

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Carpenter D. Drug-review deadlines and safety problems. *N Engl J Med* 2008;359:95-8.

20886	Alitretinoin	FDA has 5/26/97 subdate		Panretin	5/26/1998	2/2/1999	1998	18	8.28	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
21001	Almotriptan Malate	FDA has 12/20/1999 subdate		Axert	12/17/1999	5/7/2001	1999	19	16.90	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
21107	Alosetron HC1	FDA has SBW in June 2000; BBW in June 2002	This is CZA error, should have been included as BBW. Nardinelli coding is odd, however, in that it lists alosetron as having both SBW and BBW, even though the BBW comes after the SBW	Lotronex	6/29/1999	2/9/2000	1999	19	7.50	1	0	0	0	0	0	1	1	0	1	0	1	1	1	1	1	1	1
20965	Aminolevulinic acid			Levulan Kerastick	7/1/1998	12/3/1999	1998	18	17.10	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1
20511	Amlexanox			Aphthasol	4/19/1995	12/17/1996	1995	15	19.99	1	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	1
21007	Amprenavir			Agenerase	10/16/1998	4/15/1999	1998	18	5.95	1	1	1	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1
20333	Anagrelide Hydrochloride			Agrylin	1/31/1996	3/14/1997	1996	16	13.41	1	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	1
20541	Anastrozole			Arimidex	3/29/1995	12/27/1995	1995	15	8.98	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1
21264	Apomorphine Hydrochloride	Not in FDA data; may not be NME		Apokyn	12/31/2002	4/20/2004	2002	22	15.87	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
21549	Aprepitant			Emend	9/27/2002	3/26/2003	2002	22	6.00	1	1	1	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1
20420	Arbutamine Hydrochloride	FDA has 1/6/1994 subdate		Genesa	12/20/1993	9/12/1997	1993	13	44.78	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
20883	Argatroban	FDA has 8/15/1997 subdate		Acova	8/11/1997	6/30/2000	1997	17	35.13	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
21436	Aripiprazole	FDA has BBW Feb 2006	BBW added after CZA stopped coding. This is a class relabeling.	Abilify	10/31/2001	11/15/2002	2001	21	12.67	0	0	0	0	0	0	0	1	0	1	0	0	0	0	1	0	0	1
21248	Arsenic Trioxide	FDA has 3/28/2000 subdate		Trisenox	3/27/2000	9/25/2000	2000	20	6.07	1	1	1	0	0	0	0	0	0	1	1	1	0	0	0	0	0	1
20971	Articaine HCl 4%; Epinephrine			Septocaine	3/30/1998	4/3/2000	1998	18	24.50	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1
21567	Atazanavir Sulfate			Reyataz	12/20/2002	6/20/2003	2002	22	6.07	1	1	1	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1
21411	Atomoxetine	FDA has BBW Nov	BBW added after	Strattera	10/11/2001	11/26/2002	2001	21	13.70	0	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	1

20449	Docetaxel			Taxotere	7/27/1994	5/14/1996	1994	14	21.60	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20941	Docosanol	FDA has 12/22/1997 subdate		Abreva	12/19/1997	7/25/2000	1997	17	31.63	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
20931	Dofetilide			Tikosyn	3/9/1998	10/1/1999	1998	18	18.77	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20623	dolasetron mesilate			ANZEMET	9/29/1995	9/11/1997	1995	15	23.44	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20690	donepezil hydrochloride	FDA has 4/5/1996 subdate		ARICEPT	3/29/1996	11/25/1996	1996	16	7.92	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
20408	Dorzolamide			Trusopt	12/10/1993	12/9/1994	1993	13	11.97	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20862	Doxercalciferol	FDA has 3/9/1998 subdate		Hectorol	3/7/1998	6/9/1999	1998	18	15.09	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
21098	Drospirenone/Ethinyl Estradiol	FDA has 5/17/1999 subdate		Yasmin	5/14/1999	5/11/2001	1999	19	24.27	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
21427	Duloxetine Hydrochloride			Cymbalta	11/12/2001	8/3/2004	2001	21	33.17	0	0	0	0	1	1	1	1	1	0	0	0	1	0	1	0	1	1
21319	Dutasteride			Avodart	12/21/2000	11/20/2001	2000	20	11.13	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20972	Efavirenz			Sustiva	6/11/1998	9/17/1998	1998	18	3.22	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
21016	Eletriptan Hydrobromide			Relpax	10/27/1998	12/26/2002	1998	18	50.70	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20706	Emedastine Difumarate			Emadine	3/26/1996	12/29/1997	1996	16	21.14	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21500	Emtricitabine	FDA does not have BBW; we have BBW	We code significant new information added to BBW	Emtriva	9/3/2002	7/2/2003	2002	22	10.07	0	1	1	0	1	1	1	0	1	1	0	0	0	0	0	0	0	1
21481	Enfuvirtide	FDA has 9/16/02 subdate		Fuzcon	9/13/2002	3/13/2003	2002	22	6.03	1	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	1
20796	Entacapone			Comtan	1/2/1998	10/19/1999	1998	18	21.53	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21797	Entecavir	FDA has no BBW; we have BBW; also FDA has 9/29/04 subdate	We code significant new information added to BBW	Baraclude	9/30/2004	3/29/2005	2004	24	6.00	1	1	1	0	1	0	1	0	1	1	1	0	0	0	0	0	0	1
21565	Epinastine Hydrochloride	FDA has 12/20/02 subdate		Elestat	12/19/2002	10/16/2003	2002	22	10.03	0	1	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1
50778	Epirubicin			Ellence	12/15/1998	9/15/1999	1998	18	9.01	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
21437	Eplerenone	FDA has 11/29/01 subdate		Inspra	11/28/2001	9/27/2002	2001	21	10.10	0	1	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1
20444	Epoprostenol			Flolan	2/28/1994	9/20/1995	1994	14	18.71	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20738	Eprosartan Mesylate			Teveten	10/11/1996	12/22/1997	1996	16	14.37	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20718	Eptifibatide			Integrilin	4/2/1996	5/18/1998	1996	16	22.90	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1

21743	Erlotinib Hydrochloride	FDA has 7/30/04 subdate		Tarceva	7/29/2004	11/18/2004	2004	24	3.73	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	1
21337	Ertapenem Sodium			Invanz	11/30/2000	11/21/2001	2000	20	11.87	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21476	Eszopiclone	FDA has 1/31/03 subdate		Lunesta	1/20/2003	12/15/2004	2003	23	23.17	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
21187	Ethinyl Estradiol/Etonogestrel			NuvaRing	12/28/1999	10/3/2001	1999	19	21.50	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21180	Ethinyl Estradiol/Norelgestromin			Ortho Evra	12/21/2000	11/20/2001	2000	20	11.13	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20753	Exemestane	FDA has 12/21/98 subdate		Aromasin	12/18/1998	10/21/1999	1998	18	10.09	0	1	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21773	Exenatide	FDA has 6/30/04 subdate		Byetta	6/29/2004	4/28/2005	2004	24	10.10	0	1	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21445	Ezetimibe			Zetia	12/27/2001	10/25/2002	2001	21	10.07	0	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1
20363	Famciclovir			Famvir	6/30/1993	6/29/1994	1993	13	11.97	0	0	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1
20416	Ferumoxides	FDA has 2/7/1994 subdate		Feridex	7/2/1994	8/30/1996	1994	14	25.97	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
20410	Ferumoxsil			Gastromark	11/23/1993	12/6/1996	1993	13	36.46	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20625	fexofenadine HCl			ALLEGRA	7/31/1995	7/25/1996	1995	15	11.84	0	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1
20306	Fludeoxyglucose F 18	Not in our data		Fludeoxyglucose F 18	1/19/1993	8/19/1994	1993	13	19.00	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0
20696	Fomepizole			Antizol	12/6/1996	12/4/1997	1996	16	11.93	0	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1
20961	Fomivirsen Sodium			Vitravenc	4/9/1998	8/26/1998	1998	18	4.57	1	1	1	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1
21345	Fondaparinux Sodium	FDA has as priority; we originally had as standard; priority and predead have been recoded		Arixtra	2/15/2001	12/7/2001	2001	21	9.83	1	1	0	0	1	0	0	0	1	0	1	0	0	0	0	0	0	0	1
20831	Formoterol Fumarate	FDA has 6/26/1997 subdate		Foradil Aerolizer	6/24/1997	2/16/2001	1997	17	44.43	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
50717	Fosfomycin Tromethamine			Monurol	9/29/1994	12/19/1996	1994	14	26.70	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20450	Fosphenytoin Sodium			Cerebyx	2/23/1995	8/5/1996	1995	15	17.39	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21006	Frovatriptan			Frova	1/29/1999	11/8/2001	1999	19	33.80	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21344	Fulvestrant			Faslodex	3/28/2001	4/25/2002	2001	21	13.10	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21357	Gadobenate Dimeglumine			Multihance	4/27/2001	11/23/2004	2001	21	43.53	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20937	Gadoversetamide	FDA has BBW Sept 2007	BBW added after CZA stopped coding;	OptiMark	3/2/1998	12/8/1999	1998	18	21.24	0	0	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	1

20367	Imiglucerase			Cerezyme	5/21/1993	5/23/1994	1993	13	12.07	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20723	Imiquimod			Aldara	7/26/1996	2/27/1997	1996	16	7.10	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20685	Indinavir Sulfate			Crixivan	1/31/1996	3/13/1996	1996	16	1.38	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20986	Insulin Aspart Recombinant	FDA has 9/16/1998 subdate		NovoLog	9/15/1998	6/7/2000	1998	18	21.03	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
21536	Insulin Detemir			Levemir	12/5/2002	6/16/2005	2002	22	30.80	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21081	Insulin Glargine	FDA has 4/23/99 subdate		Lantus	4/9/1999	4/20/2000	1999	19	12.39	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
21629	Insulin Glulisine			Apidra	6/18/2003	4/16/2004	2003	23	10.10	0	1	1	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1
20563	Insulin Lispro			Humalog	3/14/1995	6/14/1996	1995	15	15.06	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20587	Intraleural Aerosol			Sclerosol	8/15/1995	12/24/1997	1995	15	28.34	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20351	Iodixanol			Visipaque 270, 320	3/5/1993	3/22/1996	1993	13	36.59	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20757	Irbesartan	FDA has as not predead; falls within our two week rule		Avapro	9/26/1996	9/30/1997	1996	16	12.13	0	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
20571	Irinotecan Hydrochloride			Camptosar	12/28/1995	6/14/1996	1995	15	5.56	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1
50742	Ivermectin			Stromectol	4/1/1996	11/22/1996	1996	16	7.73	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
21066	Ketotifen fumarate			Zaditor	1/4/1999	7/2/1999	1999	19	5.88	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1
20564	Lamivudine	FDA has BBW 15-Dec-97; FDA also has as predeadline		Epivir	7/7/1995	11/17/1995	1995	15	4.37	1	0	0	0	0	1	1	0	1	1	1	0	1	0	1	0	1	1
20406	Lansoprazole			Prevacid	11/15/1993	5/10/1995	1993	13	17.79	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21468	Lanthanum Carbonate Hydrate			Fosrenol	4/30/2002	10/26/2004	2002	22	30.33	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20597	Latanoprost			Xalatan	6/16/1995	6/5/1996	1995	15	11.67	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20905	Leflunomide			Arava	3/10/1998	9/10/1998	1998	18	6.05	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1
20807	Lepirudin			Refludan	12/31/1996	3/6/1998	1996	16	14.14	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20726	Letrozole			Femara	7/25/1996	7/25/1997	1996	16	12.00	0	1	1	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1
21035	Levetiracetam			Keppra	2/1/1999	11/30/1999	1999	19	9.93	0	1	1	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1
20315	Levomethadyl acetate	FDA has SBW in Aug 2003	Discrepancy with other FDA data; FDA does not list this as withdrawal in 2004 publications and in data given to Berndt et al.	Orlaam	6/21/1993	7/9/1993	1993	13	0.59	1	0	0	0	0	0	0	0	1	0	1	1	0	1	0	1	0	1

21667	L-Glutamine	FDA has 8/11/03 subdate		NutreStore	8/8/2003	6/10/2004	2003	23	10.23	0	1	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	
21130	Linezolid	FDA has 10/18/1999 subdate		Zyvox	10/15/1999	4/18/2000	1999	19	6.12	1	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	1	
21226	Lopinavir;Ritonavir	FDA has 6/01/00 subdate		Kaletra	5/31/2000	9/15/2000	2000	20	3.57	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1	
20386	Losartan potassium			Cozaar	12/3/1993	4/14/1995	1993	13	16.34	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	
20583	Loteprednol Etabonate			LOTEMAX	3/31/1995	3/9/1998	1995	15	35.31	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	
20652	Mangafodipir Trisodium	FDA has 9/15/1995 subdate		Teslascan	9/8/1995	11/26/1997	1995	15	26.63	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	
20938	Meloxicam	FDA has BBW 11-August-2005; FDA also has 12/16/98 subdate	BBW added after CZA stopped coding.	Mobic	12/15/1998	4/13/2000	1998	18	16.17	0	0	0	0	0	0	0	1	0	1	0	0	0	0	1	0	0	1	
21487	Memantine Hydrochloride			Namenda	12/19/2002	10/16/2003	2002	22	10.05	0	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	1	
20922	Mequinol			Solage	12/30/1997	12/10/1999	1997	17	23.34	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	
20586	MERETEK UBT KIT (W/ PRANACTIN)			MERETEK UBT KIT (W/ PRANACTIN)	5/11/1995	9/17/1996	1995	15	16.27	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	
50706	Meropenem	FDA has 10/30/1993 subdate		Merrem I.V.	10/28/1993	6/21/1996	1993	13	31.79	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	
40306	METADATE ER	Not in FDA data; may not be NME		METADATE ER	4/13/1998	10/20/1999	1998	18	18.25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	
20689	Mibefradil Dihydrochloride		Discrepancy in FDA data; not listed on Drugs@FDA website	Posicor	3/11/1996	6/20/1997	1996	16	15.32	0	0	0	1	0	0	0	0	1	1	0	0	1	0	1	0	1	0	1
21506	Micafungin Sodium			Mycamine	4/29/2002	3/16/2005	2002	22	35.07	1	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	1	
20687	Mifepristone	FDA has 3/18/1996 subdate		Mifeprex	3/14/1996	9/28/2000	1996	16	55.30	1	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1	
20682	Miglitol			Glyset	12/29/1995	12/18/1996	1995	15	11.67	0	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	1	
21348	Miglustat	FDA has 4/21/2001 subdate		Zavesca	4/20/2001	7/31/2003	2001	21	27.73	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	
20415	Mirtazapine	FDA has BBW 12-Jan-2005	CZA omission; therapeutic class relabeling	Remeron	1/30/1995	6/14/1996	1995	15	16.47	0	0	0	0	0	0	1	1	0	1	0	0	0	1	0	1	0	1	
20717	Modafinil			Provigil	12/30/1996	12/24/1998	1996	16	23.80	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	
20829	Montelukast Sodium			Singulair	2/21/1997	2/20/1998	1997	17	11.97	0	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	1	

21085	Moxifloxacin			Avelox	12/10/1998	12/10/1999	1998	18	12.00	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
50722	Mycophenolate mofetil			Cellcept	11/10/1994	5/3/1995	1994	14	5.72	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1
20459	Nalmefene			Revox	4/29/1994	4/17/1995	1994	14	11.61	0	0	1	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1
20763	Naratriptan			Amerge	12/4/1996	2/10/1998	1996	16	14.24	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21204	Nateglinide			Starlix	12/17/1999	12/22/2000	1999	19	12.37	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20779	Nelfinavir Mesylate	FDA has subdate of 12/26/96		Viracept	12/20/1996	3/14/1997	1996	16	2.76	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
20920	Nesiritide	FDA has 4/27/1998 subdate		Natrecor	4/24/1998	8/10/2001	1998	18	40.13	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
20636	Nevirapine			Viramune	2/23/1996	6/21/1996	1996	16	3.91	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20169	Nilutamide	FDA has BBW 29-Sep-2000	Nilutamide had BBW from the start, addition was arguably not significant; see Bennett et al, AnnalsIM, 16 September 2003, Volume 139 Issue 6, p 529	Nilandron	3/7/1994	9/19/1996	1994	14	30.48	0	0	0	0	0	1	1	0	1	0	0	0	1	0	1	0	1	1
20356	Nisoldipine			Sular	4/1/1993	2/2/1995	1993	13	22.09	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21498	Nitazoxanide			Alinia	5/29/2002	11/22/2002	2002	22	5.90	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1
21232	Nitisinone	FDA has 9/8/2000 subdate		Orfadin	12/27/1999	1/18/2002	1999	19	25.10	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
20845	Nitric oxide			INOmax	6/16/1997	12/23/1999	1997	17	30.25	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20592	Olanzapine	We have this as predead; FDA does not; FDA also has BBW Feb06	BBW added after CZA stopped coding. BBW is therapeutic class relabeling for atypical antipsychotics	Zyprexa	9/22/1995	9/30/1996	1995	15	12.30	0	1	1	0	0	0	1	0	1	0	0	0	1	0	0	0	0	1
21286	Olmесartan Medoxomil			Benicar	7/25/2000	4/25/2002	2000	20	21.30	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20688	Olopatadine Hydrochloride	FDA has 1/29/96 subdate		Patanol	1/19/1996	12/18/1996	1996	16	10.98	0	1	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1
21654	Omega-3-acid Ethyl Esters	FDA has 1/12/04 subdate		Omacor	1/9/2004	11/10/2004	2004	24	10.20	0	1	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1
20766	Orlistat	FDA has 11/27/1996 subdate		Xenical	11/26/1996	4/23/1999	1996	16	28.87	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1

20451	Porfimer			Photofrin	4/13/1994	12/27/1995	1994	14	20.48	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20667	Pramipexole Dihydrochloride	FDA has 12/28/1995 subdate		Mirapex	12/26/1995	7/1/1997	1995	15	18.18	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
21332	Pramlintide Acetate	FDA has 12/8/2000 subdate		Symlin	12/7/2000	3/16/2005	2000	20	52.00	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
21446	Pregabalin	FDA has 10/31/03 subdate		Lyrica	10/30/2003	12/30/2004	2003	23	14.23	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
21626	Prussian Blue	FDA has as no predead approval; this may be coding error on our part		Radiogardase	3/10/2003	10/2/2003	2003	23	6.87	1	1	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
20639	Quetiapine Fumarate	FDA has BBW Feb 2007	BBW added after CZA stopped coding; BBW is therapeutic class relabeling for atypical antipsychotics	Seroquel	7/29/1996	9/26/1997	1996	16	13.94	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	1
50748	Quinupristin/dalfopristin	FDA has as priority; FDA has NDA # 50747		Synercid	9/5/1997	9/21/1999	1997	17	24.53	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
20973	Rabeprazole sodium			Aciphex	3/31/1998	8/19/1999	1998	18	16.64	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20815	Raloxifene Hydrochloride	FDA has BBW added Sep 07	BBW added after CZA stopped coding	Evista	6/9/1997	12/9/1997	1997	17	6.02	1	1	1	0	0	0	1	0	1	1	1	0	1	0	0	0	0	1
21782	Ramelteon	Not in our data		Rozerem	9/22/2004	7/22/2005	2004	24	10.00	0	1	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
20984	Rapacuronium bromide			Raplon	6/25/1998	8/18/1999	1998	18	13.78	0	0	0	1	0	0	0	0	1	1	0	0	1	0	1	0	1	0
20630	Remifentanyl Hydrochloride			Ultiva	9/15/1995	7/12/1996	1995	15	9.90	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20741	Repaglinide			Prandin	7/1/1997	12/22/1997	1997	17	5.72	1	1	1	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1
21024	Rifapentine			Priftin	12/22/1997	6/22/1998	1997	17	5.98	1	1	1	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1
21361	Rifaximin	FDA has 12/26/2001 subdate		Xifaxan	12/21/2001	5/25/2004	2001	21	29.53	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
20599	Riluzole	Our original predead code was 0; think this was also coded standard; FDA has not as predead, b/c of 2 cycles		Rilutek	6/29/1995	12/12/1995	1995	15	5.46	1	0	1	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1
20474	Rimexolone			Vexol	6/1/1994	12/30/1994	1994	14	6.97	1	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	1
20835	Risedronate Sodium			Actonel	4/1/1997	3/27/1998	1997	17	11.84	0	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	1
20659	Ritonavir			Norvir	12/21/1995	3/1/1996	1995	15	2.33	1	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	1
20823	Rivastigmine Tartrate			Exelon	4/7/1997	4/21/2000	1997	17	37.00	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1
20864	Rizatriptan Benzoate			Maxalt	6/30/1997	6/29/1998	1997	17	11.97	0	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	1
20214	Rocuronium bromide			Zemuron	6/29/1993	3/17/1994	1993	13	8.58	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1
21042	Rofecoxib			Vioxx	11/23/1998	5/20/1999	1998	18	5.85	1	1	1	1	0	0	0	0	1	1	1	1	1	0	1	0	1	1

20887	Technetium tc 99m Apcitide	FDA has 8/20/97 subdate		AcuTect	8/19/1997	9/14/1998	1997	17	12.85	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
21012	Technetium tc 99m depreotide			NeoTect	6/16/1998	8/3/1999	1998	18	13.58	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20372	Technetium Tc-99m Tetrofosmin Kit			Myoview	6/7/1993	2/9/1996	1993	13	32.12	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21200	Tegaserod Maleate	FDA has SBW March 2007	SBW after CZA stopped coding	Zelnorm	2/11/2000	7/24/2002	2000	20	29.80	1	0	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	1
21144	Telithromycin	FDA has BBW Feb 2007; FDA also has March 1, 2000 subdate	BBW added after CZA stopped coding	Ketek	2/28/2000	4/1/2004	2000	20	49.80	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	1
20850	Telmisartan			Micardis	9/26/1997	11/10/1998	1997	17	13.48	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21029	Temozolomide	FDA has 8/13/1998 subdate		Temodar	8/12/1998	8/11/1999	1998	18	11.97	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
21356	Tenofovir Disoproxil Fumarate	FDA has 5/1/01 subdate	We code significant new information added to BBW	Viread	4/30/2001	10/26/2001	2001	21	5.97	1	1	1	0	1	1	1	0	1	1	1	0	0	0	0	0	0	1
20785	Thalidomide			Thalomid	12/20/1996	7/16/1998	1996	16	18.84	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20898	Thyrotropin Alfa	FDA has 12/15/97 subdate		Thyrogen	12/12/1997	11/30/1998	1997	17	11.61	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
20646	Tiagabine Hydrochloride			Gabitril	11/6/1995	9/30/1997	1995	15	22.82	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21821	Tigecycline			Tygacil	12/15/2004	6/15/2005	2004	24	6.07	1	1	1	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1
20707	Tiludronate Disodium	FDA has this as not predead; falls within our two week rule		Skelid	2/28/1996	3/7/1997	1996	16	12.26	0	1	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
21618	Tinidazole	FDA has no BBW; we have BBW; FDA has 7/17/03 subdate	There was a BBW labeling change, but not significant new safety information communicated.	Tindamax	7/16/2003	5/17/2004	2003	23	10.20	0	1	1	0	1	0	0	0	1	1	0	0	0	0	0	0	0	1
20484	Tinzaparin Sodium			Innohep	6/30/1999	7/14/2000	1999	19	12.67	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21395	Tiotropium Bromide	FDA has 12/13/2001 subdate		Spiriva Handihaler	12/12/2001	1/30/2004	2001	21	25.97	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
21814	Tipranavir	FDA has no BBW; we have BBW; FDA has 12/22/04 subdate	We code significant new information added to BBW	Aptivus	12/21/2004	6/22/2005	2004	24	6.10	1	1	1	0	1	0	1	0	1	1	1	0	0	0	0	0	0	1

20912	Tirofiban Hydrochloride	FDA has no predead; this is prob coding error on our part	Aggrastat	10/31/1997	5/14/1998	1997	17	6.41	1	1	1	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
20397	Tizanidine Hydrochloride		Zanaflex	12/6/1993	11/27/1996	1993	13	35.74	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20697	Tolcapone	FDA does not have SBW; also FDA has 6/5/96 subdate	Tasmar	6/3/1996	1/29/1998	1996	16	19.89	0	0	0	1	1	1	1	0	1	0	0	0	1	0	1	0	1	1
20771	Tolterodine Tartrate		Detrol	3/25/1997	3/25/1998	1997	17	12.00	0	1	1	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1
20505	Topiramate		Topamax	12/30/1994	12/24/1996	1994	14	23.84	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20671	Topotecan Hydrochloride		Hycamtin	12/22/1995	5/28/1996	1995	15	5.19	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1
20497	Toremifene Citrate		Fareston	1/3/1995	5/29/1997	1995	15	28.83	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
20281	Tramadol Hydrochloride	Not in our data	Ultram	11/18/1993	3/3/1995	1993	13	15.50	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
20528	Trandolapril		Mavik	9/29/1994	4/26/1996	1994	14	18.90	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1
21257	Travoprost	FDA has 7/7/2000 subdate	Travatan	7/6/2000	3/16/2001	2000	20	8.43	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
21272	Treprostinil Sodium		Remodulin	10/16/2000	5/21/2002	2000	20	19.40	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20326	Trimetrexate glucuronate		Neutrexin	2/1/1993	12/17/1993	1993	13	10.49	1	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	1
20715	Triptorelin Pamoate	FDA 6/26/1996 subdate; we have recoded	Trelstar Depot	12/16/1999	6/15/2000	1999	19	6.07	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
20720	Troglitazone		Rezulin	8/1/1996	1/29/1997	1996	16	5.95	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
21595	Trospium Chloride	FDA has 4/29/03 subdate	Sanctura	4/28/2003	5/28/2004	2003	23	13.20	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
20759	Trovafloxacin Mesylate	FDA has no SBW, has BBW	Trovan	12/30/1996	12/18/1997	1996	16	11.61	0	1	1	1	1	1	1	0	1	1	0	0	1	0	1	0	1	1
21670	Trypan Blue	FDA has 10/27/03 subdate	Vision Blue	10/24/2003	12/16/2004	2003	23	13.97	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
21214	Unoprostone Isopropyl	FDA has 2/15/00 subdate	Rescula	2/14/2000	8/3/2000	2000	20	5.70	1	1	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	1
20617	Urea C-14	FDA has 5/22/95 subdate	Pytest	5/16/1995	5/9/1997	1995	15	23.80	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1
21341	Valdecoxib		Bextra	1/16/2001	11/16/2001	2001	21	10.13	0	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1

