

Preferred Supplier Data Sheet (PSDS) for Raw Material Suppliers and Contract Manufacturers



All Raw Material Suppliers and Contract Manufacturers must provide the information requested in this form as part of the qualification procedure for acceptance as a Preferred Supplier by NASC. Any fields not applicable to your company should be completed by entering N/A.

Please return copies of the completed form(s) and requested certifications electronically to Bill Bookout at b.bookout@nasc.cc or mail to:

NASC PO Box 5168 Sun City West, AZ 85376

This information will be posted in the Members Section of the NASC Web Site for companies to download for use in qualifying and accepting the supplier.

Questions: contact Bill Bookout at the NASC office (760-751-3360 X1)

SECTION 1: SITE OVERVIEW					
NAME AND ADDRESS OF	American Laboratories, Inc.				
COMPANY OR SITE	Business Office	Business Office:			
RESPONSIBLE:	11111 M Street				
	Omaha, NE 68	3137			
WEB SITE:	Americanlabo	Americanlaboratories.com			
CONTACT PERSON	John Garcia				
TELEPHONE NUMBER:	402-339-2494	402-339-2494			
E-MAIL:	igarcia@americanlaboratories.com				
BUSINESS DESCRIPTION / SITE DETAILS: Site details can be found on the attached Site Quality Overview Datasheet (SQOD)					
FACILITY SIZE / # EMPLOYEES:	SQOD			DATE EST:	SQOD
GENERAL AND PRODUCT	SQOD			UNION:	SQOD
LIABILITY INSURANCE LEVELS:					
SPECIFY TYPE(S) OF INGREDIENT(S),		SQOD			
MANUFACTURING CAPABILITIES, PRODUCTS					
PRODUCED/SUPPLIED BY THE SITE,					
SERVICES AND THEIR INTENDED					
APPLICATIONS:					
SITE ACTIVITIES CONDUCTED:		SQOD			·
ORGANIZATIONAL CHART:		SQOD		•	

SECTION 2: EVIDENCE OF COMPLIANCE				
INDEPENDENT QUALITY CERTIFICATIONS:	None IF YES, SPECIFY:			
SERVIN IO/MISMS.	QUALITY MANAGEMENT SYSTEM STANDARD:	Q7		
	APPROVAL CERTIFICATES:	N/A		
	NUMBER AND NAME OF REGISTRAR WHO PROVIDED CERTIFICATE OF APPROVAL:	N/A		
OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS:	N/A			
WEB SITE:	americanlaboratories.com			
DATE OF LAST FDA OR STATE AGENCY CGMP INSPECTION AND OUTCOME (PROVIDE COPY OF REPORT OF OBSERVATIONS FROM LAST FDA OR STATE INSPECTION):		FDA – Nov. 2017, 483 resolved and closed		





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SECTION 3: RAW MATERIAL SUPPLIERS & CONTRACT MANUFACTURERS ONLY	,
DO YOU HAVE Q/C RELEASE REQUIREMENTS	Yes
FOR ALL SHIPMENTS WHEN THEY ARRIVE: (YES / NO)	res
DO YOU SAMPLE EVERY LOT OF RAW MATERIALS RECEIVED: (YES / NO)	No
DO YOU RE-PACK LARGE QUANTITIES INTO SMALLER QUANTITIES AT YOUR FACILITY:	Yes
(YES / NO)	165
DO YOU SAMPLE EVERY LOT: (YES / NO)	Yes
DO YOU PERFORM ANY BLENDING AT YOUR FACILITY (YES / NO)	Yes
LIST ALL INGREDIENTS HELD AT YOUR FACILITY (ATTACH A LIST/DOCUMENT IF AVAILA	
PHARMACEUTICAL:	Yes
NUTRITIONAL:	Yes
BOTANICAL:	Yes
MINERAL:	No
ENZYME:	Yes
HORMONE:	Yes
PROBIOTIC:	Yes
CHEMICAL (OTHER): Technical, Industrial and Diagnostics	Yes
METHODS CONDUCTED IN EACH ITY, (VES (NO)	
METHODS CONDUCTED IN FACILITY: (YES / NO) DO YOU USE AN IN-HOUSE LOT NUMBERING SYSTEM?	Yes
DO YOU EVER MIX MULTIPLE LOTS OF THE SAME INGREDIENT WHEN YOU BLEND?	Yes
DO 100 EVER WIX WOLTIPLE LOTS OF THE SAME INGREDIENT WHEN 100 BLEND?	Tes
TESTING INFORMATION:	
IF YOU RELY ON BOTH IN-HOUSE AND OUTSIDE CONTRACT LABS, PLEASE FILL OUT B	OTH SECTIONS
DOES THIS FACILITY RELY ON AN <u>IN-HOUSE</u> LAB? (YES / NO)	Yes
IN-HOUSE TESTS PERFORMED: (YES / NO)	Yes
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	Yes
RAW MATERIAL ASSAY? (YES / NO)	Yes, when applicable
MICROBIAL? (YES / NO – IF YES SPECIFY)	Yes, APC, Salmonella, E. coli
	when applicable
pH? (YES / NO)	Yes, when applicable
MOISTURE? (YES / NO)	Yes
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	No
HEAVY METALS? (YES / NO – IF YES SPECIFY)	Yes, when required
OTHER? (YES / NO – IF YES SPECIFY)	N/A
IF YOU HAVE AN IN-HOUSE LAB PLEASE SPECIFY WHICH	N/A
LAB ACCREDITATION ORGANIZATION(S) YOU ARE AFFILIATED WITH:	



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OUTSIDE CONTRACT LABS USED	
	LABS AND THEIR ACCREDITATION STATUS: (e.g., ISO, FDA,
USDA, AOAC, USP, NSF, NPA, A2LA, ANSI, ETC.) *PLEASE P	
NAME OF LAB #1:	
ADDRESS / LOCATION:	
ABBRESS / ESS/MISM.	
CONTACT NAME / PHONE NUMBER:	
LIST ANY CERTIFICATIONS FOR THE LAB:	
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	
RAW MATERIAL ASSAY? (YES / NO)	
MICROBIAL? (YES / NO – IF YES SPECIFY)	
pH? (YES / NO)	
MOISTURE? (YES / NO)	
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	
HEAVY METALS? (YES / NO – IF YES SPECIFY)	
OTHER? (YES / NO – IF YES SPECIFY)	
NAME OF LAB #2:	
ADDRESS / LOCATION:	
ADDITION LOOKHON.	
CONTACT NAME / PHONE NUMBER:	
LIST ANY CERTIFICATIONS FOR THE LAB:	
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	
RAW MATERIAL ASSAY? (YES / NO)	
MICROBIAL? (YES / NO – IF YES SPECIFY)	
pH? (YES / NO)	
MOISTURE? (YES / NO)	
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	
HEAVY METALS? (YES / NO – IF YES SPECIFY)	
OTHER? (YES / NO – IF YES SPECIFY)	
NAME OF LAB #3:	
ADDRESS / LOCATION:	
7.55.1.2007.2007.110111	
CONTACT NAME / PHONE NUMBER:	
LIST ANY CERTIFICATIONS FOR THE LAB:	
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	
RAW MATERIAL ASSAY? (YES / NO)	
MICROBIAL? (YES / NO – IF YES SPECIFY)	
pH? (YES / NO)	
MOISTURE? (YES / NO)	
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	
HEAVY METALS? (YES / NO – IF YES SPECIFY)	
OTHER? (YES / NO – IF YES SPECIFY)	

Commented [MC1]: ALI does not normally list outside laboratories. Do we want to list these here? If yes, QC labs (Tim Webb) will need to help.



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SECTION 4: CGMP COMPLIANCE DETAILS				
PROVIDE A BRIEF SUMMARY OF HOW THE SUPPLIER COMPLIES WITH EACH APPLICABLE ELEMENT OF THE CURRENT				
GMP GUIDELINES. NON-APPLICABLE ELEMENTS SHOULD BE NOTED AS <mark>SUCH</mark> .				
IS FACILITY ISO CERTIFIED? YES / NO: No				
IF YES SPECIFY THE ISO ST				
AND ATTACH CURRENT CE				
LIST AND ATTACH ANY OTHER CERTIFICATIONS OR N/A				
EXTERNAL AUDIT PROGRAI	EXTERNAL AUDIT PROGRAMS (E.G., NSF, USP, NPA, ISO, ETC.):			
	ECIFY MOST RECENT FACILITY INSPECTI			
FOREIGN AGENCY (DATE OF INSPECTION, AND RESULTS OF THE INSPECTION SPECIFY AGENCY):				
DATE	INSPECTION AGENCY	RESULTS OF THE INSPECTION		
November 2017	FDA	483 resolved and closed		
Daily	USDA-FSIS	No NRs		
June 2018	USDA-APHIS	No issues reported		

SECTION 5: ADDITIONAL INFORMATION	
Hazard Plan (HACCP) / DATE IMPLEMENTED:	10/4/2011
STATISTICAL PROCESS CONTROL/PROCESS	
ANALYTICAL CONTROL:	
CORPORATE BIOTERRORISM ACT	SQOD
COMPLIANCE:	
DESCRIBE ALL MEASURES TAKEN BY FACILITY TO ENSURE PRODUCT QUALITY AND PRODUCT CONTAMINATION PREVENTION.	American Laboratories, Inc. (ALI) utilizes segregation, separation and scheduling practices in the storage and processing of our products to prevent any chance of cross-contamination. Production equipment and rooms are cleaned after each different product is processed, using validated cleaning procedures. The cleaning methods have been validated to remove any residues of fat, protein, detergent, and sanitizer. Documented cleaning logs are maintained for all of ALI's processing equipment and/or rooms. In addition, material that is in a dry or dusty state is always processed in an enclosed room that has its own HVAC system with final HEPA filtration of the room air. ALI utilizes a computerized employee training program (Master Control) to document employee training on all of our cleaning and sanitizing SOP's. All employees are required to utilize sanitary hygiene practices while working on our products. All processing is fully documented on controlled ALI Manufacturing Instructions which fully meet FDA and USDA cGMP requirements. ALI maintains complete product and material traceability for all of our products.
MEMBERSHIP IN INDUSTRY TRADE GROUPS:	SQOD

SECTION 6: CONTRACT MANUFACTURERS	
HOW DO YOU GUARANTEE BANNED SUBSTANCES (STIMULANTS,	See contamination prevention notes above.
NARCOTICS, STEROIDS, DIURETICS, BETA-2-AGONISTS, BETA	
BLOCKERS, MASKING AGENTS, OR SIMILAR SUBSTANCES)	
ARE NOT PRESENT IN YOUR INGREDIENTS?	
HOW DO YOU QUALIFY AN INGREDIENT MANUFACTURER?	Per SOP 24-0116, Supplier Qualification Program

SECTION 7: AUTHENTICITY OF INFORMATION & CONTACT INFORMATION				
COMPANY NAME:	American Laboratories, Inc.			
CONTACT NAME:	John Garcia TITLE: Sale		Sales Director	
E-MAIL ADDRESS:	jgarcia@americanlaboratories.com			

Commented [MC2]: Not sure what they are looking for here?

Commented [MC3]: Not sure what they are looking for here?





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BY SIGNING BELOW, I CERTIFY THAT THE INFORMATION GIVEN BY ME TO THE NATIONAL ANIMAL SUPPLEMENT COUNCIL (NASC), INC. IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE. I UNDERSTAND THAT IF THE INFORMATION PROVIDED IS NOT THOROUGH AND COMPLETE, NASC WILL REJECT THE FORM AND RESUBMISSION OF THE FORM WILL BE REQUIRED.

SIGNATURE

DATE