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Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Room 1061, HFA-305  
Rockville, Maryland 20852

Subject: Docket No. 2004P-0075 (Citizen Petition submitted by Mylan Pharmaceuticals, Inc.)

These comments are submitted by Johnson & Johnson in response to a citizen petition filed by Mylan Pharmaceuticals, Inc ("Mylan"). The petition requests FDA to prohibit the marketing and distribution of "authorized generic" versions of innovator products until the expiration of any 180-day generic drug exclusivity applicable to another version of the product.

Mylan's petition should be denied. FDA's current policies fully comply with the statutory provisions on the 180-day prohibition on the approval of certain ANDAs, and FDA lacks the authority to prohibit the marketing and distribution of "authorized generics" as Mylan requests. Mylan has provided no evidence that its petition is in the public interest, and, to the contrary, its proposal would be anticompetitive.

#### I. BACKGROUND

Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("FDCA") establishes a 180-day period following the approval of certain abbreviated new drug applications ("ANDAs") during which FDA may not approve other ANDAs for the same drug product. While this is commonly referred to as "180 day exclusivity," in practice this period has never been truly "exclusive," as the NDA holder and its distributors and licensees have always been authorized to continue to sell the originally approved drug product throughout this 180-day period and beyond.

Mylan's citizen petition now seeks to have the FDA restrict certain kinds of marketing and distribution activities that heretofore have been routinely authorized under approved NDAs. In particular, Mylan wants the FDA to prohibit the sale of so-called "authorized generic" products, which Mylan describes as drug products that are "a private label version of a brand name product supplied by the brand company," during the 180-day period.

The objective of Mylan's request is to allow it to limit competition solely to allow it to charge a higher price at the expense of consumers and to prevent the NDA holder from engaging in a perfectly lawful competitive response. To achieve its end, Mylan asks the FDA either to require

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separate approval of an NDA holder's private label products, or to require FDA listing of these under section 510 of the FDCA prior to marketing, and to withhold its consent to either until the 180-day period has expired.

Mylan's proposal is unprecedented, inconsistent with current procedure, anticompetitive, and contrary to the public interest. Under current procedure, an NDA-holder may revise its labeling to add a distributor without any prior FDA approval and simply report that change in its annual report.<sup>1</sup> The ability to do so ensures that FDA approved product originating from the innovator manufacturer may be widely distributed. The availability of lower cost private label products establishes healthy competition with generic entries both during and after the 180-day period, leading to lower drug prices than would otherwise prevail under Mylan's proposed regulatory scheme.

## II. FDA'S CURRENT POLICY COMPLIES WITH THE LAW

### A. Allowing "Authorized Generics" During a 180-Day Exclusivity Period Is Consistent With the Statute

Mylan asserts that allowing an "authorized generic" to be marketed during the 180-day exclusivity period "is contrary to the letter and intent of the law." Mylan is flatly wrong.

Section 505(j)(5)(B) of the FDCA provides that:

"The approval of an *application submitted under paragraph (2)* shall be made effective on the last applicable date determined under the following:

\* \* \*

"(iv) 180-DAY EXCLUSIVITY PERIOD.—

"(1) EFFECTIVENESS OF APPLICATION. —Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by the first applicant." (emphasis added)

By clear statutory terms, the 180-day exclusivity period prohibits FDA from approving only applications that are filed under section 505(j)(2) of the FDCA – i.e., ANDAs containing a Paragraph IV certification. Nothing in this provision, or in any other provision of the FDCA, applies the 180-day exclusivity provision to prohibit the approval or marketing of a drug that was not approved through an ANDA. Mylan's position that FDA is violating the letter of the law is baseless.

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<sup>1</sup> 21 C.F.R. § 314.70(d)(3); "Guidance for Industry: Changes to an Approved NDA or ANDA" (Revision 1, April 2004) at 26.

There is nothing unusual in the fact that the 180-day exclusivity provision does not prohibit all competitive drugs, since none of the exclusivity periods established by Hatch-Waxman bar all competitors. The 180-day exclusivity period does not bar approval of an NDA submitted under section 505(b), including an NDA described in section 505(b)(2). If there are multiple ANDAs submitted on the same day as the first ANDA qualifying for the 180-day exclusivity, they all share the 180-day exclusivity.<sup>2</sup> The 5-year and 3-year exclusivity periods for drugs approved through NDAs block ANDAs and 505(b)(2) applications, but they do not bar approval of other full NDAs. There is simply no basis to Mylan's contention that the existence of competitive products during a 180-day exclusivity period is contrary to the language or intent of the law.

B. "Authorized Generics" Cannot Be Viewed As Legally Equivalent to Products Approved Under ANDAs

Mylan incorrectly argues that FDA has treated NDA authorized private label products equivalent to ANDA-approved generics for purposes of the 180-day exclusivity period. However, *Mylan Pharmaceuticals Inc. v. Thompson*, 207 F. Supp. 2d 476 (N.D.W.Va. 2001), relied upon by Mylan, in no way supports that proposition. In *Mylan*, after filing its ANDA, Mylan settled the ensuing patent infringement action by taking a license authorizing it to market Pfizer's NDA-approved drug product, *not* the product that was the subject of Mylan's ANDA. By not marketing its ANDA approved product, Mylan sought to park its 180-day exclusivity, to thereby forestall the entry of generic nifedipine products approved through the ANDA process.

In response to a Citizen Petition challenging this scheme, FDA appropriately ruled that Mylan was no longer eligible for the 180-day exclusivity because, by virtue of its settlement with the patent holder, it had effectively changed its certification from paragraph IV to paragraph III. While FDA also decided in the alternative that Mylan's 180-day period started to run with its commercial marketing of the innovator's product, at no time did it conclude that the private label product that Mylan was selling needed to be discontinued in favor of its ANDA-approved version.<sup>3</sup> If FDA had not ruled as it did, Mylan could have indefinitely delayed the approval of other generic competitors, thereby abusing the statute's intent. FDA's response to Mylan's attempted abuse does not support Mylan's broad assertion that FDA treats "authorized generics" as if they have been approved under ANDAs. Later, when Congress amended the FDCA in 2003, it expressly provided that the 180-day exclusivity period begins if the applicant holding the exclusivity right markets an "authorized generic", but did nothing to prohibit the marketing of "authorized generics" along with ANDA-approved versions.<sup>4</sup>

Mylan also incorrectly suggests that "authorized generics" are treated the same as drugs approved under ANDAs for all other purposes. That is not correct. The FDA does not list "authorized generics" in the Orange Book and does not assign a therapeutic equivalence rating to them. Moreover, under the Medicaid rebate program, an "authorized generic" product is subject

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<sup>2</sup> 21 U.S.C. § 355(j)(5)(iv)(II)(bb).

<sup>3</sup> Letter from FDA to Teva Pharmaceuticals, Docket No. 00P-1446/CP1 (Feb. 6, 2001).

<sup>4</sup> 21 U.S.C. § 355(j)(5)(B)(iv)(I).

to a higher rebate than generics approved under ANDAs.<sup>5</sup> Mylan's premise that "authorized generics" are indistinguishable in the marketplace from generics approved under ANDAs is simply not correct.

### III. MYLAN'S SPECIFIC PROPOSALS WOULD VIOLATE THE STATUTE

Neither of Mylan's specific proposals would be lawful. Mylan's first proposal is that FDA should impose an approval process for "authorized generics", such as a one-page application identifying the distributor and the manufacturer of the drug. Under Mylan's approach, FDA would grant final approval of such an application only after expiration of any 180-day exclusivity period for another version of the drug.

This proposal cannot be reconciled with the statutory requirements for approval of new drug applications. Section 505(d) of the FDCA sets forth the standards for approval and disapproval of NDAs, and none of those statutory criteria would permit FDA to base its action on an application for an "authorized generic" on whether approval of the drug would affect the 180-day exclusivity of a different drug. Granting only tentative approval during another drug's 180-day exclusivity period amounts to disapproval during the period of delay and therefore is not authorized.

Mylan's alternative proposal is equally impermissible. Under this approach, "authorized generics" would have to be listed with FDA under section 510 of the FDCA prior to marketing, and FDA would prohibit such listing until any 180-day exclusivity period had expired. Nothing in section 510, however, would permit Mylan's scheme.

If the distributor of the "authorized generic" has previously registered with FDA, section 510(j)(2) requires only that the distributor update its list of drugs in June and December of each year. Even if the company distributed no other drugs, section 510(c) requires only that the company register "upon first engaging" in such activity. Nothing in section 510 permits FDA to require listing of a drug prior to commercial distribution, and it in no way permits FDA to tie such a requirement to a prohibition on listing during another drug's exclusivity period. The treatment of drugs under section 510 contrasts with the section's treatment of medical devices, for which section 510(k) does require advance notice to FDA. Congress established different requirements for the listing of drugs and devices, and FDA lacks the authority to adopt Mylan's proposal to impose device-like listing requirements on drugs.

### IV. MYLAN'S PROPOSAL IS CONTRARY TO SOUND PUBLIC POLICY

Mylan urges FDA to adopt a policy that is hostile to the early introduction of multiple competitive products in the market without considering Congress's expressed intent to the contrary, and without any weighing of the public benefit that is provided by the resulting increased competition. When Congress recently considered the issue, it concluded that the marketing of multiple generics within the 180-day period was consistent with the purposes of that period. To achieve that end, the FDCA Act was specifically amended to allow for multiple "First Applicants" (filers whose ANDAs are submitted on the same day), who are expected to

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<sup>5</sup> See 42 U.S.C. § 1396r-8(c)(2)-(3), (k)(7)(A).

share the so-called 180-day exclusivity period.<sup>6</sup> In so doing, Congress rejected the notion that the potential presence of more than one generic “will negatively affect the incentive given to generic manufacturers to challenge drug patents,” as Mylan now alleges. Nor does Mylan provide any support, as required by FDA’s rules on citizen petitions, to prove that Mylan’s imagined loss of incentive would more than offset the public benefit gained from more vigorous competition during the 180-day period as Mylan implicetely asserts would be the case.<sup>7</sup>

To the contrary, it may reasonably be expected that there is more than ample incentive for would-be generics to challenge invalid patents or those that are not infringed. Indeed, there has already been an explosion in ANDA filings (and resulting ANDA litigations) under the current rules, which allow “authorized generics.” Mylan itself continues to file ANDAs with paragraph IV certifications, notwithstanding its current petition alleging that it has been discouraged from doing so.<sup>8</sup> The 180-day period, even when multiple ANDAs are submitted on the same day, is extremely valuable to ANDA applicants such as Mylan. During this period, the generic product can capture a significant segment of the market and earn substantial profit without having invested any significant resources in development of the product.<sup>9</sup> Moreover, it may retain much of that benefit even after the 180-day period has expired.

Studies have shown that generic drug entry produces declines in generic prices as the number of generic rivals increases,<sup>10</sup> and that falling prices from increased competition can continue with the entry of additional generic competitors.<sup>11</sup> Thus, additional competitors – in the form of “authorized generics” – can provide benefits for consumers of prescription drugs, even as the 180-day exclusivity period provides the first ANDA applicant protection from additional ANDA applicants. Thus, in contrast to Mylan’s unsubstantiated assertion about reduced incentives to challenge patents, the presence of an additional competitor in the form of an authorized generic is plainly pro-consumer.

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<sup>6</sup> Sec. 1102(a)(1)(iv)(II)(aa)&((bb) of the “Medicare Prescription Drug, Improvement, and Modernization Act of 2003”

<sup>7</sup> 21 C.F.R. § 10.30(b), requiring the petitioner to include “all relevant information and views on which the petitioner relies. . . .”

<sup>8</sup> See SG Cowen Analysts Report dated March 26, 2004 identifying eleven pending Paragraph IV challenges for Mylan Labs

<sup>9</sup> See FDA, GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY (July 2003), at 3, *available at* <http://www.fda.gov/cder/guidance/5710fnl.pdf>. (citing a July 1998 Congressional Budget Office report on decreases in generic drug price when more generic duplicates entered the market). The 180-day period also gives the generic company a head start to establish its product in prescription formularies.

<sup>10</sup> See *Generic Drug Entry Prior to Patent Expiration*, An FTC Study, Federal Trade Commission, July 2002, at 9 (citing Richard E. Caves, et al., “Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry” (Brookings Papers on Economic Activity, Microeconomics, Martin Neil Bailey & Clifford Winston, eds., Brookings Institution, Washington, D.C., 1991)).

<sup>11</sup> See *Generic Drug Entry Prior to Patent Expiration*, An FTC Study, Federal Trade Commission, July 2002, at 9 (citing David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002), *available at* <http://www.ftc.gov/econwork.htm>)

Finally, by providing innovators an additional alternative for recouping income on their substantial investments in developing drugs in the first place, "authorized generics" provide some incremental incentive to develop new drugs that are the long-term lifeblood of the generic marketplace. Such public benefit clearly outweighs any public interest in helping generic companies such as Mylan garner windfall profits during the 180-day exclusivity period.

V. CONCLUSION

Mylan's petition urges FDA to impose legally impermissible obstacles to the marketing of "authorized generic" products. In support of its anticompetitive proposal, Mylan offers only unfounded assertion about the supposed effect of "authorized generics" without any evidentiary support. Mylan's petition should be denied.

Sincerely,



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