DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Food and Drug Administration
Silver Spring, MD 20993

FDA REQUESTED RECALL

May 3, 2016

Steven Russell, CEO
Medaus Inc.
6801 Cahaba Valley Rd, Suite 116
Birmingham, AL 35242-9609

Dear Mr. Russell,

The U.S. Food and Drug Administration (FDA) requests that you immediately initiate a recall of all drug products intended to be sterile produced at Medaus Inc. within expiry.

This request is based on FDA observations during an inspection of your firm from March 7, 2016, through March 11, 2016. During this inspection, FDA investigators observed insanitary conditions including poor aseptic production practices in your sterile processing areas that resulted in a lack of sterility assurance. Administration of a non-sterile drug product that is intended to be sterile may result in a site-specific or systemic infection, which in turn may result in hospitalization, significant morbidity (permanent organ damage), or a fatal outcome.

Products intended to be sterile that are produced at Medaus are adulterated within the meaning of section 501(a)(2)(A) of the Federal Food, Drug and Cosmetic Act (the Act) [21 U.S.C. §§ 351(a)(2)(A)].

During the inspection of your facility FDA investigators observed the following:

1. The movement of supplies and materials into the critical ISO 5 zone creates significant contamination risks. Specifically, investigators observed supplies and materials transferred from the ISO 7 room, an environment of less clean air, into the ISO 5 hood, an environment of cleaner air, without any decontaminating step. This practice increases the risk of introduction of microbial contamination into the ISO 5 area and therefore into products undergoing aseptic manipulations.
2. Red tape used on the working surface of the ISO 5 laminar flow hood may harbor contamination.
3. Bottles of (b) (4), with screw-top lids that were stored in the refrigerators located in the ISO 7 area. These screw-top lids do not represent an adequate container closure system and may allow for the introduction of contamination from the surrounding environment. Time limits have not been established

for the storage of (b) (4) that have been (b) (4) Beyond Use Dates of (b) (4) are assigned to most of your (b) (4) without adequate justification.

4. You have failed to provide and maintain a controlled environment suitable for the processing of sterile drug products. For example:

   a. A HEPA filter is located approximately (b) (4) from return air vents in the ceiling. In addition, tall storage shelving is directly below the HEPA filters obstructing the airflow from the HEPA filters. This configuration may not allow for adequate dilution of particle-laden air throughout the clean room by HEPA-filtered air.
   b. HEPA filters in the ISO 7 area have not been tested for leaks (b) (4).
   c. Pressure differentials between the anteroom (ISO 8) and non-classified (warehouse) area are not monitored and you have no assurance that air does not enter into the classified area from the non-classified area.

We acknowledge receipt of your response dated March 26, 2016, describing your proposed corrective actions. However, your response fails to address the impact of objectionable practices and conditions on the production and distribution of drugs intended to be sterile before implementation of corrective actions.

FDA has determined that due to the lack of sterility assurance in Medaus' drug products intended to be sterile, these products present a risk of illness or injury to consumers. To date, your firm has failed to initiate a recall of all sterile products 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. 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 New Orleans District Office will provide guidance in implementing and assuring the effectiveness of your recall, including reviewing the proposed recall communication to your consignees. We are requesting that you work closely with the district office and that you provide all 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.

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

Ruth Dixon, District Director
New Orleans District Office
404 BNA Drive, Building 200, Suite 500
Nashville, TN 37217-2565
Phone 615-366-7803, Fax 615-366-7802

Due to the seriousness of this situation, FDA will issue a press release today, advising health care professionals and patients of the FDA Requested Recall letter and again warning health care professionals and patients to discontinue use or sale of these products and of the health risk associated with the use of these products.

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

Sincerely,

Melinda K. Plaisier
Associate Commissioner for Regulatory Affairs