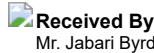
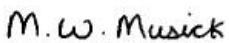

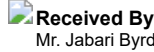


Commonwealth Of Virginia — Department Of Agriculture & Consumer Services Food Safety Program PO Box 1163 — Richmond, VA 23218 — 804-786-3520								
Firm Name: ChyloCure				Firm # 2477301				
Address: 2200 Kraft DR STE 2225 Blacksburg, VA 24060				Phone: (540) 443-9207				
Attention: Mr. Thomas Piccariello, CEO			Purpose(s): Follow-up					
Extent: Full Inspection		Inspection ID: 3826601	Start: 03/09/2021	End: 03/09/2021				
Manufacturer/Warehouse Report								
Violations								
IN=in compliance OUT=not in compliance NA=not applicable NO=not observed COS=corrected on-site during inspection R=repeat violation								
Compliance Status			Compliance Status					
Qualifications of Individuals			Sanitary Facilities and Controls					
1	IN	All individuals engaged in manufacturing, processing, packaging, or holding food receive necessary training and are qualified individuals or under the supervision of a qualified individual		27	IN	Adequate sewage disposal system		
Personnel			28			IN	Toilet rooms provided, readily accessible; kept clean and must not be source of contamination	
2	IN	Personnel with sores, infections, etc. restricted from food processing areas; report such health conditions to supervisors		29	IN	Hand-washing facilities are adequate, convenient and supplied with water at appropriate temperature		
3	IN	Personnel wear clean outer garments, have adequate hair restraints, jewelry removed		30	IN	Refuse properly stored and protected from insects, rodents, and other pests; disposed of adequately		
4	IN	Hands properly washed and/or sanitized; good hygienic practices		Equipment and Utensils				
5	IN	Gloves, if used, intact, clean, impermeable		31	IN	Utensils and equipment constructed of cleanable materials; equipment designed and used in a manner that precludes contamination from various sources; non-food-contact equipment constructed of cleanable materials		
6	IN	Proper eating, drinking, chewing gum, tobacco use, and food handling practices; correct storage of personal belongings		32	IN	Instruments and controls used for measuring temperatures, pH, acidity, water activity, etc. provided, accurate, maintained, and adequate in number		
Plant and Ground			33			IN	Gases/compressed air introduced into food or used to clean food-contact surfaces are treated in a way so food will not become contaminated	
7	IN	Premises free of harborage and/or breeding places for rodents, insects, and other pests		Processes and Controls				
8	IN	Roads, yards, parking lots, etc. maintained		34	IN	Responsibility for plant sanitation assigned to one or more competent individuals; production procedures do not contribute to allergen cross-contact and/or contamination; testing used to identify sanitation failures or food contamination, if necessary		
9	IN	Adequate drainage provided to avoid contamination of facilities and products		35	IN	Raw materials and other ingredients inspected for adulteration and stored to prevent contamination; ingredients washed or cleaned as necessary		
10	IN	Sufficient space provided for placement of equipment, storage of materials, and for production operations		36	IN	All manufacturing operations are conducted in way that prevents contamination of food and food-contact surfaces, and minimizes growth of microorganisms		
11	IN	Floors, walls, and ceilings are constructed of easily cleanable materials and kept in good repair; food and food-contact surfaces protected from contamination from pipes, fixtures, etc.		General Requirements				
12	NA	Food in outdoor bulk fermentation vessels is protected		37	IN	Finished products stored and shipped under conditions which will avoid contamination and deterioration		
13	IN	Prevent contamination by waste treatment and disposal systems; exclude pests, dirt, and filth bordering property that is not under control of firm		38	NA	Human food by-products for animal food held under sanitary conditions and labeled accordingly		
14	IN	Food processing areas effectively separated from other operations which may cause contamination of food being processed, including allergen cross-contact		Records				
15	IN	Food products and processing areas protected against contamination from light bulbs/glass; adequate lighting provided		39	IN	Records kept and available to review; meet all requirements		
16	IN	Adequate air quality/ventilation provided to prevent odors/vapors; fans and other air-blowing equipment located and operated to minimize contamination of food and food-contact surfaces		Compliance with Additional Standards				
17	IN	Doors, windows, and other openings protected by screening to eliminate entry by insects, rodents, and other pests		40	IN	Firm in compliance with all other VDACS adopted CFRs		
Sanitary Operations			41			IN	Finished product labels in compliance	
18	IN	Facility clean and in good physical repair; cleaning of facilities and equipment conducted in a manner as to avoid contamination of food products		Preventive Controls - Limited Scope				
19	IN	Detergents, sanitizers, hazardous materials, and other supplies used in a safe and effective manner; only necessary toxic substances used/stored		42	NA	Does the firm have a written food safety plan?		
20	IN	Cleaning compounds and hazardous materials identified and stored as to not contaminate food and food-contact surfaces		43	NA	Has the firm conducted a Hazard Analysis?		
21	IN	Insects, rodents, and other pests not present; insecticides and rodenticides used and stored so as to prevent contamination of food		44	NA	Does the firm have a written recall plan?		
22	IN	Food-contact and non-food-contact surfaces are cleaned and sanitized at intervals frequent enough to avoid contamination of food products		45	NA	Is the firm processing a ready-to-eat product that is exposed to environmental conditions where pathogen cross contamination could occur?		
23	IN	Cleaned and sanitized portable equipment and utensils are stored in a manner to protect food-contact surfaces from allergen cross-contact and from contamination		46	NA	Does the firm have an environmental monitoring program?		
24	IN	Single-service articles are stored and handled in a manner to protect against allergen cross-contact and contamination of food, food-contact surfaces, and food-packaging		47	NA	Does the firm receive, store, or use any ingredients composed in whole or in part of major allergens?		
Sanitary Facilities and Controls			48			NA	Does the firm's allergen controls include, as is applicable, equipment cleaning and sanitizing between runs, dedicated equipment for allergen and non-allergen containing products, physical separation of allergenic ingredients and process scheduling?	
25	IN	Water from approved source and adequate in quantity for its intended use; water temperatures and pressures maintained at suitable levels for its intended use		49	NA	Does the firm's product labeling declare all major allergens?		
26	OUT	Plumbing carries sufficient quantities of water; plumbing adequately designed, installed, and maintained in a manner to prevent contamination including backflow and cross-connection; proper floor drainage		50	NA	Based on inspection observations, does it appear the firm has implemented adequate process controls to control significant hazards (i.e. cooking, formulation [pH, Aw, etc.], cooling, and refrigeration)?		
			Preventive Controls - Modified Requirements for a Warehouse Holding Unexposed Packaged Foods					
			51			NA	Does the firm store refrigerated, packaged food that requires time/temperature control to minimize or prevent the growth of, or toxin production by, microorganisms?	
			52			NA	Has the firm established and implemented temperature controls to minimize or prevent growth of, or toxin production by, pathogens?	
			Pre-Operational Inspection					
			53			NA	Preoperational inspection conducted	
Today's findings were discussed with the most responsible person at the firm at the time of the inspection and this person was given the opportunity to respond.								
Establishment (Signature)			 Received By Mr. Jabari Byrd			Title Director of Operations		
Inspector (Signature)			 Musick, M.W.					

Firm Name: ChyloCure		Firm # 2477301	
Address: 2200 Kraft DR STE 2225 Blacksburg, VA 24060		Phone: (540) 443-9207	
Attention: Mr. Thomas Piccariello, CEO		Purpose(s): Follow-up	
Extent: Full Inspection		Inspection ID: 3826601	Start: 03/09/2021
		End: 03/09/2021	
Dietary Supplement Inspection Report			
Violations			
IN=in compliance OUT=not in compliance NA=not applicable COS=corrected on-site during inspection R=repeat violation			
Compliance Status		COS	R
Personnel			
1	IN Firm takes measures to prevent microbial contamination; control of employee hygiene		
2	IN Qualified personnel and supervisors		
Physical Plant and Grounds			
3	IN Good Manufacturing Practices are applied to facility operations		
Equipment and Utensils			
4	OUT Calibrate and replace equipment that cannot be calibrated; maintain equipment clean and sanitary		
Production and Process Control System			
5	OUT Dietary supplement is made according to the Master Manufacturing Record to ensure quality		
6	IN Required specifications are established and met; take corrective action for specification not met		
7	IN Collection of representative and reserve samples		
Quality Control			
8	IN Responsibility of quality control personnel and quality control operations		
Requirements for Components, Packaging, Labels and Product			
9	IN Requirements for components, packaging, labeling and products for use in a dietary supplement		
Master Manufacturing Records			
10	OUT Contents of Master Manufacturing Record		
Today's findings were discussed with the most responsible person at the firm at the time of the inspection and this person was given the opportunity to respond.			
Establishment (Signature)			Received By Mr. Jabari Byrd
			Title Director of Operations
Inspector (Signature) Musick, M.W.		<i>M. W. Musick</i>	

Firm Name: ChyloCure		Firm # 2477301	
Address: 2200 Kraft DR STE 2225 Blacksburg, VA 24060		Phone: (540) 443-9207	
Attention: Mr. Thomas Piccariello, CEO		Purpose(s): Follow-up	
Extent: Full Inspection		Inspection ID: 3826601	Start: 03/09/2021
		End: 03/09/2021	
Violation Details			
Equipment and Utensils; #4: 111.27 (b) You must calibrate instruments and controls you use in manufacturing or testing a component or dietary supplement. You are not verifying the calibrations of the two balances, one top loading balance and one analytical balance used for measuring dietary supplement components, at routine intervals to ensure the accuracy and precision of the instruments. Additionally, you do not have calibration test weights (with certificate of accuracy) in a range of appropriate sizes to conduct calibration verifications.			
Production and Process Control System; #5: 111.55 You must implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of the dietary supplement to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. You have not established a written master manufacturing record for each dietary supplement product.			
Master Manufacturing Records; #10: 111.205 (a) You must prepare and follow a written master manufacturing record for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch. You have not prepared written master manufacturing records for the dietary supplements you manufacture.			
Records and Recordkeeping; #18: 111.14 (b) You must make and keep records the following records: ... (2) Documentation of training, including the date of the training, the type of training, and the person(s) trained. You do not have records that document the training of all individuals performing work to produce dietary supplements. A record of training will include any training, education, or work experience that gives the individual the knowledge, skills and abilities necessary to be considered qualified for the duties assigned to them.			
Sanitary Facilities and Controls; #26: 21 CFR 117.37(b)(3)			
An air gap was not present in the equipment sink drain pipe, creating a direct connection between the equipment sink and the wastewater system.			
Additional Remarks			
Please correct the violations noted in a timely manner, and provide information on your steps to correct them to Meagan.Musick@vdacs.virginia.gov and Lisa.Ramsey@vdacs.virginia.gov. We appreciate your cooperation and actions towards compliance with 21 CFR 111.			
**NOTE: Firm signature was not obtained due to COVID-19. Inspection report was sent by email to firm personnel.			
Today's findings were discussed with the most responsible person at the firm at the time of the inspection and this person was given the opportunity to respond.			
Establishment (Signature)		 Received By Mr. Jabari Byrd	Title Director of Operations
Inspector (Signature) Musick, M.W.		<i>M. W. Musick</i>	