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Department of Health and Human Services
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COMMENTS OF MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS ON DOCKET NO. 2004P-0563: McNeil opposes Andrx's Citizen Petition request that FDA change its policy concerning the marketing of 'authorized generic' versions of brand name prescription drugs

The undersigned, McNeil Consumer & Specialty Pharmaceuticals ("McNeil"), submits these comments in response to the above-referenced Citizen Petition filed by Andrx Pharmaceuticals, Inc. ("Andrx"). In its petition, Andrx proposes a novel and unfounded legal theory to ask FDA to change the way it has viewed the marketing of "authorized generics," asking FDA to designate such products as "misbranded" under § 502(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). As discussed in these comments, there is no colorable legal theory to support, nor any appropriate basis for, such FDA action. FDA already has decided that authorized generics can be marketed, and the United States District Court for the District of Columbia has fully agreed. Therefore, Andrx's petition should be denied.

I. Andrx's Requested Actions

Andrx's Citizen Petition addresses the marketing of "authorized generics," which FDA has defined as "the marketing of a product approved under a new drug application (NDA), by that NDA holder, under that NDA, but at a lower price and not under the 'brand' name, possibly through a different channel of distribution."¹ Andrx requests FDA to seek formal public comment on the potential anticompetitive effects of the marketing of authorized generics. Specifically, Andrx requests FDA to seek advice from the Bureau of Competition and Consumer Protection of the Federal Trade Commission ("FTC") and the Antitrust Division of the Department of Justice ("DOJ"). Apparently on the theory that FDA will ultimately conclude that the marketing of authorized generics before or during the launch of the first ANDA-approved generic represents a violation of the antitrust laws, Andrx then asks FDA preemptively to prohibit such marketing of any authorized version of the branded drug, CONCERTA[®]. Notably, Andrx's petition lacks any evidence supporting its claim that such marketing is actually anticompetitive, false or misleading.

¹ Letter from William K. Hubbard to Stuart A. Williams and James N. Czaban re. Docket Nos. 2004P-0075/CP1 and 2004P-0261/CP1 ("Mylan/Teva Petition Denial"), page 2.

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II. FDA Need Not Seek Advice Regarding the Anticompetitive Effects of Authorized Generics

FDA has noted that it “does not regulate competition as a general matter.”² In this respect, when commenting on the practice of marketing authorized generics, FDA has stated that “removing the brand name or changing the channel of distribution is unlikely to pose any threats to public health.” Similarly, in explaining its authority over a manufacturing change to remove the brand name from a product, the agency has stated, “FDA does not and cannot use that authority to regulate competition in a manner that has little or no relationship to the public health.”³

Multiple federal and state agencies exercise jurisdiction over market competition issues. They investigate allegations of specific anticompetitive conduct, where such conduct is in violation of particular antitrust laws. Andrx has not alleged that McNeil, nor any other NDA-holder, would violate any antitrust laws in conjunction with their marketing of authorized generics.⁴ Instead, Andrx requests that FDA make new antitrust law by initiating an investigation of the competitive effects on the market of authorized generics. Such action is not properly within FDA’s jurisdiction; it is Congress’s role to solicit information and enact laws respecting the regulation of the market. As precedent for its request that FDA solicit the input of federal antitrust agencies, Andrx cites FDA’s consultation with the DOJ’s Antitrust Division in conjunction with its consideration of the impacts on competition of the modification of labeling related to its “man-in-the-plant” policy.⁵ There, FDA sought comments to reopen and supplement a recent notice-

² *Id.* at 12.

³ *Id.* at 2.

⁴ Andrx hints that the marketing of an authorized generic constitutes “predatory pricing.” Citizen Petition at 12 (quoting an alleged remark by Judge Irene Keeley). In fact, the act of predatory pricing requires that the price be set below-cost, a fact that has not been alleged here. Were such predatory pricing actions actually undertaken by a NDA-holder, antitrust enforcement authorities would surely retain discretion to prosecute, should they so desire.

Rather, the FTC and other agencies with jurisdiction for market competition issues are likely to see Andrx’s request for what it is – a bald attempt to secure its own regulatory protection from competition. If granted, Andrx’s request could, ironically, itself ultimately have an anticompetitive effect on the market, by narrowing consumer choice for generic drugs and inhibiting healthy price competition in the generic drug market. This is because, in many areas of U.S. commerce, different private labeled products (e.g., CVS or Walgreen brands) often are manufactured by the same source without required disclosure of that fact. In the drug market, these manufacturers include generic drug companies – that under Andrx’s proposal could be required to discontinue this common practice. Thus, Andrx’s approach would have broad repercussions in opening a “Pandora’s box” of new legal duties and disclosures for both authorized generics and ANDA generics and is, in any regard, not an issue for FDA review.

⁵ *Id.* at 8. See also 44 Fed. Reg. 37234 (June 26, 1979) (reopening the comment period to allow comments on the economic effects of the rulemaking proposal to modify the “man-in-the-plant” policy). The man-in-the-plant regulation change cited by Andrx established that a label may contain the name of *either* the manufacturer, the packer, or the distributor, and that the specific labels of “manufacturer,” “packer” and “distributor” had particular meanings. The purpose of these regulations was to end practices that were seen as overtly deceptive.

In this singular cited example over two decades ago, where FDA took action to end overt consumer deception, it viewed the fact that its action had the result of potentially serving consumers’ economic interests as an incidental benefit. In no case did FDA assert that it had the authority or the inclination to take action with the primary purpose of furthering consumer economic interests, much less consumer desires to make “political” statements in their drug purchase choices. Final Rule, Requirements for Designating a Manufacturer’s Name on a Drug Product Label, 45 Fed. Reg. 25760, 25763 (April 15, 1980) (“This regulation, *which is intended to end a consumer deception*, proceeds under paragraphs (a)

and-comment period for a new rule that it had been considering implementing. By contrast, here Andrx asks FDA to initiate an inquiry into the anticompetitive effects of a long-standing industry practice that is clearly permitted by the relevant statutory and regulatory scheme. Such initiative is outside FDA's mission and jurisdiction.

III. Authorized Generic Drugs Are Not Prohibited by Law or Regulation

Andrx's request for action is narrowly characterized as a request that FDA prohibit marketing of an authorized generic form of CONCERTA[®] before or during the initial product launch of the first ANDA-approved version of the drug. However, Andrx's arguments would actually require FDA to go much further than to restrict authorized generics during ANDA product launches. Indeed, its argument that the labeling of authorized generic drugs is misleading would require FDA to prohibit all future marketing of authorized generic drugs on the ground that they are misbranded, despite FDA law and longstanding agency policy that clearly establishes that authorized generic drugs are not false and misleading.

Congress has had more than one opportunity, and has chosen not, to restrict or prohibit the marketing of authorized generics. The Food and Drug Administration Modernization Act of 1997 ("FDAMA") included requirements for making and reporting manufacturing, specification, labeling and other changes.⁶ The FDAMA established a three-tiered reporting system, with the standard for assessing the impact of a change on its "effects ... on the identity, strength, quality, purity or potency of the drug as [they] may relate to the safety or effectiveness of the drug."⁷

FDA issued guidance addressing and clarifying these provisions of the FDAMA, providing that, for example, where only "minor labeling changes" occur, including labeling changes to add a distributor's name, they need only be reported in a company's annual report.⁸ The marketing of authorized generics fits comfortably within this well-established regulatory scheme. Congress also opted not to restrict the marketing of authorized generic products when it passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"). The MMA modified the language of the 180-day exclusivity provision applicable to ANDA applicants submitting a paragraph IV certification, but did nothing to regulate authorized generics.

The fact that authorized generics may compete with ANDA generic products, even during the ANDA holder's 180-day exclusivity period, was affirmed by the United States District Court for the District of Columbia the very day Andrx submitted its petition to FDA. The court completely rejected the argument that authorized generics are not allowed under the Federal Food, Drug, and Cosmetic Act and supported FDA's position that the agency has no statutory authority to delay entry into the market of authorized generics.⁹ Andrx should not be allowed now to second-guess FDA and the court.

and (b)(1) of [section 502 of the FDCA].... If consumers' economic interests are also served by less deceptive label information, that does not make the subject matter of the rule an improper subject for FDA regulatory action." (emphasis added)).

⁶ Pub. L. No. 105-115 (codified at § 506A of the FDCA).

⁷ 21 U.S.C. § 356a(c)(2).

⁸ Guidance for Industry: Changes to an Approved NDA or ANDA, 26 (April 2004). It is simply not misleading under this regulatory scheme for a brand manufacturer to market a generic product containing truthful labeling noting the entity distributing the product.

⁹ See *Teva Pharmaceuticals v. FDA*, 2004 WL 3037715 (D.D.C. December 23, 2004). The court decided the case at step one of the traditional *Chevron* analysis for review of agency decisions (i.e., that the statute speaks clearly to the precise question at issue), and went to far as to state, "The court *cannot*

IV. Authorized Generic Drugs Are Subject to Carefully Considered FDA Labeling Requirements and Are Not False and Misleading in Any Particular

In its petition, Andrx attempts to characterize authorized generic products as being so like the brand name product that their lack of brand labeling is misleading. Other than this completely novel and misguided “*per se*” labeling violation theory, however, Andrx presents no basis to support its petition. It does not allege any legally relevant FDCA violation related to generic drug bioequivalence or adulteration, or any violation of FDA’s careful and deliberate regulatory process with respect to the labeling of products approved under both the NDA and ANDA processes. Although Andrx’s argument is based on the alleged omission of information from labeling, its arguments do not satisfy the FDCA’s definition of misleading labeling found at Section 201(n), which focuses on the consequences of using the drug as recommended in the labeling at issue in the light of any omitted material fact.¹⁰ No negative safety or efficacy consequences result from the use of the authorized generic, nor are any alleged by Andrx.

Andrx speculates about the possible “politically” decision-driven choices by some individuals in their drug purchases. Its position, however, is unsupported by any evidence at all and is highly implausible. In an age where product version utilization is driven largely by HMOs, PBMs, and other insurance-related entities, consumers rarely dictate such decisions. Consumers do benefit, however, from the overall lower prices of drugs resulting from the availability of both authorized generics and other generics. In all cases, accurate labeling information is provided about the manufacturer, distributor or packer of the product.

In fact, were branded manufacturers to actually attempt to distinguish authorized generics from other generics in any fashion, that attempt would itself risk being found misleading by FDA. FDA considers all generic product versions to be functionally the same. Thus, Andrx’s approach would lead to the very type of differentiation among generics, implying different quality “tiers,” that FDA has long attempted to dispel.¹¹

fathom any reason to apply § 355(j)(5)(B)(iv), a provision clearly addressing only ANDAs, to limit the introduction into the market of a generic drug of a NDA holder” (emphasis added).

¹⁰ 21 U.S.C. Section 321(n). “If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material *with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.*” (Emphasis added.)

¹¹ See, e.g., FDA’s letter of February 4, 1998, signed by Stuart Nightingale, M.D., Associate Commissioner for Health Affairs, FDA, entitled, “Therapeutic Equivalence of Generic Drugs; Letter to Health Practitioners,” wherein FDA states, “products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is brand name or generic drug product.”

V. Conclusion

Andrx's arguments fail in all regards. Market competition issues are outside FDA's mission and jurisdiction; FDA already has considered this issue and determined that long-standing law and policy allow for authorized generics – a fact recently upheld by the court in the strongest terms; the labeling for authorized generics is not *per se* misbranded, as Andrx suggests; no safety or efficacy problems are created with the approval or labeling of authorized generics, and; granting Andrx's request would not address any pertinent issues but would create new problems. FDA should, therefore, deny Andrx's Citizen Petition.

Respectfully submitted,
MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS


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President