GPhA
Generic Pharmaceutical Association

1620 I Street, NW • Suite 800 • Washington, DC 20006
202-833-9070 • Fax: 202-833-9612 • Email: info@gphaonline.org

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Bernard Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. 01N-0101

Dear Dr. Schewtz:

I am writing to provide the comments of the Generic Pharmaceutical Association (GPhA) on Docket No. 01N-0101 titled "Issues Associated With the Intersection of the 180-Day Generic Exclusivity and Pediatric Exclusivity; Request for Comments." Earlier this year by unanimous vote, the GPhA Board of Directors approved the policy outlined below with regard to the activation of the 180-day period of generic market exclusivity ("Generic Exclusivity") when Pediatric Exclusivity is in effect.

As you know, the Hatch-Waxman Act established Generic Drug Exclusivity to reward the first generic manufacturer to file an abbreviated new drug application ("ANDA") containing a "Paragraph IV" certification challenging a patent listed in the Orange Book. In a February 22, 2001 letter to Senator Orrin Hatch, Associate Commissioner for Legislative Affairs Melinda Plaisier wrote "While we acknowledge that it is your position that the intent of the authors of both pediatric and 180-day exclusivity provisions was that they run consecutively and not overlap, we have been unable to find any statutory language or legislative history to support this view." This is inconsistent with current law and contrary to the intentions of Congress to provide an incentive to challenge patents.

Generic and Pediatric Exclusivity were enacted in separate statutes to encourage distinctly different research. Generic Exclusivity was included in Hatch-Waxman to reward generic companies for accelerating entry through "Paragraph IV" patent challenges. Pediatric Exclusivity was enacted in FDAMA to reward innovator companies for conducting research in potential pediatric uses of drugs.

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The relevant statutory language confirms that Pediatric Exclusivity and Generic Exclusivity are separate and distinct rewards that were intended to run consecutively, not concurrently. In fact, FDAMA expressly contains a tolling provision for any period of Generic Exclusivity. Thus, 21 U.S.C. § 355a(c)(2)(B), which creates Pediatric Exclusivity, states that "the period during which an [ANDA] application may not be approved under...section 355(j)([5])(B)...shall be extended by a period of six months after the date the patent expires (including any patent extensions.)"[1] For any so-called "Paragraph IV" ANDA applications filed after the first such application, "the period during which ...[the] application may not be approved under...section 355(j)(5)(B). Thus, when pediatric exclusivity is awarded, the FDAMA requires FDA to "extend[]" the Generic Exclusivity period "by a period of six months." This tolling provision of FDAMA ensures that Pediatric Exclusivity and Generic Exclusivity will always run consecutively and will never run concurrently.

In addition, 21 U.S.C. § 355(j)(5)(B)(iv) expressly provides FDA with discretion to ensure that Pediatric Exclusivity does not extinguish Generic Exclusivity. That section states that "Paragraph IV" applications filed after the first such application "shall be made effective not earlier than one hundred eighty days after" one of the applicable triggering events occurs. Thus, FDA has the discretion to defer final approval of subsequent "Paragraph IV" applications for more than 180 days in order to effectuate the clear Congressional desire to reward generic first filers.

No other interpretation finds support in the language and legislative history of these two statutes, and any contrary interpretation would eliminate the crucial incentive to challenge patents that Hatch-Waxman provides.

Sincerely,

William Nixon
President and CEO

[1] As a result of an administrative renumbering, the reference in the 1997 Act to "section 355(j)(4)(B)" corresponds to section 355(J)(5)(B) of the 1984 Act. See Mova Pharmaceutical Corp. V. Shalala, 140 F.3d 1060, 1062 n. 1 (D.C. Cir. 1998) (discussing the redesignation of paragraphs 355(j)(3) to (8) as paragraphs 355(j)(4) to (9)).

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Rockville, MD 20852

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