

Vaccines, Blood & Biologics

Stem Cell Pharma Inc.

By Certified Mail - Return Receipt Requested

Nov 22 2006

Alfred T. Sapse, M.D., President
Stem Cell Pharma Inc.
1701 Katie Avenue #20
Las Vegas , Nevada 89119

Dear Dr. Sapse:

This letter describes the results of a Food and Drug Administration (FDA) inspection conducted on July 6, 2006. FDA investigator Anthony Keller met with you to review your firm's clinical investigation involving the implantation of amnion tissue to treat a variety of illnesses. FDA conducted this inspection under the agency's Bioresearch Monitoring Program, which includes inspections designed to review the conduct of clinical research involving investigational new drugs.

The inspection revealed that under your direction, at least one physician obtained human placentas from a local hospital, carried them to his office, processed the tissue, and implanted it in at least 16 subjects that you recruited. You did not establish or maintain standard operating procedures for the following critical operations: obtaining the placenta from donors; donor eligibility screening; procedures for storage, processing of placentas to obtain amnion tissue and cells, and disposition of the placentas; testing of the placenta for contaminants; screening of the subjects' suitability in accepting the amnion tissue and cell implants for a non-homologous use; implantation procedures; and subject follow-up for adverse experiences subsequent to the implantation. You did not provide the investigator(s) with a protocol, investigational plan, and or investigator's brochure for conducting the study.

As described below, we have determined that your actions have violated the Public Health Service Act (PHS Act) and the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The amnion tissue and cells are a biological product as defined in section 351(i) of the PHS Act [42 U.S.C. § 262(i)], in that they are a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or analogous product, or arsphenamine or derivative of arsphenamine, applicable

to the prevention, treatment, or cure of a disease or condition of human beings. The amnion tissue and cells are also a drug within the meaning of section 201(g) of the FD&C Act [21 U.S.C. § 321(g)], in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man.

In order to introduce or deliver for introduction a biological product into interstate commerce, a valid biologics license (BLA) must be in effect [42 U.S.C. § 262(a)]. A BLA is issued only after a showing of safety, purity and potency for the product's intended use. Before approval, biological products may generally be distributed for clinical use in humans only if the sponsor has an investigational new drug (IND) application in effect [21 U.S.C. § 355(i); Title 21, Code of Federal Regulations (21 CFR) Part 312]. The amnion tissue and cells are not the subject of an approved BLA, and you do not have an IND in effect.

The amnion tissue and cells obtained from the placenta are human cells, tissues, or cellular and tissue-based products (HCT/Ps) as defined in 21 CFR § 1271.3(d). Under 21 CFR Part 1271, HCT/Ps are not subject to license or IND requirements if certain criteria are met. However, these criteria are not met here. An IND application is required for the amnion tissue and cell implants because they are intended for non-homologous use (21 CFR § 1271.10(a)(2); 21 CFR § 1271.3(c)).

As a result, you violated applicable regulations governing the proper conduct of clinical studies involving investigational new drugs. For example:

- You failed to submit an IND application to FDA (21 CFR § 312.20(a); 21 CFR § 312.40(a)).
- You began a clinical investigation without an IND application in effect (21 CFR § 312.20(b)).
- You failed to comply with the general responsibilities of sponsors of clinical investigations, specified in 21 CFR § 312.50, such as providing investigators with information needed to conduct an investigation properly.

You also failed to permit the FDA investigator to have access to and copy records on the subjects that you recruited to receive amnion tissue and cell implants, in violation of 21 CFR § 312.58.

Furthermore, your firm's web site, www.alfredtrsapsemd.com, promotes these implants and represents that they are safe and effective in treating a variety of illnesses, in violation of 21 CFR § 312.7(a).

We request that you notify this office, in writing, of the steps you have taken or will take to correct the noted violations and to prevent their recurrence. Please include any documentation necessary to show that correction has been achieved.

You may submit an IND application to the FDA pursuant to Title 21 CFR Part 312. Information to assist you in submitting an IND application is available at <http://www.fda.gov/cber/ind/ind.htm>. Questions regarding submission of an IND application and assistance may be directed to the FDA's Center for Biologics Evaluation and Research Office of Communications, Training, and Manufacturers Assistance at (800) 835-4709. If an IND application is submitted, no clinical investigation is permitted to proceed until the IND application is in effect, as described in 21 CFR §§ 312.20 and 312.40. These regulations are available at <http://www.gpoaccess.gov/cfr/index.html>.

Please send your written response to:

Ms. Bhanu Kannan
Division of Inspections and Surveillance (HFM-664)
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
1401 Rockville Pike, Suite 200N
Rockville, Maryland, 20852-1448
Telephone: (301) 827-6221

We request that you send a copy of your response to the FDA District Office listed below.

Sincerely,

/s/

Mary A. Malarkey
Director
Office of Compliance and Biologics
Quality
Center for Biologics Evaluation and
Research

cc:

Barbara Cassens, District Director
Food and Drug Administration
1431 Harbor Bay Parkway
Alameda , California 94502-7070

