Nowcos Co., Ltd 2/14/18

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS

Warning Letter 320-18-34

February 14, 2018

Mr. Hyang Seon Ro
President and CEO
Nowcos Co., Ltd.
A-1004, BYC Highcity
131 Gasan digital 1-ro
Geumcheon-gu, Seoul
Korea, South

Dear Mr. Ro:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Nowcos Co., Ltd. at 37 Ayamok-gil, Sojeong-myeon, Sejong-Si, from July 31 to August 4, 2017.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We have not received a response from your firm for corrective actions to the deviations identified during the inspection. We acknowledge your January 11, 2018, correspondence regarding placement of your firm on Import Alert 66-40.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. Your firm failed to establish written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).

You have not validated the processes used to manufacture your over-the-counter (OTC) drug products. You did not perform process qualification studies. You also lack an ongoing program for monitoring process control to ensure stable manufacturing operations and consistent drug quality. See FDA's guidance document, *Process Validation: General Principles and Practices*, for general principles and approaches that FDA considers appropriate elements of process validation at **https://www.fda.gov/downloads/drugs/guidances/ucm070336.pdf (https://www.fda.gov/downloads/drugs/guidances/ucm070336.pdf)**.

2. Your firm failed to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality and purity (21 CFR 211.160(b)).

You failed to validate your test methods, establish procedures for sampling raw materials and finished products, and perform growth promotion testing on media used for microbial testing of finished OTC drug products.

3. Your firm failed to establish and follow adequate written procedures for cleaning and maintenance of equipment (21 CFR 211.67(b)).

You have not conducted cleaning validation studies to demonstrate that your cleaning procedures for non-dedicated production equipment are adequate to prevent cross-contamination.

4. Your firm failed to establish and follow an adequate written testing program designed to assess the stability characteristics of drug products and to use results of such stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)).

Your stability studies are inadequate to ensure the OTC drug products you manufacture remain within specification throughout their labelled expiry period.

CGMP Consultant Recommended

Based upon the nature of the violations identified at your firm, we strongly recommend engaging a consultant, qualified as set forth in 21 CFR 211.34, to assist your firm in meeting CGMP requirements.

Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.

Conclusion

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing other violations.

Because of the findings of the FDA inspection described in this letter, FDA placed your firm on Import Alert 66-40 on December 27, 2017.

Until you correct all violations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug manufacturer.

Failure to correct these violations may also result in FDA continuing to refuse admission of articles manufactured at Nowcos Co., Ltd. at 37 Ayamok-gil, Sojeong-myeon, Sejong-Si, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to **CDER-OC-OMQ-Communications@fda.hhs.gov (mailto:CDER-OC-OMQ-Communications@fda.hhs.gov)** or mail your reply to:

CDR Frank Verni, R.Ph.
Compliance Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4359
10903 New Hampshire Avenue
Silver Spring, MD 20993
USA

Please identify your response with FEI 3009968674.

Sincerely,
/S/
Francis Godwin
Acting Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

cc:
Mr. Heekwon Hong
Executive Director, Production
Nowcos Co., Ltd.
37 Ayamok-gil, Sojeong-myeon
Sejong-Si
Korea, South

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