

September 05, 2008

Jimmy Mitchell, R.Ph., M.P.F., M.S.
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane, Parklawn Building
Mail Stop 10C-03
Rockville, Maryland 20857

Dear Mr. Mitchell,

I write to confirm our previous discussions regarding prices charged to 340B covered entities for certain Warner Chilcott products during the time period from the first quarter of 2005 through the first quarter of 2008. As we have explained, a review of our government pricing programs, conducted as a part of Warner Chilcott's routine compliance procedures, revealed pricing errors with respect to certain of our products subject to discounts under Section 340B of the Public Health Service Act and our Pharmaceutical Pricing Agreement ("PPA") with the Secretary of the Department of Health and Human Services.

Warner Chilcott's review revealed that the 340B ceiling prices on a number of Warner Chilcott products, (see list of affected products at [Attachment A](#) to this letter), were calculated inaccurately. The ceiling prices for 340B entities were calculated as Average Manufacturer Price reduced by the statutory minimum rebate percentage (15.1%) without making applicable adjustments to the formula for price increases in excess of CPI-U, as required by the provisions of 42 U.S.C. §§ 256(a)(2) and 1396r-8(c)(2)(A). This error in calculation for the 340B entities resulted in some products being priced higher than permitted under the PPA. The calculation error did not impact Medicaid or Veteran Affairs/Federal Supply Schedule pricing. As soon as Warner Chilcott discovered these pricing errors, we promptly undertook to identify their scope and to correct the problem. We have verified that all 340B pricing calculations done after the first quarter of 2008 are accurate. In order to ensure that a similar error does not happen again, Warner Chilcott is monitoring these calculations going forward, and has strengthened the controls, including monitoring controls, and documentation surrounding the government pricing process.

We have conducted a recalculation of affected 340B ceiling prices and purchase prices for the first quarter of 2005 through the first quarter of 2008, and determined that the total refunds due to 340B covered entities for all products purchased during that recalculation period, established consistent with the record maintenance requirement at Section II(d) of the PPA, is approximately \$3 million. We are preparing letters to each of the affected 340B entities, detailing the purchase volume and price differential of each Warner Chilcott product that our records reflect the entity purchased at a price above the applicable 340B ceiling. The letters will also include a refund check in the appropriate amount and an acknowledgement and release form that the entity will be requested to complete and return to Warner Chilcott.

Warner Chilcott will monitor these disbursements and use its best efforts to ensure that all entitled entities receive their refunds in a timely fashion. We anticipate that we will be able to transmit letters and checks to affected covered entities within approximately the next three months. Any covered entity that purchased any of the products listed in Attachment A under the 340B program that has questions regarding the refund it receives or that does not receive a letter and refund check by December 15, 2008, should contact Jim Black (973-442-3200) at Warner Chilcott.

As we have discussed, Warner Chilcott consents to the posting of this letter on the Office of Pharmacy Affairs' website to help inform 340B covered entities. If you have any questions relating to this letter or the process we have established, or if you need any additional information, please do not hesitate to contact me.

Very truly yours,

/Susanna J. Gray/
Assistant General Counsel
Warner Chilcott

Encl.

cc: Mary Riordan (via Federal Express and electronic mail, with encl.)
Deirdre Duzor (via Federal Express and electronic mail, with encl.)

Attachment A

LBLR	Core	Size	Description
430	112	24	Doryx 100 100 D-R Tabs
430	838	19	Doryx 100MG 100's
430	836	20	Doryx 75 60
430	111	20	Doryx 75 60 D-R Tabs
72	260	12	Dovonex Cream 120G Tube
430	3020	17	Dovonex Cream 120G Tube
72	260	6	Dovonex Cream 60G Tube
430	3020	15	Dovonex Cream 60G Tube
72	2540	6	Dovonex Oint 60G
430	3010	15	Dovonex Oint 60G
72	2540	12	Dovonex Oint 120G Tube
430	3010	17	Dovonex Oint 120G Tube
72	1160	6	Dovonex Sol 60ML BTL
430	3030	15	Dovonex Sol 60ML BTL
87	782	41	Duricef 250MG/5ML 100ML
87	782	42	Duricef 250MLG/5ML 50ML
87	783	5	Duricef 500MG/5ML 75ML
87	783	41	Duricef 500MG/5ML 100ML

87	784	46	Duricef 500MG 50's CAPS
87	784	48	Duricef 500MG 50's CAPS
430	780	19	Duricef 500MG 50's CAPS
430	2782	15	Duricef 250MG/5ML 50ML
430	2782	17	Duricef 250MG/5ML 100ML
430	2783	16	Duricef 500MG/5ML 750ML
430	2783	17	Duricef O/S
430	696	24	Eryc
430	570	14	Estrostep FE 5 X 28S
430	696	24	Eryc
430	482	14	Femcon FE 35 28x5
430	145	14	Femhrt 0.5/25mcg 28x5
430	145	23	Femhrt 0.5/25mcg 90's
430	544	14	Femhrt 28 X 5
430	544	23	Femhrt Bottle
430	6201	40	Femring 0.05 MG/Day
430	6202	40	Femring 0.1 Strength
430	389	24	Femtrace .45 **
430	390	24	Femtrace .9 **
430	391	24	Femtrace 1.8 **
430	530	14	Loestrin 24 FE
430	227	23	Natachew
430	226	40	Natafort Prenatal Tabs
430	582	14	Ovcon 35
430	580	14	Ovcon 35 - 28 Day
430	581	14	Ovcon 35 FE CHEW
430	585	14	Ovcon 50
430	182	15	Pyridium Plus 150/15 30's
430	435	14	Sarafem 10 28
430	436	14	Sarafem 20 28
430	3230	15	Taclonex
430	3230	16	Taclonex