AstraZeneca

3229 '02 JAN -9 A9:59

Date: JAN 08 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket 01N-0496
Pilot Project of the Patient Profile Viewer

Dear Sir/Madam:

AstraZeneca Pharmaceuticals LP (AstraZeneca) would like to participate in the pilot project testing of the Patient Profile Viewer. Shown below is a listing of our experience with submission of clinical study datasets in the format described in the 1999 guidance.

AstraZeneca's experience with preparing and submitting Datasets

Date Submission	NDA	Product Name	Type of Submission	# of Clinical Study Datasets
09/28/99	21-093	ATACAND HCT	NDA	1
11/01/99	20-541	ARIMIDEX	sNDA	6
12/03/99	21-153	NEXIUM	NDA	38
02/28/00	21-154	NEXIUM	NDA	7
04/01/00	21-231	ZOMIG	sNDA	1
06/29/00	20-547	ACCOLATE	sNDA	1
12/15/00	20-533	*NAROPIN	sNDA	3
01/24/01	21-324	ENTOCORT	NDA	38
03/28/01	21-344	*FASLODEX	NDA	4
04/26/01	50-706	*MERREM	sNDA	3
05/18/01	50-706	*MERREM	sNDA	1
06/26/01	21-366	*CRESTOR	NDA	15
09/27/01	20-838	*ATACAND	sNDA	5
11/05/01	21-399	*IRESSA	NDA	6

*Under Review

AstraZeneca is familiar with the standards recommended by CDISC.

01N-0496

APE 8

US Regulatory Affairs
AstraZeneca Pharmaceuticals LP
1800 Concord Pike PO Box 8355 Wilmington DE 19803-8355

Please direct any questions or requests for additional information to me, or in my absence, to Dr. E. Jane Valas, Associate Director, at 302-886-2122.

Sincerely,

Donna M. Whiting
Associate Director
Regulatory Systems Management
Regulatory Affairs
Telephone: 302-886-2133
Fax: 302-886-2822

DW/EJV

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5630 FISHERS LANE
ROCKVILLE MD 20857

MD 207 9-06

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