

January 7, 2003

Dockets Management Branch (HFA-305) Food and Drug Administration 5600 Fishers Land, Room 1061 Rockville, MD 20852

RE: Docket Number 02D-0324 - Guidance for Industry – Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals (Draft Guidance)

Dear Sirs:

I have been asked to comment on the feasibility of using a real estate investment trust ("REIT") structure as an alternative form of ownership for farmland used for the production of bioengineered plants to be used for the manufacturing of drugs, biologics and medical devices for use in humans and animals. This request was based on a question and comment made at a public forum in Iowa in November regarding potential mandatory ownership of production farmland by the company desiring to produce the drug derived from the bioengineered crop (the "End-user").

Agricultural real estate ownership in the United States continues to be very fragmented today, with most farms being locally owned family businesses. It is important to note that corporate ownership of agricultural production farmland is currently limited or forbidden in nine states, and over half the states in the U.S. have limitations on non-resident ownership of agricultural real estate.

The REIT structure offers significant potential advantages to both current individual landowners and entities desiring to produced drugs from bioengineered plants:

The ability to offer current owners of agricultural assets 1) an interest in a broader, more diversified portfolio of agricultural assets, 2) conversion rights into publicly-traded REIT shares, and 3) deferred income tax recognition on the exchange of land for a partnership interest in the REIT. This structure compares favorably with the other available tax deferred structures commonly deployed which take advantage of the like-kind exchange rules under Section 1031 of the Internal Revenue Code of 1986, as amended.

020-0324

C532

The ability for the End-user to procure the amount and type of land necessary and desired for their needs. Accountability for FDA compliance would continue to be the primary responsibility of the end user via a triple net lease structure. The REIT structure compares favorably to existing fixed asset financing methods used by End-users for other production facilities.

The strategy to use a REIT will offer the alternative for current individual landowners to access public equity markets, offering a lower cost of equity dollars than private equity. In addition, as revenue and cash flow streams become more stable as a result of contract production and enhanced risk management practices, the ability to access lower-priced public debt markets becomes feasible. These factors enable a REIT to offer End-users the professionally managed production assets necessary to meet their needs in a geographically diverse manner.

The business case for REIT ownership of agricultural real estate has only recently become feasible with the changes in tax laws created by the REIT Modernization Act and by IRS private letter rulings requested by the timber industry. Agricultural Real Estate Investors, LLC was formed to create an agricultural REIT to offer individual agricultural real estate owners a diversification and estate-planning tool while providing End-users an efficient partner. Its Members bring a collective 91 years of agricultural experience and currently manage over \$450 million of agricultural property, both for third parties and themselves. The Managing Directors have been involved in the acquisition and disposition of over 300,000 acres of agricultural real estate valued at over \$600 million.

Please feel free to contact me at 317-598-0525 or by email at doug@ausenbaugh.com with additional questions.

Sincerely,

Douglas W. Ausenbaugh

Managing Member