élan

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April 21, 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: List of Attendees and Copy of Presentation for Meeting at FDA in regards to CLONIDINE TRANSDERMAL SYSTEMS

Dear Dr. Buehler:

As requested, I have attached a list of attendees and a copy of our presentation for the meeting on April 29, 2003. We would appreciate a copy of the complete list of attendees as well as the pre-meeting materials in advance of the meeting.

We appreciate the opportunity to participate in the meeting.

Sincerely,

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

Attachments

OIP-0470 LST 1

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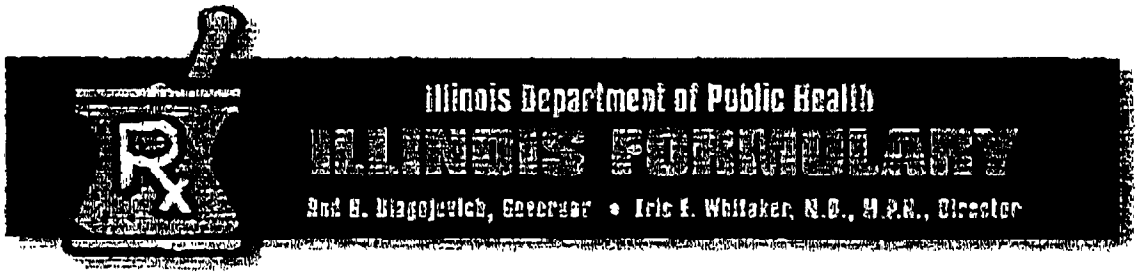
LIST OF ATTENDEES

Name	Title	Department
ELAN Drug Delivery		
Thomas Byrnes	General Mgr.	Elan Transdermal Tech.
R. Wayne Wiley, R.Ph.,	Sr. Director	Regulatory Affairs
Chris Adams,	Asst. Director	Research & Development
Marla Church, J.D.	Consultant	Intellectual Properties
David L. Rosen, R.Ph., J.D.	Consultant	McDermott, Will & Emery

ELAN SUMMARY COMMENTS

Elan wishes to thank the FDA for the invitation to this meeting. We have the following comments which will be presented at the meeting in regards to the Boehringer-Ingelheim (BI) Citizen Petition regarding ANDA approval requirements for clonidine transdermal systems as well as the BI presentation.

1. FDA has established rigorous approval requirements for transdermal products.
   - Elan, as a company with approved NDAs, ANDAs and active INDs for transdermal products - fully supports the current FDA rigorous approval requirements for transdermal products
   - The current FDA standards for transdermal products safeguard the American public
2. The Petitioner is attempting to interfere with generic competition.
   - The Citizen Petition merely raises hypothetical scenarios
   - The activity is consistent with actions taken by numerous innovators for many other brand products near patent expiry
   - Public Information available from the Illinois State Formulary indicates that BI's subsidiary, Roxane Labs, has obtained formulary approval to market an authorized version of Catapres TTS under the NDA as a generic listing. (see attached).
3. Elan firmly believes that FDA should continue to rely on its longstanding established criteria for ANDAs seeking approval of transdermal products.
4. Elan's ANDA has undergone a thorough technical review and has met FDA's criteria for a safe and effective generic transdermal clonidine patch. Elan's ANDA should be approved based on these standards.
5. 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). Elan reserves the right to provide a formal written response to the docket in response to the presentation within a reasonable time frame after this meeting.



Illinois Formulary Home | 2003 Submissions

Submissions from January 1, 2003 through January 31, 2003

The following lists new generic drug submissions received by the Department of Public Health for incl in the Illinois Formulary for the Drug Product Selection Program (after review by the Technical Adviso Council in compliance with Public Act 91-766), from January 1, 2003 through January 31, 2003. Prodı will become available for Illinois pharmacists' interchange on the latter of the "61st day" or the FDA approval date, *provided* a hearing before the Technical Advisory Council has not been scheduled for th specific product.

GENERIC NAME	REFERENCE BRAND NAME	APPLICATION HOLDER	DOSAGE FORM	STRENGTH (S)	DATE INFORMATION RECEIVED	FDA APPROVAL DATE	61st DAY	HEARIN STATUS
ammonium lactate	LacHydrin	Clay-Park	cream	eq 12% base	January 31, 2003	May 1, 2002	April 2, 2003	
amoxicillin	Amoxil	Ranbaxy	powder for oral suspension	200mg/5ml, 400mg/5ml	January 6, 2003	November 29, 2002	March 8, 2003	
clonidine authorized generic	Catapres-TTS	Roxane	film, extended release, transdermal	0.1mg/24 hours, 0.2mg/24 hours, 0.3mg/24 hours	January 22, 2003	October 10, 1984	Not applicable	
clotrimazole	Mycelex	Roxane	troche	10mg	January 14, 2003		March 16, 2003	
ethinyl estradiol; norethindrone acetate	Loestrin 21 1/20	Barr	tablets	0.02mg; 1mg	January 29, 2003		March 31, 2003	
ethinyl estradiol; norethindrone acetate	Loestrin 21 1.5/30	Barr	tablets	0.03mg; 1.5mg	January 29, 2003		March 31, 2003	
ethinyl estradiol; norethindrone acetate	Loestrin FE 1/20	Barr	tablets	0.02mg, 1mg	January 29, 2003		March 31, 2003	
ethinyl estradiol, norethindrone acetate	Estrostep 21	Barr	tablets	0.02mg; 1mg, 0.03mg; 1mg, 0.035mg; 1mg	January 29, 2003		March 31, 2003	
flecainide acetate	Tambocor	Barr	tablets	50mg, 100mg, 150mg	January 30, 2003	October 28, 2002	April 1, 2003	
fludrocortisone acetate	Florinef	Barr	tablets	0.1mg	January 30, 2003	January 21, 2003	April 1, 2003	

gabapentin	Neurontin	Eon	capsules	100mg, 300mg, 400mg	January 17, 2003		March 19, 2003	
hydrocortisone; neomycin sulfate; polymyxin B sulfate	Cortisporin Otic Solution	Alcon/Falcon	otic solution	1%; eq 3.5mg base/ml; 10,000U/ml	January 15, 2003	December 24, 2002 (bioequivalence waiver)	March 17, 2003	
hydrocortisone, neomycin sulfate; polymyxin B sulfate	Cortisporin Otic Suspension	Alcon/Falcon	otic suspension	1%, eq 3.5mg base/ml; 10,000U/ml	January 15, 2003	December 24, 2002 (bioequivalence waiver)	March 17, 2003	
isotretinoin	Accutane	Ranbaxy	tablets	10mg, 20mg, 40mg	January 22, 2003	December 24, 2002	March 24, 2003	
metronidazole	Flagyl	Able	tablets	250mg, 500mg	January 25, 2003		March 25, 2003	
mirtazepine	Remeron SolTabs	Barr	orally disintegrating tablet	15mg, 30mg	January 30, 2003		April 1, 2003	
mometasone furoate	Elocon	Clay-Park	ointment	0.1%	January 31, 2003	March 18, 2002	April 2, 2003	
mupirocin	Bactroban	Alpharma	ointment	eq 2% base	January 28, 2003		March 30, 2003	
mupirocin	Bactroban	Teva	ointment	eq 2% base	January 6, 2003		March 8, 2003	
tamoxifen citrate	Nolvadex	Barr	tablets	eq 20mg base	January 29, 2003		March 31, 2003	
tizanidine hydrochloride	Zanaflex	Barr	tablets	eq2mg base, eq 4mg base	January 30, 2003		April 1, 2003	
torsemide	Demadex	Par	tablets	5mg, 10mg, 20mg, 100mg	January 22, 2003		March 24, 2003	

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Questions or Comments

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