CGMP Self-Audit Summary

	ltem	Date of Self-Audit
1	Number of Compliance	
1.	(Yes Boxes Checked)	
	Number of Not Applicable	
2.	(N/A Boxes Checked)	
3.	Total Number of Questions	70
4	% Compliance	
4.	[#1 ÷ (#3 - #2)] × 100	

Current Good Manufacturing Practice Self-Audit for compliance with 21 CFR 507

Self Auditor:	Date of Audit:
Facility Name:	

	507.14 Personnel	Comments
□Yes □No □N/A	1) Does management take reasonable precautions to ensure that all people working in direct contact with animal food, equipment, and packaging materials are Qualified Individuals?	
□Yes □No □N/A	2) Is there documentation that all <i>Qualified Individuals</i> have the education, training, or experience, or combination thereof, necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties?	
□Yes □No □N/A	3) Is there documentation that all <i>Qualified Individuals</i> receive training on animal food hygiene and animal food safety, including the importance of employee health and personnel hygiene?	
□Yes □No □N/A	4) Do <i>Qualified Individuals</i> maintain adequate personal cleanliness?	
□Yes □No □N/A	5) Do <i>Qualified Individuals</i> wash hands in adequate hand-washing facilities when appropriate?	
□Yes □No □N/A	6) Do <i>Qualified Individuals</i> remove and/or secure jewelry and other personal objects to prevent them from falling into animal food?	
□Yes □No □N/A	7) Do Qualified Individuals store clothing and other personal belongings outside the manufacturing area?	
□Yes □No □N/A	8) Are necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food packaging materials being taken?	





507.17 Plant and Grounds		Comments
□Yes □No □N/A	9) Are grounds maintained (equipment stored properly, litter and waste removed, weeds and grass within immediate vicinity of facility are trimmed to not harbor pests)?	
□Yes □No □N/A	10) Are driveways, yards, and parking areas maintained so they are not a source of contamination?	
□Yes □No □N/A	11) Is there adequate drainage on grounds so sitting water is not a source of contamination?	
□Yes □No □N/A	12) Is the facility suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control?	
□Yes □No □N/A	13) Is waste treated and disposed of in a way that does not constitute a source of contamination in areas where animal food is stored?	
□Yes □No □N/A	14) Is the facility constructed so that drips or condensate from fixtures, ducts, and pipes do not serve as a source of contamination?	
□Yes □No □N/A	15) Is adequate ventilation (mechanical or natural) provided where necessary and appropriate to minimize vapors (steam) and fumes?	
□Yes □No □N/A	16) Is adequate lighting provided?	
□Yes □No □N/A	17)Are light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food made of shatter-proof glass?	
□Yes □No □N/A	18) Are protective coverings being used where necessary and appropriate to prevent contamination of bulk feed stored outdoors?	



□Yes □No	19) Are areas over and around the bulk animal food controlled to eliminate harborages of	
	pest?	



507.19 Sanitation		Comments
□Yes □No □N/A	20) Is the animal food stored outdoors in bulk being checked on a regular basis for pests, pest infestation, and product condition related to safety of the animal food?	
□Yes □No □N/A	21) Are the building, structures, and fixtures clean and maintained?	
□Yes □No □N/A	22) Are animal food-contact and non-contact surfaces of utensils and equipment clean, maintained, and stored to protect against contamination of animal food?	
□Yes □No □N/A	23) If wet cleaning is being used, are animal- food contact surfaces sanitized and dried before use?	
□Yes □No □N/A	24) Are cleaning compounds and sanitizing agents safe under conditions of use?	
□Yes □No □N/A	25) Are toxic materials being stored only for maintaining clean and sanitary conditions, laboratory test procedures, plant and equipment maintenance and operation, or those necessary for use in plant operations?	
□Yes □No □N/A	26) Are the toxic materials in #25 identified, used, and stored in such a way to protect against contamination?	
□Yes □No □N/A	27) Are other toxic materials (pesticides, fertilizers, etc.) stored in an area where animal food is not manufactured, processed, or exposed?	
□Yes □No □N/A	28) Is pest control in place and effective?	
□Yes □No □N/A	29) Is trash stored and disposed of properly?	



	507.20 Water Supply and Plumbing	Comments
□Yes □No □N/A	30) Is water safe for its intended use and drawn from an adequate source?	
□Yes □No □N/A	31) Is running water at a suitable temperature and pressure?	
□Yes □No □N/A	32)If it is water reused, is it safe for its intended use and not add contamination?	
□Yes □No □N/A	33) Does plumbing carry sufficient amounts of water for intended use?	
□Yes □No □N/A	34) Does plumbing sufficiently carry sewage and liquid waste from the facility so it is not a source of contamination?	
□Yes □No □N/A	35)Does plumbing provide sufficient floor drainage?	
□Yes □No □N/A	36) Does plumbing ensure no backflow from piping system empty wastewater or sewage near areas of manufacturing or animal food?	
□Yes □No □N/A	37)Is sewage and liquid disposal waste disposed of through an adequate sewage system or through other adequate means?	
□Yes □No □N/A	38)Does the facility provide employees with accessible toilet systems that are kept cleaned and well-maintained?	
□Yes □No □N/A	39) Does the plant provide hand washing facilities to prevent employees' hands from becoming a potential source of contamination?	



	507.22 Equipment and Utensils	Comments
	40) Are all equipment and utensils designed	
□Yes □No	and constructed of such material and	
□N/A	workmanship to be adequately cleaned and	
,	properly maintained?	
	41) Are all equipment and utensils designed,	
	constructed, and used appropriately to	
□Yes □No	avoid the adulteration of animal food with	
□N/A	non-food grade lubricants, fuel, metal	
	fragments, contaminated water, or any	
	other contaminants?	
□Yes □No	42) Is equipment installed to facilitate the	
	cleaning and maintenance of the	
□N/A	equipment and adjacent spaces?	
	43) Are all animal food contact surfaces made	
	of nontoxic materials that withstand the	
	environment of their use, the action of	
□Yes □No	animal food, and the action of cleaning	
□N/A	compounds, cleaning procedures, and	
	sanitizing agents and maintained in a way	
	to protect animal food from being	
	contaminated?	
	44) Are all holding, conveying, manufacturing,	
□Yes □No	and processing systems designed,	
□N/A	constructed, and maintained in a way to	
	protect against the contamination of animal	
	food?	
	45) If freezers and cold storage compartments	
□Yes □No	are used to hold animal food, are they	
□N/A	fitted with accurate temperature-measuring	
	devices?	
	46) If there are instruments and controls used	
	in measuring, regulating, or recording	
	temperature or other conditions to control	
□Yes □No	or prevent the growth of undesirable	
□N/A	microorganisms, are they accurate,	
	precise, adequately maintained, and	
	adequate in number for their designated	
	uses?	

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	Comments	
□Yes □No □N/A	48) Is all animal food accurately identified?	
□Yes □No □N/A	49) Are all animal food-packaging materials safe and suitable?	
□Yes □No □N/A	50) Is the overall cleanliness of the plant under the supervision of one or more competent individuals assigned responsibility for this function?	
□Yes □No □N/A	51) Are adequate precautions taken so that plant operations do not contribute to contamination?	
□Yes □No □N/A	52) Are chemical, microbial, or other testing procedures used where necessary to identify sanitation failures or possible animal food contamination?	
□Yes □No □N/A	53) Is all animal food that becomes adulterated rejected, treated, or processed to eliminate adulteration, or disposed of in a manner that protects against the contamination of other animal food?	
□Yes □No □N/A	54) Is all animal food manufacturing, processing, packing, and holding conducted under conditions and controls necessary to minimize the potential for growth of undesirable microorganisms to protect against the contamination of animal food?	
□Yes □No □N/A	55) Are shipping containers and bulk vehicles holding ingredients examined upon receipt?	
□Yes □No □N/A	56) Are all raw materials cleaned as necessary to minimize contamination?	
□Yes □No □N/A	57) Are all raw materials and other ingredients stored in a way that protects against contamination and deterioration?	
□Yes □No □N/A	58) Are ingredients susceptible to mycotoxins and used in a proper manner?	
□Yes □No □N/A	59) Are all raw materials or other ingredients that must be frozen, kept frozen and thawed properly?	
□Yes □No □N/A	60) Is all animal food maintained, manufactured, and packaged under conditions which minimize the potential for the growth of microorganisms?	
□Yes □No □N/A	61) Is work-in-progress ad rework handled to protect against undesirable microorganisms?	
□Yes □No □N/A	62) If water activity or pH are used to prevent the growth of microorganisms, are they used properly?	

□Yes □No	63) If ice is used, is the water it was made from safe for	
□N/A	use?	



507.27 Holding and Distribution		Comments
□Yes □No □N/A	64) Is animal food held in appropriate places that protect from the contamination of pests, chemicals, and other products?	
□Yes □No □N/A	65)Are unpackaged or bulk animal foods held to protect cross-contamination?	
□Yes □No □N/A	66) Are shipping containers (bulk, trucks, tote bags, paper or plastic bags, etc.) designed, constructed of appropriate material, and maintained to protect against contamination?	
□Yes □No □N/A	67) Are containers properly cleaned?	
□Yes □No □N/A	68) Are containers inspected to protect cross-contamination before loading?	
□Yes □No □N/A	69) Do the animal food labels follow AAFCO suggestion which contains the instructions of safely using and intended animal species?	
□Yes □No □N/A	70) Do you accept returned products to your facility? If yes, do you have procedure to control them? Who will decide whether to accept or reject? Where are they placed? Who will justify the corrective action for them?	

FACILITY NAME: ADDRESS:	
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