**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.
TO: David M. Miller, R.Ph and Owner

FIRM NAME
Millers of Wyckoff, Inc.

CITY, STATE AND ZIP CODE
Wyckoff, NJ 07481

STREET ADDRESS
678 Wyckoff Ave.

TYPE OF ESTABLISHMENT INSPECTED
Producer of Sterile and Non-Sterile Drug Products

---

c. Custom Compound (b) (4) Modified Capsule lot #03082017@1: (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/100U 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:

---

EMPLOYEE(S) SIGNATURE
[Signature]

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Nancy Scheraga, CSO

DATE ISSUED
05/18/2017
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/100U 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 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 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.
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)