DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

SEP 0 9 2014

FDA REQUESTED RECALL

Christopher Van Downing, President and Co-Owner
Ashley Michelle Downing, Director, Vice President, and Co-Owner
Downing Labs LLC
4001 McEwen Rd Suite 110
Dallas, TX 75244-5020

Dear Mr. and Mrs. Downing:

The Food and Drug Administration (FDA) is requesting that you immediately initiate a recall of all sterile drug products produced at Downing Labs LLC dba NuVision Pharmacy aka NuVision Pharmacy, Inc.[1] within expiry.

This request is based on FDA findings during a June 3 to July 16, 2014, FDA inspection of the Downing Labs facility (doing business as NuVision Pharmacy) in Dallas, Texas. During this inspection, FDA investigators found that you identified non-sterility in several different lots of drug products intended to be sterile that were produced at your facility. At least 19 purportedly sterile drug product lots produced between June 2013 and May 2014 tested positive for microbial contamination. In addition, three lots failed endotoxin testing. Given the high rate of contamination, there is a high probability that contaminated units from other purportedly sterile drug product lots produced at the Downing Labs facility are currently in distribution. Based on the inspectional findings, FDA has serious concerns about the conditions and practices at the Downing Labs facility for the production of sterile drugs, which result in a lack of sterility assurance.

Administration of a non-sterile drug product intended to be sterile may result in a local or systemic infection, which in turn may result in hospitalization, significant morbidity (permanent organ damage), or a fatal outcome.

Sterile drug products produced at the Downing Labs facility are adulterated within the meaning of sections 501(a)(2)(A) and 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) [21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B)].

1 On January 15, 2014, Downing Labs, LLC acquired NuVision Pharmacy, Inc. Ashley Michelle Downing (nee Sharp) was the sole director of NuVision Pharmacy, Inc. from May 1, 2013, until the acquisition. Since the acquisition, Mrs. Downing has been the co-owner, Director, and Vice President/Secretary/Treasurer of Downing Labs, LLC dba NuVision Pharmacy aka NuVision Pharmacy, Inc. Downing Labs operated under NuVision Pharmacy Inc.'s Texas Board of Pharmacy license until June 25, 2014, at which time Downing Labs was licensed by the Texas Board of Pharmacy.

During the recent inspection, FDA investigators found:

- At least 19 lots purported to be sterile (out of approximately (b) (4) lots) produced in the past year (i.e., June 2013 to May 2014) at the Downing Labs facility tested positive for microbial contamination, and three additional lots failed endotoxin testing. Given the high rate of contamination, there is a high probability that contaminated units from other purported to be sterile drug product lots produced at the Downing Labs facility are currently in distribution. Although sterility testing of a limited sample of the lots of drug products distributed between June 2013 and June 2014 did not reveal contamination, microbiological contamination is episodic and non-uniformly distributed. Because of its very low statistical power, the final quality control test for sterility will only infrequently detect microbial contamination.

- The completed investigations of the sterility and endotoxin failures at the Downing Labs facility in the past year (i.e., June 2013 to May 2014) were not thorough. The proposed root causes are merely suppositions. The investigations concluded that: (a) the sterility failures may be due to (b) (4) failures and/or poor aseptic technique of the operator during (b) (4) and (b) the failures may be due to elevated endotoxin levels in the active pharmaceutical ingredients used to produce the drugs. However, you have not provided any sound scientific data to support these suppositions. For example, Downing Labs has not shown via testing that incoming active pharmaceutical ingredient (API) lots have elevated bioburden or endotoxin levels. In addition, the corrective actions that Downing Labs implemented (including retraining operators, changing (b) (4) models, and destroying API lots) are not effective because from June 2013 through May 2014 there were on average approximately two failures per month at the Downing Labs facility which were attributed to the same root causes. In addition, the investigations by the Downing Labs facility are inadequate because they were not extended to other potentially affected lots. The continued failures indicate that Downing Labs has not yet identified and corrected the root causes of the failures.

- Major renovations were made to Downing Labs' cleanroom (e.g., repositioning of (b) (4) HEPA filters in the ISO 5 area in April 2014). These renovations were made without any evidence of additional controls (such as cleaning or segregation) implemented to protect sterile drugs from contamination. Prior to recertification of the cleanroom on May 21, 2014, Downing Labs produced lots of purportedly sterile drug products in the ISO 5 area. In addition, Downing Labs does not have sufficient documentation to demonstrate that the May 21, 2014, recertification included smoke studies under dynamic conditions. The lots produced during this time period (except the two that failed sterility testing) were distributed.

- You identified vials with fibers, particles, and/or cloudiness from at least 184 different lots of drugs purported to be sterile. You released the lots for distribution after attempting to cull the "bad vials" based on visual inspection which included magnification, a light source, and a black and white background. You did not investigate any of these events.

We acknowledge receipt of your responses to the Form FDA-483 dated August 6, 2014, and August 20, 2014, which describe your proposed corrective actions. Your responses do not address the impact of objectionable conditions on the production of sterile drugs produced and distributed prior to implementation of adequate corrective actions. In addition, the corrective actions you have implemented are insufficient to address all of the objectionable conditions found at your firm and to assure sterility.

FDA has determined that the Downing Labs facility's sterility assurance problems are likely to adversely impact all drugs aseptically produced at the Downing Labs facility and that there is a significant probability that purportedly sterile drugs produced under these poor conditions would be non-sterile. Due to the lack of sterility assurance at the Downing Labs facility of purportedly sterile drug products, products made at the facility present a risk of illness or injury to consumers. To date, Downing Labs has not initiated a voluntary recall of all sterile products produced at the Downing Labs facility that are within expiry. FDA action is necessary to protect the public health and welfare. FDA will classify this FDA requested action as a Class II recall for the products for which there is a lack of sterility assurance. A Class II recall is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote. FDA recommends level A (100%) effectiveness checks be performed to the user level.

FDA's recall policy and guidance is found in Title 21 Code of Federal Regulations (CFR), Part 7. FDA's Dallas District Office will provide guidance in implementing and assuring the effectiveness of your recall of these products, including reviewing the proposed recall communication to your consignees. We are requesting that you work closely with the district office and that you provide any necessary information regarding the recall in a timely manner. Title 21 CFR, Part 7 provides for, among other things, publishing your recall in an upcoming issue of the weekly FDA Enforcement Report.

We note that on July 26, 2013, FDA issued a request for NuVision Pharmacy, Inc. to immediately initiate a recall of all lots of all sterile products produced at the Downing Labs facility that were within expiry based on findings during an inspection in 2013 that documented poor sterile production practices and raised concerns about a lack of sterility assurance of NuVision's sterile drug products. NuVision's failure to recall the products, and the recent evidence of sterility failures at the Downing Labs facility suggests that although you continue to produce drugs at the facility, you have not corrected the problems identified in 2013.

Due to the seriousness of this situation, FDA is issuing a press release today, advising consumers of the FDA Requested Recall letter and warning health care providers and healthcare professionals to discontinue use or sale of the purportedly sterile products produced at the Downing Labs facility and of the health risk associated with the use of these products.

Failure to comply with this request can result in further regulatory action being taken against you, your firm, and the adulterated products distributed by your firm.

Please respond to this letter within two business days of receipt. Your response to this letter should be directed to:

Reynaldo R. Rodriguez, Jr, District Director
Dallas District Office
4040 North Central Expressway, Suite 300
Dallas, TX 75204
Phone 214-253-5201, Fax 214-253-5318

Sincerely,

for Melinda K. Plaisier
Associate Commissioner for Regulatory Affairs