PERRIGO®

2336 '03 MAY -1 A9:12

April 30, 2003

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: Submission of Electronic Documents

To Whom It May Concern:

Please find attached one original and one copy of the document CP 03P-0160 (Comments On Citizen Petition Submitted by Genpharm Inc.) that was sent to the FDA by electronic submission on Tuesday, April 29, 2003.

If you have any questions regarding this material, please contact Brian R. Schuster by phone at 269-673-9745.

Best Regards,

Tricia Pasek

Tricia Pasek
RA, Administrative Assistant

Encl.

03P-0160 C 1

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Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857

Re: CP 03P-0160

COMMENTS ON CITIZEN PETITION SUBMITTED BY GENPHARM INC.

L. Perrigo Company ("Perrigo") submits the following response to the Citizen Petition submitted by Genpharm Inc. ("Genpharm") on April 15, 2003. The Genpharm petition asks that FDA refuse to approve Perrigo's 505(b)(2) new drug application ("NDA") for loratadine tablets, 10 mg.

Each of the reasons that Genpharm advances as a basis for its requested relief is either wrong or immaterial to the question of whether Perrigo's 505(b)(2) NDA should be approved.[1]

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[1] Genpharm says in a footnote that a Perrigo communication about the status of the various loratadine applications "appears to constitute pre-approval promotion." Perrigo's communication was intended to shed light on the confusing regulatory issues surrounding the switch of Claritin from Rx to OTC and the various 505(b)(2) NDAs and ANDAs that had been submitted. Perrigo made no safety or effectiveness claims for its product that would raise questions of pre-approval promotion. As the attached "Loratadine Update" shows, Genpharm's marketing partner has disseminated materials that go beyond the referenced communication from Perrigo. Perrigo's communication was in direct response to the attached materials and was intended to correct inaccuracies therein.

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Genpharm contends that Perrigo's loratadine product may not be approved as a 505(b)(2) NDA because it is not sufficiently different, in Genpharm's view, from Claritin®, 10 mg. Therefore, Genpharm argues that Perrigo may only obtain approval of an abbreviated new drug application ("ANDA") rather than a 505(b)(2) NDA.

The simple answer is that there is no support in the statute, FDA's regulations or its 505(b)(2) guidance document (*Guidance for Industry: Applications Covered by Section 505(b)(2)*) for the proposition Genpharm advances. Section 505(b)(2) does not restrict the types of drug products for which an application may be submitted. Similarly, while the ANDA section of the law, § 505(j), does limit the types of products for which an ANDA may be submitted, it contains no corresponding limitation on those products which may properly be the subject of a 505(b)(2) NDA.

While FDA's regulations, 21 C.F.R. § 314.101(d)(9), and the 505(b)(2) guidance document do say that one may not submit a 505(b)(2) NDA for a product that is a duplicate of the listed drug and is eligible for approval under § 505(j), the facts of this case do not support the argument Genpharm advances. At the time Perrigo submitted its 505(b)(2) NDA for an over-the-counter ("OTC"), 10 mg. loratadine tablet product, the reference listed drug, Claritin®, was a prescription drug. Therefore, Perrigo could not have submitted an ANDA for an OTC 10 mg. loratadine product. As Genpharm is well aware, an ANDA drug must bear the same labeling as the reference listed drug. A prescription drug and an OTC drug cannot bear the same labeling. Moreover, the

505(b)(2) guidance document specifically says that a 505(b)(2) application may be submitted to change a prescription indication to an OTC indication.

The fact that FDA approved Schering-Plough's supplemental NDA to convert Claritin® from prescription to OTC status while Perrigo's 505(b)(2) NDA was pending does not change the fact that Perrigo's application was properly submitted as a 505(b)(2) NDA.

Genpharm conveniently ignores the fact that FDA has already approved Wyeth's 505(b)(2) NDA for Alavert, a 10 mg. orally disintegrating tablet version of loratadine. That 505(b)(2) NDA was approved on December 19, 2002 after FDA had already approved Schering's supplemental NDA to convert its orally disintegrating tablet to OTC status. Moreover, it is our understanding that Wyeth also has a pending ANDA for an orally disintegrating tablet.[2] If Genpharm's arguments had any legal merit -- which they do not -- FDA would not have been able to approve Wyeth's 505(b)(2) NDA.

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[2] Indeed, a citizen petition has been filed by Andrx Pharmaceutical Inc. arguing that Wyeth's marketing of its 10 mg. orally disintegrating tablet under § 505(b)(2) constitutes commercial marketing of generic loratadine within the meaning of § 505(j)(5)(B)(iv)(I), therefore triggering Wyeth's exclusivity for its ANDA for the same product. While we take no position on the merits of Andrx's petition, it is a further example that Perrigo's 505(b)(2) NDA was properly filed.

Perrigo is in the same position as Wyeth. The only difference is that Perrigo is seeking approval for a tablet as opposed to an orally disintegrating tablet. FDA cannot treat Perrigo differently than it has treated Wyeth.

Genpharm makes much of Perrigo's supposed "motivation" for submitting a 505(b)(2) NDA. Those arguments are irrelevant. Perrigo submitted a 505(b)(2) NDA because that was a regulatory option available to it. Recent reports in the trade and lay press have indicated that the price of loratadine at the consumer level has remained high notwithstanding the switch of some loratadine products to OTC status. Approval of Perrigo's product will improve competition and result in lower costs to consumers.

Finally, Genpharm argues that even if Perrigo's 505(b)(2) NDA was properly submitted, FDA may not approve Perrigo's 505(b)(2) application until the end of the 30-month stay or a court decision of invalidity or non-infringement in an action brought by Schering against Perrigo. First, there has been a court decision in a patent case between Schering and Perrigo that satisfies the court decision requirement of the statute. Second, Genpharm's contention that a court decision must be one between Schering and Perrigo is not supported by FDA or the courts.

1. There is a Court Decision of Invalidity in a Paragraph IV Lawsuit Brought by Schering Against Perrigo.

As Genpharm is well aware, on August 8, 2002, Judge Bissell of the U.S. District Court for the District of New Jersey ruled that claims 1 and 3 of Schering's Patent No. 4,659,716 (the '716 patent) were invalid. Schering Corp. v. Geneva Pharmaceuticals, Inc., 64 U.S.P.Q. 2d 1032 (D.N.J. 2002). Subsequently, in a separate case brought by Schering against Perrigo as a result of Perrigo's paragraph IV certification in its ANDA for loratadine tablets, Judge Bissell issued an order finding claims 1 and 3 of the '716 patent invalid. See attached order of August 29, 2002. Therefore, there has been a court order of invalidity in a paragraph IV lawsuit brought by Schering against Perrigo.

Schering also brought another lawsuit against Perrigo as a consequence of Perrigo's 505(b)(2) NDA. That case was filed on December 2, 2002. In its complaint, a copy of which is attached, Schering acknowledged that the '716 patent had already been declared invalid in the earlier case against Perrigo but stated that it was filing this lawsuit "to preserve Schering's rights . . . ." (¶ 23). Schering also stated that the lawsuit should be stayed pending a ruling by the Federal Circuit in Schering's appeal in the Geneva case. Accordingly, Schering and Perrigo agreed to a stay which was signed by Judge Bissell on January 21, 2003, a copy of which is attached.

The stay in the 505(b)(2) case is predicated upon the incontrovertible fact that there is nothing to litigate between Schering and Perrigo. Perrigo already has obtained a

district court order finding that the '716 patent is invalid. If Schering sought now to relitigate that issue in the 505(b)(2) case, the complaint would be promptly dismissed on res judicata or collateral estoppel grounds. Therefore, similar to Teva Pharmaceuticals, USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999) (dismissal on grounds of lack of subject matter jurisdiction equivalent to a court order of non-infringement), there is a court order of patent invalidity that requires FDA to approve Perrigo's 505(b)(2) NDA.

2. There is No Requirement for a Court Decision Between Schering and Perrigo

Even if there was not already a decision of invalidity in a case involving Schering and Perrigo, there is no such statutory requirement. Genpharm quotes 21 U.S.C. § 355(c)(3)(C)(i) and highlights the words "the court" and "the court decision." Genpharm argues that the use of the definite article "the" as opposed to the indefinite article "a" means that the only court decision that can terminate the 30-month period is a court decision involving Perrigo's 505(b)(2) NDA. The case law demonstrates that the word "the" does not carry the weight Genpharm would like it to.

In Mylan Pharmaceuticals, Inc. v. Shalala, 81 F. Supp. 2d 30 (D.D.C. 2000), Judge Roberts recognized that the "180-day exclusivity provision in clause (iv) of section 355 (j)(5)(B) must be read in conjunction with the 30-month stay provision in clause (iii). The regulation at issue recognizes this fundamental point by defining 'court' in precisely

the same way for both clauses."[3] Judge Roberts further noted that "[t]he chief linguistic difference between clause (iii) and clause (iv) is that the former refers to 'the court' while the latter refers to 'a court.'" Contrary to the weight Genpharm attaches to the word "the," Judge Roberts held that "[t]his difference is of no great moment in light of the interplay between the clauses."

After the Mylan decision and a second case also involving Mylan, Mylan Pharmaceuticals, Inc. v. Henney, 94 F. Supp. 2d 36 (D.D.C. 2000), FDA issued its court decision guidance document (*A Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*). In that document FDA said that it "will interpret the term *court* as found in § 505(j)(5)(B)(iii)(I) [the approval provision for ANDAs] and 505(j)(5)(B)(4) [the 180-day exclusivity provision] to mean the first court that renders a decision finding the patent at issue invalid, unenforceable or non-infringed. When it is the district court that renders such a decision, FDA may approve the ANDA as of the date the district court enters its decision." As Genpharm notes, this guidance document does not specifically deal with 505(b)(2) applications, but there is absolutely no reason to apply a different meaning of the terms "court" or "court decision" for 505(b)(2) NDAs and ANDAs. Indeed, the definition of "court decision" that was challenged in the two Mylan cases and that was the subject of the court decision guidance

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[3] Judge Roberts held that the regulation, 21 C.F.R. § 314.107(e), was invalid because it defined court to mean "the court that enters final judgment from which no appeal can be taken."

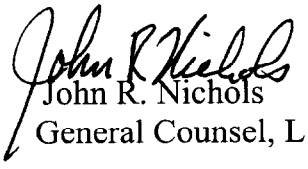
document was set forth in 21 C.F.R. § 314.107. The title of that regulation is: "Effective date of approval of a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act." Therefore, the definitions of "court" or "court decision" are the same for both ANDAs and 505(b)(2) NDAs.

As FDA has long ruled, the 180-day exclusivity of a first ANDA filer can be triggered by a decision of non-infringement or invalidity in an unrelated patent case. That position has been upheld in the courts. Teva Pharmaceuticals USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999); Minn. Mining and Mfg. Co. v. Barr Labs, Inc., 289 F.3d 775 (Fed. Cir. 2002). If an unrelated patent case triggers exclusivity and if "court" and "court decision" mean the same thing for approval and exclusivity purposes, a company should be able to obtain approval of its 505(b)(2) NDA or ANDA based upon a patent case in which it is not a party.

Therefore, the decision rendered by the district court in Schering v. Geneva Pharmaceuticals Inc. finding the relevant patent claims to be invalid is, by itself, a "court decision" that permits approval of Perrigo's 505(b)(2) NDA, notwithstanding the fact that the 30-month period has not run. Even if that was not the case, however, the district court's finding of invalidity in the Schering v. Perrigo ANDA case establishes beyond any doubt that the court decision requirement has been satisfied.

In conclusion, Genpharm's petition is nothing but a thinly veiled attempt to delay approval of Perrigo's 505(b)(2) NDA at the eleventh hour. FDA should reject the petition and promptly approve Perrigo's 505(b)(2) NDA.

Sincerely,



John R. Nichols
General Counsel, L. Perrigo Company