCHF, LACF, AF]*	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 , 108, 113, 114, 160, 117, 65 FR 76092 (shell eggs), 172, 174, 179
	Starch products[As applicable, PCHF, LACF, AF]*	a) Bakery products b) Cereal flours and rlated products c) Macaroni and noodle products	CFR 21, Chapter I, Subchapter B, parts 136, 137, 139, 108, 113, 114, 117, 172, 174

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Type of food	Category Title	Food products/processes included	Scopes mapped to FDA regulations (As applicable)*
	Food Additives (Direct and Indirect) [As applicable: PCHF, Seafood HACCP, Juice HACCP, LACF, AF, Produce Safety]*	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 l) Irradiation in the production, processing and handling of food m) Unavoidable contaminants in food for human consumption and food-packaging material	CFR 21, Chapter I, Subchapter B, parts 109, 117, 170, 172, 173, 174, 175, 176, 177, 178, 179, 180, 168, 169, 109, 117
	Nuts and Edible Seed Products [As applicable: Produce Safety; PCHF]*	a) Cacao products b) Tree nut and peanut products	CFR 21, Chapter I, Subchapter B, parts 112, 163, 164, 117, 172, 174

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Type of food	Category Title	Food products/processes included	Scopes mapped to FDA regulations (As applicable)*
	Food Ingredients and (food) substances [As applicable: PCHF, Seafood HACCP, Juice HACCP, LACF, AF, Produce Safety] *	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 181, 182, 184, 186, 189, 109, 117, 172, 174, 179
	Fats and Oils [As applicable: PCHF, LACF, AF]*	Margarine	CFR 21, Chapter I, Subchapter B, parts 166, 117, 172, 174
B.) Animal Food	Low Acid Canned Food [LACF + PCAF]*	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.
	Animal Food [As applicable: PCAF, LACF]*	Animal food 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, 113, 108

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Type of food	Category Title	Food products/processes included	Scopes mapped to FDA regulations (As applicable)*
	Medicated Feed	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

Adapted from: International Accreditation Service (IAS) – Application for Third Party Certification Body Accreditation Under the Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA) - IAS/FSMA/006; March 6, 2019