



June 13, 2011

Minh Doan
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Bldg. 31, Room 2424
Silver Springs, MD

Dear Ms. Doan:

In response to the FDA announcement to re-establish the Medical Imaging Drugs Advisory Committee (Docket # FDA-2011-N-0002), the Academy of Molecular Imaging and the Society for Molecular Imaging would like to nominate two candidates for consideration by the FDA.

The first nominee is Dr. Carol Marcus, currently at Harbor-UCLA Medical Center. Because of her extensive experience with radiopharmaceutical safety she has been invited to serve on a number of committees in the past for both the U.S. Pharmacopeia and the FDA. The second nominee is Dr. Jorge Barrio, currently Distinguished Professor of Molecular and Medical Pharmacology, UCLA, School of Medicine. Dr. Barrio has been elected to many boards and panels, including the Advisory Panel on Radiopharmaceutical and the Committee for Revision, by the U.S. Pharmacopeia. We have attached both CV's for your perusal.

The Academy of Molecular Imaging (AMI) and the Society for Molecular Imaging (SMI) are currently merging to become the World Molecular Imaging Society (WMIS). As part of our mission we have designed the structure to include an Office of Regulatory Affairs. Dr.'s Marcus and Barrio will chair this office and will continue to interact with the FDA on behalf of the WMIS. Our goal is to create a liaison with the regulatory agencies and our membership that will be beneficial to both.

The Academy of Molecular Imaging currently runs the two registries for CMS, the National Oncologic PET Registry and the new Fluoride Registry. In order to meet the need for additional information and data with regard to the use of Fluoride in PET, the AMI is also running a Fluoride Clinical Trial with 19 sites participating and over 300

patients registered to date. This will continue under the new, merged organization of WMIS.

We would appreciate it if the FDA would consider at least one of the nominees we have proposed for the newly re-established committee and we look forward to hearing from you. Your official response to this communication would be greatly appreciated. We look forward to working with you in the future.

Sincerely,

A handwritten signature in black ink, appearing to read "Gelovani". The signature is written in a cursive style with a large initial "G".

Dr. Juri Gelovani, President
Academy of Molecular Imaging

A handwritten signature in black ink, appearing to read "Robert Gillies". The signature is written in a cursive style with a large initial "R".

Dr. Robert Gillies, President
Society for Molecular Imaging