



05/28 11:00-11:37

June 2, 2000

EpicYTE Pharmaceutical, Inc.
5810 Nancy Ridge Drive
Suite 150
San Diego, California, 92121

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

Re: FDA Regulation of OTC Drug Products Hearing

Dear Colleague,

As stated in previous communications (May 5 letter and e-mail), EPICYTE Pharmaceutical, Inc. (San Diego) will be providing comment at the Public Meeting on FDA Regulation of OTC Products (June 28-29, 2000). The EPICYTE presentation at the hearing will require five(5) minutes; as the presenter, I have provided below a summary.

Sincerely,

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EPIcyte Summary: Over- the-Counter Drug Products **FDA Public Hearing, June 28-29, 2000**

Epicyte Pharmaceutical, Inc.
5810 Nancy Ridge Drive
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San Diego, California. 92121

Presenter: Kevin J Whaley, PhD

EPIcyte Pharmaceutical, Inc. (San Diego, CA) intends to develop and market products that prevent transmission of infectious diseases. Infectious diseases are the leading cause of international mortality, and account for nearly half of all deaths for people under age 45.

Since 90% of all infectious diseases begin on a mucosal surfaces, there is a real need for products to protect mucosal surfaces (oral, gastrointestinal, respiratory, genitourinary) and prevent transmission of infectious diseases.

The active agent in EPIcyte prevention products are plantibodies. Plantibodies are human antibodies produced in plants for low cost and large capacity. The plantibodies are purified from the plants and formulated as pharmaceuticals. Plantibodies will supplement and mimic the prevention role of mucosal antibodies. Healthy humans produce antibodies in large quantities (approximately 4 g/day, more than all other antibody types combined) at mucosal surfaces.

One example of the need for personal protection technology for preventing transmission of infectious pathogens is the expanding AIDS epidemic. The world community has had limited options for preventing sexual transmission of HIV and other pathogens. Vaginal microbicides are an emerging technology for preventing the sexual transmission of these pathogens. EPIcyte's contribution to this product category will be a vaginal immunoprotectant for blocking STD/HIV transmission. EPIcyte is also developing plantibodies that will prevent mucosal transmission of respiratory and gastrointestinal pathogens.

Although some of these transmission prevention products will be used in hospital and other medical settings, the broader healthy population is constantly at risk for acquiring infectious disease. We believe that the best interests of individuals and public health will be served by making one venue of availability for transmission preventives to be over-the counter. EPIcyte intends to include the Division of OTC at the FDA during the development and clinical evaluation of plantibodies for the prevention of transmission of infectious diseases.

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