

Food and Drug Administration
Rockville MD 20857

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November 13, 1998

Jorge R. Barrio, Ph.D.
Professor of Molecular and Medical Pharmacology
UCLA School of Medicine
Box 956948
Los Angeles, California 90095-6948

Dear Dr. Barrio:

This is to confirm that the Food and Drug Administration (FDA) will meet with you and other representatives of the Institute for Clinical PET on Tuesday, November 17, 1998, to discuss the Agency's preliminary findings on the safety and effectiveness of two positron emission tomography (PET) drug products, [¹³N] ammonia and [¹⁸F] fludeoxyglucose. The meeting, which will begin at 9 a.m., will be held at 5630 Fishers Lane, Conference Room 1066, in Rockville, Maryland.

We intend to begin the meeting with a brief overview of FDA's approach to reviewing PET drugs. We will then explain how the Agency conducted its review of the safety and effectiveness of [¹³N] ammonia and discuss our preliminary findings on the indications reviewed. Following this discussion, we will describe how the Agency is conducting its review of the safety and effectiveness of [¹⁸F] fludeoxyglucose and address certain issues concerning that review. A draft agenda for the meeting is attached.

The meeting has been placed on FDA's upcoming meetings calendar, which can be accessed at FDA's Web site at www.fda.gov/po/upcoming.html. Interested members of the public may attend the meeting. After our discussions are concluded, interested persons will be provided an opportunity to express their views.

Please contact me if you have any questions about the meeting.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

Attachment

98D-0266

LET3

AGENDA

INFORMAL DISCUSSION OF LITERATURE REVIEWS OF SAFETY AND EFFICACY DATA FOR PET AMMONIA AND FDG

Moderator: Jane Axelrad, Associate Director for Policy, CDER

Opening Remarks from FDA	Jane Axelrad
Opening Remarks from the Institute for Clinical PET	Jorge Barrio
Background	Patricia Love
Presentation of PET Ammonia Literature Review	Florence Houn
Discussion of PET Ammonia Literature Review	
Presentation of PET FDG Literature Review	Victor Raczkowski
Discussion of PET FDG Literature Review	
Summary Discussion and Closing Remarks	