Advanced
Magnetics, Inc.

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 98D-0785: Revised Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics (June 2000)

Dear Sir or Madam:

This letter comments on the Food and Drug Administration's (FDA's) May 2003 draft "Guidance for Industry: Developing Medical Imaging Drugs and Biologics" (hereinafter the "Draft Guidance").

The Draft Guidance in Part 2: Clinical Indications, Section IV. contains a lengthy discussion on establishing the clinical usefulness of medical imaging contrast agents. This is discussed at several places in the Draft Guidance including lines 298 to 300 and Section B. Clinical Usefulness.

Requiring demonstration of clinical usefulness is an unnecessary regulatory requirement that increases the regulatory burden placed on research of new diagnostic imaging agents and will prevent the development of potentially important new contrast agents. It is generally accepted by industry trade organizations and medical societies that the clinical usefulness of agents shown to be effective for structure delineation and detection of disease or pathology is generally well established, and should not have to be established anew by the sponsor.

This was acknowledged in the previous Draft Guidance dated June 2000 on page 10, paragraph 2 which states:

"For an indication of disease or pathology detection or assessment, identification with sufficient validity and reliability of a disease or condition *is adequate to demonstrate* clinical usefulness *provided that it is reasonable to infer* that the test results lead to more appropriate management. "

Clinical utility and patient management is distinctly separate claims and unless a sponsor seeks such a claim this data should not be required. It is extremely difficult to demonstrate clinical usefulness for a contrast agent as this often requires lengthy outcomes

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studies and requires a hypothetical impact on patient management as it is neither ethical nor permissible to base actual patient management based on the results of an investigational new drug.

The "Clinical Utility" of a contrast agent that is used in disease detection may depend on many independent factors, such as the age of the patient and co-morbid conditions. If a disease detection indication is established determining how that information is used by the clinician is an attempt to determine and direct the practice of medicine.

It should be sufficient for a contrast agent to show that it improves structure delineation or disease or pathology detection without showing how this information is used clinically or how it affects patient management unless those claims are specifically requested.

Sincerely,

Mark C. Roessel

Mark C. Roessel
Vice President, Regulatory Affairs

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