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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 03P-0089

To Whom it May Concern:

This correspondence supplements the above-referenced Citizen Petition submitted by Andrx Pharmaceutical, Inc., on February 27, 2003. It addresses comments submitted by Wyeth on March 13, 2003, in response to the Andrx petition.

The Andrx petition requested that the Commissioner of Food and Drugs determine that the ongoing marketing of loratadine in 10 milligram orally disintegrating tablets by Wyeth pursuant to an approval under section 505(b)(2) of the Act constitutes "commercial marketing" of generic loratadine within the meaning of section 505(j)(5)(B)(iv)(I). The petition observed that Wyeth has been commercially marketing generic loratadine under the name Alavert since December 2002, and asked the Commissioner to declare that Wyeth's generic exclusivity would expire 180 days after such commercial marketing commenced.

In comments dated March 13, 2003, Wyeth disputes the legal argument that its marketing of generic loratadine pursuant to approval of an NDA under section 505(b)(2) constitutes "commercial marketing" of generic loratadine within the meaning of section 505(j)(5)(B)(iv)(I). Nonetheless, Wyeth declares that "in the interest of fairness" it "will not claim any exclusivity with respect to its loratadine orally disintegrating tablets ANDA beyond August 9, 2003, the date that is 180 days after Wyeth's ANDA for generic loratadine received final approval."

As described below, Andrx accepts Wyeth's proposed compromise and now requests that the Commissioner resolve the Andrx petition by declaring that Wyeth's exclusive right to market generic loratadine will expire on August 9, 2003.

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Argument

In its petition, Andrx contends that the marketing of a product under section 505(b)(2) satisfies the "commercial marketing" prong of section 505(j)(5)(B)(iv) if the 505(b)(2) product is bioequivalent to the product that is the subject of the 505(j) ANDA. In other words, a manufacturer may not avoid triggering the 180-day period of generic exclusivity by marketing its generic product under section 505(b)(2) instead of section 505(j). Wyeth disputes this argument; it maintains that generic exclusivity may only be triggered following approval of an ANDA under section 505(j) and may not be triggered by marketing under a section 505(b)(2) NDA.

Wyeth does not deny that Alavert, the product it is marketing under its section 505(b) NDA, is in fact *bioequivalent* to the generic product that is the subject of its section 505(j) ANDA. Rather, Wyeth relies on a formalistic reading of the relevant statutory provisions which, if adopted, would permit a company to market a generic drug without competition indefinitely as long as it can qualify under section 505(b)(2). Wyeth's position cannot be right, and it implicitly concedes as much by offering to forsake generic exclusivity 180 days after a date that is before the date on which it will commence commercial marketing under its 505(j) ANDA.

Briefly, Wyeth's legal position is incorrect for the following three reasons, each of which is addressed more fully in the original petition.

First, Wyeth fails to acknowledge FDA's clear authority to determine for itself when commercial marketing of a generic drug has actually begun. In 21 C.F.R. § 314.107(c)(4), the agency reserves for itself authority to "deem" commercial marketing to have occurred, even if the first ANDA filer attempts to postpone initiation of the 180-day generic exclusivity.[1] A drug manufacturer may engage in activity that it contends is not "commercial marketing" under section 505 (j)(5)(B)(iv), but the agency may conclude otherwise. Thus, FDA has authority to declare that Wyeth began "commercial marketing" of generic loratadine for purposes of section 505(j) when it received final effective approval of its ANDA.

Second, Wyeth fails to distinguish persuasively the FDA's response to Teva's recent Citizen Petition in Docket No. 00P-1446/CP1 concerning generic nifedipine. In that matter, the FDA declared that the "commercial marketing" prong of section 505(j)(5)(B)(iv) is triggered when a generic drug company markets a product that is equivalent to the product for which it received the first ANDA approval, even if it has not marketed its product under the ANDA. The

[1] Section 314.107(c)(4) requires the first ANDA filer to notify FDA of the date that it commences commercial marketing of its drug product, and defines that date, in relevant part, as "the first date of introduction or delivery for introduction into interstate commerce outside the control of the manufacturer of a drug product." The regulation then provides: "If an applicant does not promptly notify FDA of such date, the effective date of approval *shall be deemed to be the date of the commencement of first commercial marketing.*" Id. (emphasis added).

FDA's adjudication of that petition was upheld in relevant part by the federal court that reviewed it. Mylan Pharmaceuticals, Inc. v. Thompson, 207 F. Supp. 2d 476, 488 (N.D. W. Va. 2001).

Third, Wyeth ignores the legislative intent underlying the Drug Price Competition and Patent Term Restoration Act. In enacting that 1984 law, Congress sought to "make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984). The Act creates an incentive for generic drug companies to challenge brand-name drug patents, namely the 180 days of generic exclusivity in section 505(j)(5)(B)(iv). But this 180-day period represents a careful balance between the need for such an incentive and the danger that lengthier generic exclusivity would harm consumers by preventing competition *among* generic companies. Wyeth's legal argument would tip the balance in favor of indefinite exclusivity and against reasonable competition.

Action Requested

For the reasons stated above, Andrx stands by its legal argument set forth in its Citizen Petition. Nonetheless, Andrx will accept Wyeth's offer to forsake generic exclusivity after August 9, 2003. Andrx accepts this compromise, and requests that the Commissioner adjudicate the Andrx petition by: (1) deeming Wyeth's commercial marketing of generic loratadine to have begun on February 10, 2003, the date Wyeth received final, effective approval of its ANDA; (2) declaring the Wyeth's exclusivity for loratadine will expire on August 9, 2003; and (3) adopting appropriate measures to implement Wyeth's offer.

Respectfully submitted,

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