DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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OCT 8 2003

William B. Schultz, Esq.
Ronald W. Weich, Esq.
Zuckerman Spaeder LLP
1201 Connecticut Ave., N.W.
Washington, D.C. 20036-2638

Re: Docket No. 03P-0089/CP1

Dear Messrs. Schultz and Weich:

This responds to your citizen petition dated February 27, 2003 (Petition), and your supplement to this petition dated March 21, 2003 (Supplement), both submitted on behalf of Andrx Pharmaceutical, Inc. (Andrx). You request that the Food and Drug Administration (FDA) determine that the ongoing marketing of 10 milligram orally disintegrating loratadine tablets (loratadine) by Wyeth-Ayerst Laboratories (Wyeth), pursuant to an approval under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (Act) (which marketing commenced before Wyeth's abbreviated new drug application (ANDA) for generic loratadine was approved), constitutes "commercial marketing" within the meaning of section 505(j)(5)(B)(iv)(I) of the Act. In your Supplement, you request that FDA adjudicate the 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 for this product; (2) declaring that Wyeth's 180-day commercial marketing exclusivity for generic loratadine expired on August 9, 2003; and (3) adopting appropriate measures to implement an offer made by Wyeth to end this exclusivity after August 9, 2003. For the reasons described below, your Petition is denied, and your Supplement is denied in part and granted in part.

Wyeth's offer to waive or relinquish its marketing exclusivity for generic loratadine after August 9, 2003, is reflected in its comments to your Petition.[1] You accepted this offer on behalf of Andrx in your Supplement.[2] In light of Wyeth's offer and Andrx's acceptance, the determinations requested in your Petition and at (1) and (2) of your Supplement, as recounted above, are moot. Accordingly, because we need not make these determinations to resolve your Petition, the requests in the Petition and at (1) and (2) of the Supplement, above, are denied.

We acknowledge that this response does not address the substance of the question essentially posed by the Petition (i.e., whether marketing of a product approved under section 505(b)(2) of

[1] See comments from James N. Czaban, Esq., Heller Ehrman White & McAuliffe LLP, on behalf of Wyeth, dated March 13, 2003, at 1 and 4, and April 25, 2003, at 3.
[2] See Supplement at 1 and 3.

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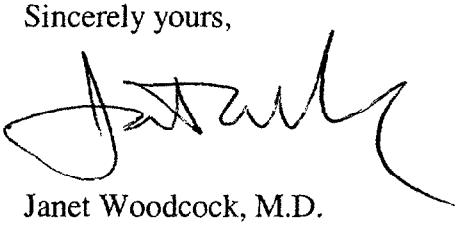
the Act constitutes "commercial marketing" of a generic version of that product under section 505(j)(5)(B)(iv)(I) of the Act). As noted above, this issue is moot in the specific situation at hand. However, if Andrx should perceive a general need for FDA to articulate its position on this issue, it may communicate this need to the Agency, and seek the development of generally applicable guidance, in the manner provided for by FDA's good guidance practices regulation (21 CFR 10.115).

With regard to the request in your Supplement set forth at (3), above, we will implement Wyeth's offer by approving ANDAs for generic loratadine as they become eligible for approval after August 9, 2003. This request is therefore granted.

Sincerely yours,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research