



Dear Medical Imaging Drug Advisory Committee Members and Invited Consultants:

On June 28-29, we will hold an important meeting concerning three positron emission tomography (PET) drugs used in medical imaging: 1) F-18-fludeoxyglucose in oncology and myocardial viability; 2) N-13-ammonia in myocardial perfusion; and 3) O-15-water in cerebral perfusion. Unlike other NDAs that have been reviewed by the Committee, at this time, these drugs do not have an official commercial sponsor. However, in accordance with section 121 of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act), FDA has been working to develop appropriate procedures for the approval of PET drugs. These procedures may include findings of safety and efficacy based on published literature for at least these three commonly used PET drugs. If, based on the literature, FDA is able to make a finding that these drugs are safe and effective for these indications, this finding could form the basis for submission of new drug applications for these products.

Enclosed is background information containing the Center for Drug Evaluation and Research's reviews of the literature on these drugs for these indications as well as copies of the referenced articles on which the reviews rely. The Committee will be asked its opinion on whether the existing literature supports a finding of safety and effectiveness for these drugs for particular indications. At the meeting, we will be providing a brief overview of the Center's other activities in implementing section 121 of the Modernization Act, as well as detailed information concerning our reviews of the literature on these drugs.

Thank you for your willingness to participate in this meeting, and I look forward to your assessments.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia Y. Love", written over a horizontal line.

Patricia Y. Love, M.D., M.B.A.

Director

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