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April 8, 2003

Gary Buehler, Pharm D., R.Ph.
Director, Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North II
Document Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: MEETING AT FDA ON CLONIDINE TRANSDERMAL SYSTEMS
ANDA 76-157

Dear Dr. Buehler:

Thank you for inviting Elan to the meeting at FDA, scheduled for Tuesday, April 29, 2003 from 12:30-2:00 PM By this correspondence, we formally accept the invitation to attend the meeting on Clonidine Transdermal Systems.

Currently, we anticipate bringing up to eight Elan representatives. In order to adequately prepare for the meeting and ensure that we have appropriate representation for the topics to be discussed, we request that a copy of the pre-meeting materials (from Boehringer and/or FDA) as well as a complete list of attendees be provided to us as far in advance of the April 29th meeting as is possible.

We understand that this is a public meeting, and that information provided at the meeting will be made part of the docket for Boehringer Ingelheim's (BI) Citizens Petition (No 01P-0470). We expect that any new arguments made or documents provided by BI or its counsel at the meeting will be filed in the docket and that we will have an opportunity to respond to them after the meeting. We note that because this is a public meeting, we do not anticipate presenting any proprietary information about our clonidine transdermal product at the meeting. However, we will be prepared to comment more generally on the unfounded nature of the BI claims.

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In our view, BI is using the Citizens Petition process – including asking for a meeting with the FDA – solely as a mechanism to delay market entry of generic products that would compete with its clonidine transdermal patch product. FDA should not allow itself to be a party to this delaying tactic, and should approve any generic clonidine patch as soon as it is able, without waiting for the meeting or response to the BI Citizens Petition.

We will follow up directly with your Division concerning meeting logistics and the availability of meeting materials and appreciate the opportunity to participate in the meeting.

Sincerely,

for

Roger Wayne Wiley, R.Ph
Sr Director, Regulatory Affairs