

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Los Angeles District 19701 Fairchild, Irvine, CA 92612 949-608-2900 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 02/12 - 03/05/2019
	FEI NUMBER 3014199548

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Bhavyata (NMI) Ramani, Vice President

FIRM NAME BMD Skincare, Inc.	STREET ADDRESS 8445 Canoga Ave
CITY, STATE AND ZIP CODE Canoga Park, CA 91304	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

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

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

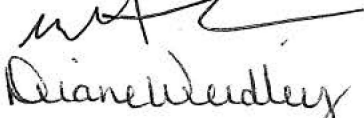
A. Your firm does not have stability studies of the following drug products produced by your facility to determine the expiration date. Your firm determines the expiration date by using the earliest expiration date of the raw materials or two years expiration from the date of production, whichever is shorter.

- HQRA (hydroquinone 4%)
- HQRA 3 (hydroquinone 3%/hydrocortisone 0.50%)
- HQRA + (hydroquinone 4%/tretinoin 0.1%)

B. Your firm does not have batch records to show that the drug products produced for the stability studies are using the same formulations and the same container closure system as the drug products produced for distribution. The stability reports do not identify the product lot numbers and only reference the formulation number. For example,

- Night Cream Enhancer (hydroquinone 4%) 1.8 oz Lot # ^{(b) (4)} [REDACTED]
- RA Cream 0.025% (tretinoin 0.025%) 1 oz Lot # ^{(b) (4)} [REDACTED]
- RA Cream 0.025% (tretinoin 0.025%) 1.8 oz Lot # ^{(b) (4)} [REDACTED]
- RA Cream 0.05% (tretinoin 0.05%) 1 oz Lot # ^{(b) (4)} [REDACTED]
- RA Cream 0.05% (tretinoin 0.05%) 1.8 oz Lot # ^{(b) (4)} [REDACTED]

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
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- RA Cream 0.1% (tretinoin 0.1%) 1 oz Lot # (b) (4)
- RA Cream 0.1% (tretinoin 0.1%) 1.8 oz Lot # (b) (4)
- Skin Lightening Cream #5 (hydroquinone 5%) 1 oz Lot # (b) (4)
- Skin Lightening Cream #5 (hydroquinone 5%) 1.8 oz Lot # (b) (4)
- Skin Lightening Cream #8 (hydroquinone 8%) 1.8 oz Lot # (b) (4)
- Skin Lightening Cream # 12 (hydroquinone 12 %) 1.8 oz Lot # (b) (4)
- Vitamin C HQ Serum (Hydroquinone 4%) 1 oz Lot # (b) (4)

C. Your firm did not conduct investigations into the failure of the stability samples. For example,

- 1) The Night Cream Enhancer stability samples at (b) (4) °C/(b) (4) %RH failed pH at (b) (4) and (b) (4) time points. The specification was (b) (4) to (b) (4). The results were (b) (4) and (b) (4) respectively.
- 2) The Night Cream Enhancer stability samples at (b) (4) °C/(b) (4) %RH failed viscosity at (b) (4) and (b) (4) time points. The specification was (b) (4) to (b) (4). The results were (b) (4) and (b) (4) respectively.
- 3) The Night Cream Enhancer stability samples at (b) (4) °C/(b) (4) %RH failed pH at (b) (4) and (b) (4) time points. The specification was (b) (4) to (b) (4). The results were (b) (4) and (b) (4) respectively.
- 4) The Night Cream Enhancer stability samples at (b) (4) °C/(b) (4) %RH failed viscosity at (b) (4) and (b) (4) time points. The specification was (b) (4) to (b) (4). The results were (b) (4) and (b) (4) respectively.
- 5) The Skin Lightening Cream # 5 1.8 oz stability samples at (b) (4) °C/(b) (4) %RH failed pH at (b) (4) and (b) (4) time points. The specification was (b) (4) to (b) (4). The results were (b) (4) and (b) (4) respectively.

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6) The Skin Lightening Cream # 5 1.8 oz stability samples at $(b)(4)$ °C, $(b)(4)$ %RH failed viscosity at $(b)(4)$, $(b)(4)$ and $(b)(4)$ time points. The specification was $(b)(4)$ to $(b)(4)$. The results were $(b)(4)$ respectively.

7) The Skin Lightening Cream # 5 1.8 oz stability samples at $(b)(4)$ °C, $(b)(4)$ %RH failed viscosity at $(b)(4)$ and $(b)(4)$ time points. The specification was $(b)(4)$ to $(b)(4)$. The results were $(b)(4)$ and $(b)(4)$ respectively.

8) The Skin Lightening Cream # 5 1.8 oz stability samples at $(b)(4)$ °C, $(b)(4)$ %RH failed pH at $(b)(4)$ and $(b)(4)$ time points. The specification was $(b)(4)$ to $(b)(4)$. The results were $(b)(4)$ and $(b)(4)$ respectively.

9) The Skin Lightening Cream # 5 1 oz stability samples at $(b)(4)$ °C, $(b)(4)$ %RH failed pH at $(b)(4)$ time points. The specification was $(b)(4)$ to $(b)(4)$. The result was $(b)(4)$.

OBSERVATION # 2

Each lot of components is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically,

A. Your firm is using a drug substance not suitable for its intended purpose. The supplier's certificate of analysis for the Retinoic Acid USP Lot # $(b)(4)$ indicated that the drug substance was to be used as "For research purposes only. Not for drug or clinical use in humans or human food additive use." This lot of Retinoic Acid USP was used to produce the following drug products.

- RA Cream 0.025% Lot # 210A
- RA Cream 0.05% Lot # 218A
- RA Cream 0.1% Lot # 212A

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B. Your firm failed to confirm that the quality of (b)(4) was suitable for use in the production of non-sterile drug products.

For example, the following drug products were produced using (b)(4):

- HQRA Lot # 206A
- HQRA 3 Lot # 224A
- HQRA + Lot # 202A
- Night Cream Enhancer Lot # 214A
- Skin Lightening Cream #5 Lot # 193A
- Skin Lightening Cream #8 Lot # 171A
- Skin Lightening Cream #12 Lot # 222A

OBSERVATION # 3


The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed. Specifically,

A. The Quality Unit does not perform a review of complete Batch Production Records indicated by a verification signature on such records.

For example, the following drug products were released for distribution without a documentation showing that the batch production records were reviewed and released by the quality unit.

- Night Cream Enhancer Lot # 214A
- HQRA Lot # 206A
- HQRA 3 Lot # 224A

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B. Your firm's quality control manager (EDA) is also overseeing the bulk product compounding and filling operations including verifying weighed materials and manufacturing steps. The quality control manager is responsible for all quality functions within the facility including bulk and finished product testing.

OBSERVATION # 4

There was a failure to handle and store components at all times in a manner to prevent contamination.

Specifically,

Monitoring of required storage conditions of a components is not performed. The supplier recommended storage condition of Retinoic Acid USP (b)(4), Lot # (b)(4) is (b)(4) °C, protect from light and store under (b)(4) (b)(4) Retinoic Acid Lot # is stored in an unmonitored refrigerator inside the (b)(4) room. This lot was used to produce RA Cream 0.025% Lot # 210A, RA Cream 0.05% Lot # 218A, and RA Cream 0.1% Lot # 212A.

OBSERVATION # 5


Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

A. Your firm cannot locate the receiving and testing records of drug substances that are used to produce drug products at your facility. For example,

- 1) Retinoic Acid USP Lot # (b)(4) (Control # (b)(4)) was used to produce the following drug products.
- RA Cream 0.025% Lot # 210A
 - RA Cream 0.05% Lot # 218A
 - RA Cream 0.1% Lot # 212A

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2) Hydroquinone USP Lot # (b)(4) was used to produce the following drug products.

- Skin Lightening Cream # 5 Lot # 193A
- Skin Lightening Cream # 8 Lot # 171A

3) Hydrocortisone USP Lot # (b)(4) (Control # (b)(4) was used to produce HQRA 3 Lot # 224A.

B. Your firm has not qualified the suppliers of the drug substances that are used to produce finished drug products at your facility.

For example,

1) Retinoic Acid USP Lot # (b)(4) from Supplier (b)(4) was used to produce the following drug products.

- RA Cream 0.025% Lot # 210A
- RA Cream 0.05% Lot # 218A
- RA Cream 0.1% Lot # 212A

2) Hydroquinone USP Lot # (b)(4) with Control # (b)(4) from Supplier (b)(4) was used to produce the following drug products.

- Skin Lightening Cream # 12 Lot # 222A
- Night Cream Enhancer Lot # 214A
- Vitamin C HQ Serum Lot # 196A

OBSERVATION # 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity.

Specifically,

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Your firm has not conducted preservative effectiveness testing to show that the amount of preservative in the finished drug products is adequate to inhibit microbiological growth through the product expiration date.


For example, the following drug products contain the standard cream base as a component which contain (b) (4) % of Phenoxyethanol as a preservative.

- HQRA (hydroquinone 4%)
- HQRA 3 (hydroquinone 3%/hydrocortisone 0.50%)
- HQRA + (hydroquinone 4%/tretinoin 0.1%)
- Night Cream Enhancer (hydroquinone 4%)
- RA Cream 0.025% (tretinoin 0.025%)
- RA Cream 0.05% (tretinoin 0.05%)
- RA Cream 0.1% (tretinoin 0.1%)
- Skin Lightening Cream #5 (hydroquinone 5%)
- Skin Lightening Cream #8 (hydroquinone 8%)
- Skin Lightening Cream #12 (hydroquinone 12%)

OBSERVATION # 7
 Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,
 Process validation has not been conducted for the following drug products.

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- HQRA 3 (hydroquinone 3%/hydrocortisone 0.50%)
- HQRA + (hydroquinone 4%/tretinoin 0.1%)
- Night Cream Enhancer (hydroquinone 4%)
- RA Cream 0.025% (tretinoin 0.025%)
- RA Cream 0.05% (tretinoin 0.05%)
- RA Cream 0.1% (tretinoin 0.1%)
- Skin Lightening Cream #5 (hydroquinone 5%)
- Skin Lightening Cream #8 (hydroquinone 8%)
- Skin Lightening Cream #12 (hydroquinone 12%)
- Vitamin C HQ Serum (hydroquinone 4%)

OBSREVATION # 8

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design, of adequate size and suitably located to facilitate operations for its intended use.


Specifically,

Your firm has not qualified the equipment that is used to produce drug products at your facility.

For example,

- (b) (4), Model: (b) (4), S/N: (b) (4)
- (b) (4), Model: (b) (4), S/N: (b) (4)
- (b) (4), Model: (b) (4), S/N: (b) (4)
- (b) (4), Model: (b) (4), S/N: (b) (4)
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OBSERVATION # 9

Batch production and control records are not prepared for each batch of drug product produced and do not include complete information relating to the production and control of each batch.

Specifically,

- A. There are no batch production and control records for the labeling operations.
- B. There are no documentations regarding verification of the printed labels against the master label.
- C. A complete labeling control records, specimen, and copy of labeling of the drug products are not maintained.

OBSERVATION # 10

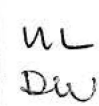
Samples taken of drug products for determination of conformance to written specifications are not representative.

Specifically,

You firm does not have justification for sampling ^{(b) (4)} finished products containers, ^{(b) (4)} samples for finished product release testing is representative of the lot produced. For example,

- Skin Lightening Cream # 8 Lot # 171A produced ^{(b) (4)} units
- HRQA Lot # 202A produced ^{(b) (4)} units
- RA Cream 0.025% Lot # 210A produced ^{(b) (4)} units
- RA Cream 0.05% Lot # 218A produced ^{(b) (4)} units
- RA Cream 0.1% Lot # 212A produced ^{(b) (4)} units

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OBSERVATION # 11

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, you compound drug products that:

- A. Are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or
- B. Are not identical or nearly identical to an approved drug, but it contains a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include;


- RA Cream 0.025%
- RA Cream 0.05%
- RA Cream 0.1%

OBSERVATION # 12

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels required per 503B(a)(10)(A):

- A. The statement "This is a compounded drug,"
- B. The lot or batch number
- C. The established name of the drug
- D. The dosage form and strength
- E. The date that the drug was compounded
- F. The expiration date
- G. The storage and handling instructions

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H. The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"

I. The quantity or proportion of each active and inactive ingredient

Examples of drug product labels that do not contain this information:

- HQRA (hydroquinone 4%)
- HQRA 3 (hydroquinone 3%/hydrocortisone 0.50%)
- HQRA + (hydroquinone 4%/tretinoin 0.1%)
- Night Cream Enhancer (hydroquinone 4%)
- RA Cream 0.025% (tretinoin 0.025%)
- RA Cream 0.05% (tretinoin 0.05%)
- RA Cream 0.1% (tretinoin 0.1%)
- Skin Lightening Cream #5 (hydroquinone 5%)
- Skin Lightening Cream #8 (hydroquinone 8%)
- Skin Lightening Cream #12 (hydroquinone 12%)
- Vitamin C HQ Serum (hydroquinone 4%)


OBSREVATION # 13

The container of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Specifically, the following information is not found on your drug containers required per 503B(a)(10)(B):

A. The following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 (or any successor Internet Web site or phone number).

Examples of drug product containers that do not contain this information:

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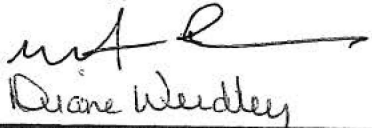
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- RA Cream 0.025% (tretinoin 0.025%)
- RA Cream 0.05% (tretinoin 0.05%)
- RA Cream 0.1% (tretinoin 0.1%)
- Skin Lightening Cream #5 (hydroquinone 5%)
- Skin Lightening Cream #8 (hydroquinone 8%)
- Skin Lightening Cream #12 (hydroquinone 12%)
- Vitamin C HQ Serum (hydroquinone 4%)

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