DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

November, 12, 2014

Debra L. Vinnedge
Children of God for Life
943 Deville Dr East
Largo, FL 33771

Dear Debra L. Vinnedge:

We thank you for writing to express your concerns over the use of human cell lines in the development of Ebola vaccines. We appreciate the opportunity to discuss the topic of vaccine development and the role FDA plays in protecting the public's health.

In its capacity as a regulatory agency, FDA is responsible for ensuring the safety and efficacy of the products which fall under its purview, including vaccines. As part of that mission, FDA provides guidance to industry regarding vaccine development to promote the production of safe and effective vaccines, and assist vaccine manufacturers in complying with FDA regulations.

FDA's "Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications" describes general parameters for manufacturers to consider when selecting a cell substrate and other biological materials to be used in vaccine production.

Some vaccines licensed by FDA for use in the United States are manufactured from viruses that are grown in human diploid cell lines, such as MRC-5 or WI- 38 cells. These cell lines were derived from aborted human fetal tissue. These abortions, which occurred decades ago, were not undertaken with the intent of producing vaccines. No new fetal tissue is needed to produce cell lines to make these vaccines. These vaccines make important contributions to public health by preventing significant morbidity and mortality from infectious diseases. Additionally, these established cell lines, which have a track record of safety, may be used to develop new vaccines that may make important future public health contributions. An inability to use these cells in the production of the licensed vaccines noted above would deprive the U.S. of these important vaccines, and an inability to use them to develop future vaccines could adversely impact future public health advances.

In your letter you asked specifically about the development of Ebola vaccines. Due to federal disclosure regulations (21 CFR 601.50 and 21 CFR 601.51), FDA is prohibited from disclosing, or even acknowledging, any information regarding unapproved products unless the sponsor has provided written consent for FDA to release such information.

We hope you find the above information helpful. If you have further questions or concerns, please contact us at ocod@fda.hhs.gov or at 1-800-835-4709/240-402-8021.

Sincerely,

Rachael Conklin
Consumer Safety Officer
Consumer Affairs Branch
Division of Communication and Consumer Affairs
Center for Biologics Evaluation and Research
US Food and Drug Administration