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July 14, 2000

VIA REGULAR MAIL

Janet Woodcock, M.D.
Center for Drug Evaluation
Food & Drug Administration
6027-42 Woodmont Building II
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Rockville, MD 20825

Re: Docket No. 99P-5215/CPI

Dear Dr. Woodcock:

This letter responds to your letter of June 26, 2000, in which you stated that FDA "has not yet resolved" the issues raised in the Citizen Petition filed on December 3, 1999 under the above-referenced docket number. FDA's own regulations, however, impose upon it a mandatory duty to respond to Citizen Petitions "within 180 days of receipt of the petition." 21 C.F.R. § 10.30(e)(2). FDA's failure to respond to the Citizen Petition by May 30, 2000 violates this duty.

FDA's failure to comply with the mandatory response requirement is unjustified because FDAMA's pediatric exclusivity provision accomplishes the goals of the Pediatric Rule, *i.e.*, it brings off-label pediatric uses on-label. The comments that FDA received in response to its May 5, 2000 request for comments on FDAMA's pediatric exclusivity provision, *see* 65 Fed. Reg. 26,217 (2000), show that the Pediatric Rule is unnecessary and inconsistent with FDAMA:

- Most commenters agree that FDAMA's exclusivity provision is working well. As the National Institutes of Health has explained, "FDAMA has had an immediate and positive impact on drug development for children to an extent not seen during the preceding 30 years." Letter from National Institutes of Health to FDA Dockets Management Branch (June 3, 2000) at 1 (providing data to substantiate assertions). Similarly, the American Academy of Pediatrics commented that "[t]he pediatric exclusivity program is the most successful program the FDA has developed to generate studies of medications in children." Letter from American Academy of Pediatrics to FDA Dockets Management Branch (June 5, 2000) at 1: *see* Letter from PhRMA to FDA Dockets Management Branch (June 5, 2000) at 1 (explaining that FDAMA's exclusivity provision . . . has markedly improved pediatric development" and that "tremendous progress has been made towards providing meaningful new information on the pediatric uses of drugs").
- Some commenters complain that the exclusivity provision is working too well and thus delaying access to a large number of generic drugs. *See, e.g.*, National Association of Pharmaceutical Manufacturers to FDA Dockets Management Branch (June 2, 2000) at 1,

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3; Letter from Byron Chemical Co. to FDA Dockets Management Branch (June 2, 2000) at 1.

- Some commenters suggest that the pediatric exclusivity provision should be expanded to provide greater assistance to vulnerable patient populations such as cancer sufferers. See, e.g., Letter of Children's Oncology Group to FDA Dockets Management Branch (June 2, 2000) at 2; Letter of The Children's Cause Inc. to FDA Dockets Management Branch (June 5, 2000) at 3.

These comments, all of which testify to the effectiveness of FDAMA's pediatric exclusivity provision in expanding pediatric drug availability, confirm that FDA's Pediatric Rule is unnecessary and improperly promulgated, as set forth in our Citizen Petition.

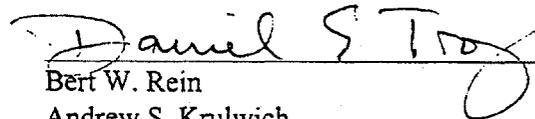
The fact that the effectiveness of FDAMA's pediatric exclusivity provision now has been extensively documented makes FDA's failure to comply with the mandatory 180-day response deadline all the more inexcusable. We thus will consider FDA's failure to respond substantively to our Citizen Petition by Monday, July 31, 2000 as an effective denial of the Petition and reserve all rights to seek relief in an appropriate judicial forum thereafter.

Respectfully submitted,

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