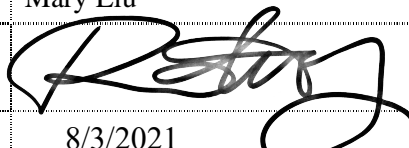


HS Biopharmaceuticals, Inc

Title:	Supplier Qualification Form	Effective Date:	August 03, 2021
SOP#	F-003-b	Revision:	00
Written by:	Rae Martin	Reviewed by:	Mary Liu
Signature:	<i>Rae Martin</i>	Signature:	
Date:	August 03, 2021	Date:	8/3/2021

1. Supplier Information

 Verification

 Re-verification

Supplier Name:	Jiaxing Hengjie Biopharmaceutical CO., LTD.		
Address:	No.20 Tongyi Road, Xinfeng Industrial Park, Jiaxing, Zhejiang 314005, China.		
Contact Person:			
Name:	Li Bin	Phone:	+0086 13736405010
Title:	Quality Manager	Email:	quality@hsnutra.com
Description of Product/Service:	Manufactures and sells the following ingredients to HB Biopharmaceuticals, Inc: 1. Chondroitin Sulfate Sodium 2. Chicken Collagen 3. D Glucosamine HCL/2KCL/2NACL 4. Shark Cartilage Powder 5. Fish collagen 6. Methyl-Sulfonyl-Methane(MSM) 7. Hyaluronic Acid 8. Bovine Collagen		

2. Verification Requirements

Required (Y/N)	Item/Document	Acceptable	
		Yes	No
Y	FDA registration number <u>19126595900</u>	Y	
Y	Registration/Permit/Certification from local authorities	Y	
Y	Compliance Standing	Y	
Y	Procedures, processes, practices, and records related to the dietary supplement cGMP (CFR111)	Y	
Y	Procedures, processes, practices, and records procedures, processes, and practices related to food safety including but not limited to Allergen Control Program, Food Safety Plan, Food Defense, Intentional Adulteration Mitigation if applied.	Y	
Y	Supply Questionnaire (F-002-I)	Y	
Y	Third-party certifications	Y	
Y	On-site audit report and CAPA follow-up if applied	Y	
	FDA Inspection Report and 483s CAPAs follow-up		
	Other:		
	Other:		

Remarks: The supplier holds an effective business and drug manufacturing licenses issued by local authorities (see Exhibit A and B). According to the FDA compliance profile (EXB C), the foreign supplier has registered in FDA and it has no FDA recalls, import alert, warning letters, or 483s in the last three years except a shipment of glucosamine from the supplier was subject to an FDA import refusal on 09/06/2018 due to "lack adequate direction for use; False; Misbranded". The supplier stated that the shipment was an sample for a potential pharmaceutical customer, which was an isolated incident. The supplier has not supplied any pharmaceutical grade of ingredients to the US.

The supplier has filled out Supplier Questionnaire form and submitted supporting documents (EXB D and EXB E), indicating that the supplier has established and implemented dietary supplement cGMP 21CFR111) and food safety systems.

The supplier has been certified by NSF that they are in compliance with 21CFR111 and certain applied requirements of 21CFR117 (see EXB F) The last onsite audit performed by NSF was on March 16-18, 2021. The NSF audit report (see EXB G) and corrective action report (see EXB H), and the supplier's CAPAs (see EXB I) were found acceptable.

The supplier also received certifications of ISO9001(see EXB J), ISO22000 (see EXB K), MSC(Marine Stewardship Council Standards)(see EXB L), and HALAL(see EXB M).

A food safety plan (see EXB N) was reviewed and found acceptable.

Based on all the above-mentioned information, the supplier is approved as a foreign supplier for HS Biopharmaceuticals, Inc.

3. Results: Approved Rejected

Remarks:

4. Signatures

Performed by (Qualified Individual)

Name (print): **Rae Martin**

Title: President of Continuum Partner Consulting

Signature: *Rae Martin*

Date: August 16, 2021

Reviewed by (Supply Chain Management)

Name (print): **Mary Liu**

Title: CEO

Signature: 

Date: August 16, 2021

