

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 10 Waterview Blvd. 3rd Floor Parsippany, NJ 07054 973-331-4900 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 4/4-6,11,17,25/2017, 5/18/2017
	FEI NUMBER 3004600183

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: David M. Miller, R.Ph and Owner

FIRM NAME Millers of Wyckoff, Inc.	STREET ADDRESS 678 Wyckoff Ave.
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CITY, STATE AND ZIP CODE Wyckoff, NJ 07481	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products
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THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

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

OBSERVATION 1

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, the firm has no stability data to support the 90 day beyond use date for Coenzyme Q-10 in Oil 25mg/ml injectable lot #02062017@21 (coenzyme Q10).

OBSERVATION 2

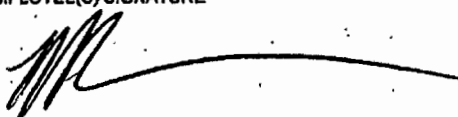
Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

a. Coenzyme Q-10 in Oil 25mg/ml injectable lot #02062017@21 (coenzyme Q10), produced on 2/6/2017 and dispensed on an unknown date was not tested for potency.

b. Mineral Mix lot#03152017@50 (b) (4) produced on 3/15/2017 and delivered on 3/16/2017 was not tested for potency.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Nancy Scheraga, CSO	DATE ISSUED 05/18/2017
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- c. Custom Compound ((b) (4) Modified Capsule lot #03082017@1 ((b) (4) (b) (4), produced on 3/7/2017 and delivered on 3/8/2017, was not tested for potency.
- d. Adrenal Capsule lot #01182017@50 (b) (4) produced on 1/19/2017 and delivered on 1/25/2017, was not tested for potency.
- e. Acetylcysteine/Co-Q10/Lipoic Acid/Vitamin D3 250mg/75mg/50mg/1000U Capsule lot #02082017@79 (coenzyme Q10), produced on 2/13/2017 and dispensed on an unknown date, was not tested for potency.

OBSERVATION 3

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

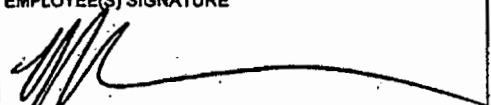
Specifically, Coenzyme Q-10 in Oil 25mg/ml injectable lot #03272017@78, produced on 2/6/2017 and Mineral Mix lot #03152017@50, produced on 3/15/2017 were not tested for sterility and endotoxin.

OBSERVATION 4

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically, there is no identity testing of the following active ingredients:

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- a. Coenzyme Q10 used for the sterile production of Coenzyme Q-10 in Oil 25mg/ml injectable lot #02062017@21 on 2/6/2017 and Acetylcysteine/Co-Q10/Lipoic Acid/Vitamin D3 250mg/75mg/50mg/1000U Capsule lot #02082017@79 on 2/13/2017.
- b. (b) (4) used for the sterile production of Mineral Mix lot#03152017@50 on 3/15/2017.
- c. (b) (4) used for the production of Custom Compound (b) (4) Modified Capsule lot #03082017@1 on 3/7/2017.
- d. (b) (4) used for the production of Adrenal Capsule lot #01182017@50, on 1/19/2017.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

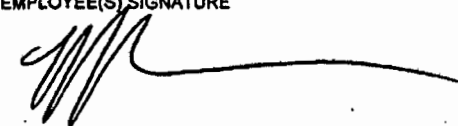
Specifically, the environmental monitoring program performed in the ISO 5 (b) (4) and ISO 7 clean room is inadequate. For example,

- a. The personnel working within the ISO 5 (b) (4) perform (b) (4) sampling every (b) (4) and not (b) (4) such as Coenzyme Q-10 in Oil 25mg/ml injectable lot #02062017@21 and Mineral Mix lot#03152017@50.
- b. The ISO 5 (b) (4) was not monitored for viable and non-viable particulates during the production of sterile products Coenzyme Q-10 in Oil 25mg/ml injectable lot #02062017@21 and Mineral Mix lot#03152017@50.

OBSERVATION 6

There firm's use of disinfecting agents in the cleanroom and ISO 5 areas is inadequate and infrequent.

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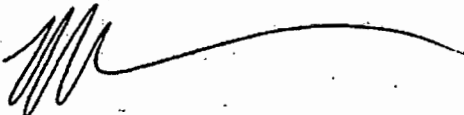
Specifically, there is no data to support the contact times for the cleaning agents in the ISO 5 (b) (4) and ISO 7 cleanroom. Examples of cleaning agents and contact times are as follows:

(b) (4)

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Nancy Scheraga, CSO

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