DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Medical Products and Tobacco Program Operations Office of Medical Products and Tobacco Operations, U.S. Food & Drug Administration 12420 Parklawn Drive, ELEM-2032 Rockville, MD 20857 (301)796-5521 Industry Information: www.fda.gov/oc/industry	2/11/2014 -25/2014
	FEI NUMBER 2431784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Andrew Ameye, Vice President, Product Supply

FIRM NAME	STREET ADDRESS
ALK-Abello, Inc.	35 Channel Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Port Washington, NY 11050	Allergenic Extract Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Product is not manufactured as described in the approved licensed. For example:

A. Customers place orders for special mix lots, which are composed of a (b) (4) (b) (4) aqueous allergenic finished licensed products. The customer orders are not linked to the specific patients. Approximately (b) (4) special mix lots can be manufactured per week.

B. An appropriately identified reserve sample(s), representative of each lot or batch of product is not retained and or stored under conditions consistent with product labeling and /or the same immediate container –closure system. Specifically, reserve samples are not maintained for special mixed lots.

C. Each lot of special mix allergenic extract is not tested prior to release for conformance with all approved release specification for allergenic extracts. Special mix lots are only tested for conformance with sterility and visual inspection specification prior to final release.

D. The sterility test method used for release testing of special mix allergenic extract products has not been validated for the intended purpose. The procedure for sterility testing as described SOP 117.05 (16143version 03) version Sterility Testing For Sterile Preparation Manufactured in the Aseptic Processing Area(APA), has not been validated to show that the special mix allergenic extracts which can contain up to (b) (4) different extracts are not bacteriostatic and/or fungistatic.

2. Procedures designed to prevent microbiological contamination of sterile products are deficient. Specifically,

A. Frequency of environmental monitoring performed on the Laminar Air Flow (LAF) Units in the Small Volume Production area (Room (b) (4)) where licensed (Made to Stock) and special mix products are aseptically manufactured is deficient. The (b) (4) LAF units in the aseptic filling area (Room (b) (4)) are only monitored (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Susan M Jackson	Susan M. Jackson, CSO	2/25/2014

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These LAF units can be used to manufacture up to (b) (4) special mix lots per week.

B. During the observation of aseptic filling activities for Made to Stock Acremonium aqueous lot 1133949, and Fire Ant Lot 00001156868, both filling operators working in the observed to have facial skin exposed in grade (b) (4) (b) (4) area (Room (b) (4).

3. The written procedure for special mix manufacturing, SOP 16150 - 3.0 The Manufacturing of Made to Order Special Mixes is silent with respect to procedures for line clearance between lots manufactured in laminar air flow units. The Small Volume Production area (Room (b) (4) where special mixes are manufactured is equipped with (b) (4) (b) (4) laminar flow hoods and a total of up to (b) (4) lots of special mixes can be manufactured per day.

4. The manufacturing procedure for the use of (b) (4) (b) (4) products processed into special mixes does not have a documented requirement for mixing of the (b) (4) products prior to custom special mixing. Filling instructions requires the (b) (4) be mixed for (b) (4) RPM for (b) (4) (b) (4) (b) (4). In addition, Made to Stock labeled vials requires the customer to "shake vial well before using".

5. Batch manufacturing records and Process Simulation batch records for special mix allergenic extract and custom orders do not include complete information relating to production of each batch. Specifically, batch manufacturing records and process simulation records do not include complete information such as the laminar air flow units used in aseptic filling of the lot. In addition, the batch production records do not contain complete information for (b) (4) solutions used to (b) (4) (b) (4) extract for special mixes and custom orders.

6. There is a failure to thoroughly investigation deficiencies for distributed product. Specifically, (b) (4) Lot 1E01299 failed stability at the (b) (4) month test point for pH and precipitation (OOS (b) (4) This (b) (4) Lot 1E01299 was used in allergenic extract dilutions. Final products with the (b) (4) diluent have been marketed and are still within expiry. The firm failed to evaluate all products in which the (b) (4) was used as a diluent.

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A. A Biological Product Deviation Report was not filed for OOS (b) (4) [redacted] Lot 1E01299 which failed stability at (b) (4) months for pH and precipitation.

7. Current lot numbering SOP WIN 11662 version 01 effective 10 June 2013 (b) (4) Process Order is deficient in that this SOP fails to clearly describe the lot numbering system utilized for all batches manufactured. SOP WIN 11662 only describes how to create a process work order.

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