ARTISAN LABS	Recall SOP-014	Issued By/Date: 220427 Approved By/Date: 220427

1.**Purpose**:
This procedure outlines the methods for responding to a notic of nonconforming and potentially unsafe products in order to prevenet, eliminate or reduce likelihood of harm to the customer.

2.**Scope**:
Applies to all products manufactured at Artisan Labs and all processing associated with those products.

3.**Associates Responsible**:
All Department Management

4.**Materials and equipment needed**:
Data Ninja

5.**Associated SOP:**
Recall Flowchart

5.**Procedure**:

A. **Product Recall of Bulk Manufactured by Another Supplier or Goods manufactured by Artisan Labs**
   a. An agreement should be established between the client and Artisan Labs that communications regarding recalls will occur between the two parties affecting any current or previous purchase orders.
   b. Upon receipt of notice of recall, information detailing recall and requested processes must be fully communicated to all management parties.
   c. If Artisan Labs is in possession of a client's bulk that has been manufactured by another supplier and is being recalled, all responsibility and decisions pertaining to the recall lies with the customer. Artisan Labs may collect information requested by the client, but ultimately the responsibility is that of the client and all further carried out steps must be in coordination with the client.
   d. Customers must be informed if an internal deviation or hazard with the manufactured product has occurred. The customer solely determines whether to move forward with any possible reworking of the product, or to recall the product depending on the seriousness of the potential hazard.
   e. Artisan may need to provide information that includes but not limited to:
      i. Product name and lot number
      ii. Manufacturing Reports

a. QC line Report
b. Line History Report
c. Production Cleaning Checklist
d. Scrap Report

iii. Any previous non-conformances
iv. Micro Results
v. Investigation of deviation and root cause

B. Product in Process

a. Products manufactured by Artisan Labs or a third party should be halted and stored in the proper designated holding area until the client has given a final notice of the product's status and/or disposal instructions.

C. Documentation

a. Product status will need to be changed in DATA NINJA under the MFG Record. The status of the product batch and/or final goods lot code will need to be changed to "HOLD". A description of the client's disposal request will also need to be documented.

Document history	
Version No.	Reason for change
01 02	New document Separated Complaint and Recall. Distinguished notification process and responsibility of parties.