Kirkpatrick & Lockhart LLP

1800 Massachusetts Avenue, NW
Suite 200
Washington, DC 20036-1221
202.778.9000
202.778.9100 Fax
www.kl.com

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Gary L. Yingling
202.778.9124
Fax: 202.778.9100
gyingling@kl.com

VIA FEDERAL EXPRESS DELIVERY

Division of Dockets Management
U.S. Food and Drug Administration
Room 1061 (HFA-305)
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 2003P-0408
Comment in Opposition to the TorPharm Citizen Petition that Criticized FDA's NDA Approval for Pexeva™ (Paroxetine Mesylate) Tablets

Dear Sir or Madam:

On behalf of our client, Synthon Pharmaceuticals, Ltd. ("Synthon"), we submit these Comments to the above-referenced Docket, opposing the Citizen Petition filed on September 3, 2003 by TorPharm, Inc. ("TorPharm"), and the supplemental comments filed on September 19, 2003. In that Petition, TorPharm seeks an immediate withdrawal of Synthon's new drug application ("NDA") for Pexeva™ paroxetine mesylate tablets (NDA 21-299), which the Food and Drug Administration ("FDA") approved three months ago, culminating a three-year review process. TorPharm provides no substantive legal, scientific, or public health basis on which the FDA may withdraw approval of Synthon's NDA. Rather, TorPharm's allegations are an abuse of the Citizen Petition process and a transparent attempt to use spurious, unfounded, and inaccurate arguments to block the lawful marketing of an FDA-approved drug product.

Inserting a new twist to one of the brand drug industry's oldest strategies for stalling the market entry of competing drugs, TorPharm misuses the Citizen Petition avenue in an effort to block competition for its generic paroxetine hydrochloride product. Ironically, Torpharm, a generic drug company, adopts a discredited brand industry argument by attacking FDA's authority to approve NDAs that are submitted pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"). Yet, when viewed properly, TorPharm's Petition represents an inappropriate attempt to expand the FDC Act's 180-day market exclusivity provision beyond that which Congress intended or FDA contemplated. As such, the Petition should be denied wholesale.

A. Background

Synthon filed a 505(b)(2) NDA for paroxetine mesylate oral tablets on July 26, 2000, almost 20 years after Congress created the 505(b)(2) approval pathway via the Drug Price Competition and Patent Term Restoration Act. In accordance with 21 C.F.R. § 314.54 and FDA's Draft Guidance on 505(b)(2) applications,[1] Synthon's application provides evidence of safety and efficacy from a variety of sources, including published literature, clinical studies conducted by Synthon, and FDA's previous finding of the safety and efficacy of the related chemical compound, paroxetine hydrochloride hemihydrate (i.e., GlaxoSmithKline's ("GSK") Paxil® tablets, NDA 20-031). The reference to Paxil was based on the fact that Synthon's drug product contains the same "active moiety" (i.e., paroxetine free base) as Paxil, but in a different "salt" form (mesylate versus hydrochloride hemihydrate).

FDA approved Synthon's NDA on July 3, 2003. Because Synthon's drug product contains the same active moiety, but not the same "active ingredient", as Paxil, the two drug products are not "therapeutically equivalent" under the applicable FDA policies. Therefore, Synthon's product is not a true "generic" drug and is not "AB" rated to Paxil. As a result, Synthon's paroxetine mesylate is not automatically substitutable for Paxil by the pharmacist. Nevertheless, it is a bioequivalent alternative to Paxil in that it provides a therapeutic dose of the paroxetine active moiety that is equivalent to that of Paxil, at a significantly more affordable price.

By contrast, on July 30, 2003, Torpharm received FDA approval of its ANDA 75-356 for a generic version of paroxetine hydrochloride tablets that will be automatically substituted for Paxil. Paxil's U.S. sales total approximately $2.5 billion annually. These sales may continue to grow as GSK obtains FDA approval of new indications for the drug.[2] Torpharm sought solitary access to this billion-dollar market by attempting to file the first abbreviated new drug application ("ANDA") with a "Paragraph IV" patent certification. FDA thwarted that plan by awarding "shared exclusivity" among several ANDA sponsors. Fearing that its market share is slipping away, TorPharm seeks to block the one competitor whose product has already been approved, by claiming that the NDA approval was illegal.[3]

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[1] FDA Draft Guidance for Industry: Applications Covered by Section 505(b)(2) (1999).

[2] *See* FDA's NDA Supplement approval letters for Paxil, adding the indications for generalized anxiety disorder (NDA 20-031/S-035, October 2, 2002) and post-traumatic stress disorder (NDA 20-031/S-029, December 14, 2001).

[3] We note that, just today, FDA announced the approval of another generic competitor for paroxetine hydrochloride tablets: Alphapharm's ANDA 75-716 was approved on September 29, 2003.

B. TorPharm's Petition Asks FDA To Inappropriately and Illegally Extend TorPharm's 180-Day Exclusivity To Synthon's NDA

1. 180-Day Exclusivity Applies Only To ANDAs, Not NDAs

Under the FDC Act, a company may seek approval from FDA to market a generic drug before the expiration of a patent relating to the reference listed drug ("RLD") upon which the generic is based, if the company challenges a "listed" patent as invalid, not infringed, or unenforceable. Additionally, the first company to submit an ANDA with such a patent challenge will be granted the exclusive right to market the generic drug for 180 days. To be eligible for 180-day exclusivity, the generic applicant must: (1) file a substantially complete ANDA; (2) certify in its ANDA that the patent in question is unenforceable, invalid or is not infringed by the generic product (known as a "paragraph IV certification"); and (3) notify the patent holder and NDA holder of the submission of the ANDA. If eligibility still exists at the time the ANDA is approved, the 180-day exclusivity stops FDA from approving any later-filed ANDAs for identical products that also contain a paragraph IV certification to the same patent. 21 USC § 505(j)(5)(B)(iv); 21 CFR § 314.107(c).

The statute and its implementing regulations are clear – 180-day exclusivity applies only to ANDAs, not NDAs. Because Synthon's paroxetine mesylate product was filed pursuant to an NDA under Section 505 of the FDC Act, the firm is not eligible for 180-day exclusivity and, thus, it cannot block subsequent generic drugs under that provision. Likewise, its marketing of paroxetine mesylate cannot be blocked by another company's 180-day exclusivity. The statutory provisions of Section 505(j) simply do not apply. In particular, the statutory provision on 180-day exclusivity is presented in the subsection *governing ANDAs*, and reads:

> If the application contains a certification described in subclause IV of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted *under this subsection* [containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after –
> (I) the date the Secretary receives notice from the applicant under the previous application of first commercial marketing of the drug under the previous application, or
> (II) the date of a decision of a court in an action described in clause (ii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (emphasis added). There is no corresponding statutory provision under Section 505(b) of the FDC Act.

FDA gave effect to this plain language in the statute when it promulgated the applicable implementing regulations. The regulation clearly states that the 180-day exclusivity provisions apply to ANDAs only, as follows:

> If an *abbreviated* new drug application contains a certification that a relevant patent is invalid, unenforceable, or will not be infringed and the application is for a *generic copy* of the same listed drug for which one or more substantially complete *abbreviated* new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable, or would not be infringed, approval of the subsequent *abbreviated* new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier:
> (i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or
> (ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.

21 C.F.R. § 314.107(c) (emphasis added). In the regulation preamble providing notice to the public on FDA's interpretation of the statute, FDA also said, under the heading "The 180-day exclusivity period": "This provision does not apply to 505(b)(2) applications." 54 Fed. Reg. 28872, 28894 (July 10, 1989). Any change to apply the exclusivity period beyond ANDAs would, therefore, require notice and comment rulemaking, and is likely to be opposed by industry members who have relied on the present FDA interpretation for 14 years.

As further evidence of Congress' intent and FDA's interpretation, the statutes and regulations also are clear that 505(b)(2) NDAs *are* subject to the patent certification provisions and five-year and three-year exclusivity provisions of the FDC Act. 21 U.S.C. § 355(b)(2)(A), (b)(3), (c)(3); 21 C.F.R. § 314.107(d) ("The agency will also delay the effective date of the approval of an abbreviated new drug application under section 505(j) of the act or a 505(b)(2) application if delay is required by the exclusivity provisions in § 314.108."); § 314.108. Had they intended to subject 505(b)(2) NDAs to the 180-day exclusivity provisions, then, they obviously could have done so, but refrained.

There is simply no justification for TorPharm's claim that a 505(b)(2) should be subject to the FDC Act's 180-day exclusivity provisions.

2. Synthon's NDA Was Ineligible For Submission As An ANDA

Fearing the above-noted conclusion, TorPharm conjures up a "novel" theory that Synthon's NDA "should" have been filed as an ANDA pursuant to the suitability petition process. If that had been the approval avenue, TorPharm alleges that the 180-day provision would apply and TorPharm's exclusivity would have blocked FDA's approval of Synthon's NDA. Again, this series of speculative "if/then" propositions misses the mark.

The fact is, Synthon's paroxetine mesylate drug product was not eligible for filing as an ANDA, nor via the suitability petition process. In order to be filed as an ANDA, the drug product's active ingredient would have to be the "same" as the RLD. 21 U.S.C. § 355(j)(2)(A)(ii); 21 C.F.R. § 314.94(a)(5)(i). In this case, Synthon's product is formulated with a different salt of the paroxetine base chemical, i.e., mesylate instead of hydrochloride hemihydrate. Pursuant to well-settled agency policy, different salts cannot support the sameness condition required by 505(j). Rather, FDA "considers a salt or ester of an active ingredient to be a *different active ingredient*." 54 Fed. Reg. at 28878 (emphasis added); *see also* 54 Fed. Reg. at 28881. For ANDA purposes, therefore, Synthon's mesylate active ingredient is not the same as Paxil's hydrochloride hemihydrate active ingredient or TorPharm's hydrochloride active ingredient, and Synthon's drug product could not be submitted under Section 505(j) of the FDC Act.

Similarly, the suitability petition process is limited to product changes from the RLD that involve the strength, dosage form, route of administration, or combination of active ingredients. 21 U.S.C. § 355(j)(2)(C); 21 C.F.R. § 314.93(b), (e)(1)(ii). An applicant is not permitted to petition for any other kinds of changes from an RLD. 54 Fed. Reg. at 28878, citing H. Rept. 98-857, Part 1, 98th Cong., 2d Sess. at 23 (1984). In fact, FDA has specifically determined that "an applicant may not petition to submit an ANDA for a different active ingredient in a single active ingredient drug product." *Id.* Again, FDA has said that a change in salt form of an active ingredient in a single ingredient product is not the type of change from the RLD that may be accomplished via a suitability petition. *Id.* (FDA "will not approve petitions that seek permission to submit an ANDA for a drug product which substitutes a different salt or ester of an active ingredient from that of a listed drug"). *See, e.g.*, Docket No. 85P-0258, FDA Letter to Apkon Labs denying a suitability petition for a new ester for benzoyl metronidazole suspension, dated March 19, 1986; Docket No. 89P-0103, FDA Letter to Burroughs Wellcome for a new salt for allopurinol sodium injection, dated July 14, 1989. Moreover, in 1992, FDA considered – and rejected – TorPharm's theory that a 505(b)(2) NDA be treated as an ANDA when a suitability petition may have been possible. 57 Fed. Reg. 17950, 17952 (April 28, 1992). Instead, FDA agreed with industry that "the policies and procedures for 505(b)(2) applications are or should be distinct from those for suitability petitions." *Id.*

Even if the suitability petition avenue had been open to Synthon, TorPharm's 180-day exclusivity still would not have blocked the imaginary Synthon ANDA, since it was not "a generic copy of the same listed drug" as required by FDA's regulation. *See* 21 C.F.R. § 314.107(c). As explained in Section B.1. above, Synthon's NDA is for a different active ingredient – paroxetine mesylate – thus, it would not be a generic copy of the listed drug but, rather, an allowed ANDA for a different drug product. Since 180-day exclusivity only blocks "any subsequent ANDA's for the same drug product", the exclusivity would not bar the approval of an ANDA for a different drug product that had been authorized via a suitability petition. 54 Fed. Reg. at 28894. For example, when FDA approves a suitability petition, it recognizes that the new drug product is not the same as the reference listed drug by refusing to provide an AB-rating denoting equivalence and substitutability. *See* Docket No. 01P-0125 (August 2, 2001 approval of suitability petition for 100 mg amiodarone hydrochloride tablets, where that strength is not AB-rated to Eon's 400 mg tablet); Docket No. 01P-0379 (December 17, 2001 approval of suitability petition for 75 mg and 100 mg azathioprine tablets, where those strengths are not AB-rated to AAI Pharma's 50 mg tablet). Consequently, even if TorPharm's fictional "what if" scenarios are correct (which they are not), FDA would not be barred from approving Synthon's NDA.

Finally, on this point, FDA already dismissed TorPharm's argument when it accepted Synthon's NDA for filing. Specifically, upon the filing of Synthon's NDA, the Agency as a routine matter considered whether the ANDA (and suitability petition) filing route was available to Synthon. *See* FDA Draft Guidance for Industry: Applications Covered by Section 505(b)(2) (1999).[4] FDA's answer was "no."

3. TorPharm's Exclusivity Is Not Guaranteed, Nor Absolute

TorPharm's Petition stems from its misguided notion of what 180-day exclusivity represents. TorPharm's assertions imply that it is a "right" to which TorPharm is entitled. Further revealing its mistake, TorPharm implies that, as the first to file an ANDA with a Paragraph IV certification, the firm should enjoy an exclusive right to market a drug product with a paroxetine-based chemical that will compete with Paxil. In direct contrast to this theory, FDA has explained repeatedly that the statutory scheme creating market exclusivity does not "grant" a period of market exclusivity, nor does it entitle any one applicant to be the sole competitor to the RLD.

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[4] FDA has provided examples of applications that may be accepted pursuant to section 505(b)(2) of the FDC Act, including an "application for a change in an active ingredient such as a different salt, ester, complex, chelate, clathrate, racemate, or enantiomer of an active ingredient in a listed drug containing the same active moiety." FDA Draft Guidance for Industry: Applications Covered by Section 505(b)(2) (1999).

Instead, exclusivity delays the effective date of approval of certain later-filed applications. 54 Fed. Reg. at 28896. In addition, full NDAs can always be filed under Section 505(b)(1) of the Act, even for generic versions of the drug. *Id.* ("The exclusivity provisions of the act do not provide any protection from the marketing of a generic version of the same drug product if the generic version is the subject of a full new drug application submitted under section 505(b)(1) of the Act."). Similarly, as in this case, the NDA holder can license its product to an "authorized" generic distributor, with whom any 180-day-exclusivity "winner" will have to compete.

FDA applied these market exclusivity concepts to 180-day exclusivity as well – notably, in letters to TorPharm and its parent company. Specifically, FDA explained that "the exclusivity [scheme] is already structured in such a way that eligibility for exclusivity does not guarantee 180 days as the sole marketed generic drug." FDA Letter to ANDA Applicant for Gabapentin from Gary Buehler, dated January 28, 2003 (explaining that Torpharm's 180-day exclusivity was lost to Purepac's successful defense of its section viii statement). FDA goes on to explain that "the court decision trigger could start exclusivity before an ANDA is approved, or uncertainty over the patent could result in no marketing of an approved product until an affirmance in the Federal Circuit of a district court win." *Id.* Likewise, "when approval of an ANDA eligible for exclusivity is blocked by another applicant's eligibility for exclusivity, the applicants that are eligible for the 180-day period of generic drug exclusivity may share the same exclusivity period." *Id.*; *see also*, FDA Letter to Apotex Corporation (TorPharm parent) from Gary Buehler dated July 30, 2003 (confirming shared exclusivity for ANDA Sponsors of paroxetine hydrochloride tablets).

Given the above, TorPharm is well aware that "there is no guarantee in the statute that, even in such compelling circumstances, an ANDA applicant will benefit from exclusivity. The value of exclusivity appears to be a function of timing, strategy, and luck." *Id.* As such, its argument here is not only incorrect, but suspect, and there is no support for its claims of "irreparable loss" and "immediate harm".

C. TorPharm's Attack On FDA's Implementation Of Section 505(b)(2) Of The FDC Act Is Unfounded

As TorPharm notes, numerous public comments have been filed to counter the argument posed originally by Pfizer Inc. that Section 505(b)(2) of the FDC Act provides FDA with only limited authority to approve NDAs filed under that statutory provision. Rather than re-describe the legislative history, statutory provisions, FDA notice-and-comment rulemaking, and FDA policy statements that support the present implementation of 505(b)(2) NDAs, Synthon references those previously-filed public comments. *See, e.g.*, Docket No. 99D-4809, Comments filed by Gary L. Yingling dated September 19, 2000, in response to FDA's "Draft Guidance for Industry on Applications Covered by Section 505(b)(2)"; Docket No. 01P-0323, Comments filed by the

Generic Pharmaceutical Association dated December 10, 2001, in response to Pfizer's Citizen Petition (Synthon is a member company of this trade organization). In summary, Pfizer's (and TorPharm's) argument flies in the face of the plain reading of the statute, 15 years of reasonable interpretation by FDA without industry opposition, and acquiescence to FDA's interpretation by Congress via the passage of later amendments to the FDC Act. As such, the argument should be dismissed and the TorPharm Petition denied.

D. TorPharm's Petition Is A Baseless Attack On FDA's Scientific Discretion In Approving Synthon's NDA

TorPharm repeats several times its false allegation that Synthon did not conduct clinical trials to establish the safety and effectiveness of the paroxetine mesylate drug product. As this allegation is blatantly untrue, we can only surmise that TorPharm is trying to "scare" the public with unfounded claims in hopes of increasing its market share for paroxetine hydrochloride. Moreover, the pharmaceutical industry as a whole is well aware that the clinical studies and supporting safety and efficacy data contained in an NDA are confidential and proprietary information.[5] Synthon will not be baited by TorPharm into publishing its proprietary data in this public forum. Suffice it to say that Synthon's NDA contained all of the information required by FDA under the regulations that implement Section 505(b)(2) of the FDC Act. Moreover, given the fact that Synthon's paroxetine mesylate product provides the same active moiety at the same blood levels as Paxil, Synthon's references to the history of known safety and efficacy data for paroxetine hydrochloride were scientifically appropriate and regulatorily required, in order to provide FDA with a complete picture of nonclinical pharmacology and toxicology, human pharmacokinetics and bioavailability, and clinical safety and efficacy profiles for the new drug. 21 C.F.R. § 314.50.

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[5] In fact, FDA is required to treat much of the documentation submitted in an NDA as confidential material that is exempt from public disclosure under FDA's regulations and the Freedom of Information Act ("FOIA"). 21 C.F.R. §§ 314.430(e). After approval of an NDA, the information properly available for public disclosure includes a Summary Basis of Approval (now, called a Drug Approval Package) summarizing the safety and effectiveness data. 21 C.F.R. § 314.430(e). The Summary Basis of Approval includes only a summary of the data contained in the NDA. *Id.* More specific information may be disclosed only if it does not fall within the disclosure exemption for trade secrets and confidential commercial information. *Id.* FDA broadly defines "trade secret" materials to include, in part, any commercially valuable plan or process used for the making, preparing or processing of trade commodities, and said to be the end product of either innovation or substantial effort. 21 C.F.R. § 20.61(a). Similarly, privileged "commercial or financial information" includes valuable data used in one's business of a type customarily held in strict confidence. 21 C.F.R. § 20.61(b). The specific information contained in Synthon's NDA clearly fall within this definition. Any materials in these categories are privileged and confidential and not available for public disclosure. 21 C.F.R. § 20.61(c).

The fact that Synthon's NDA contained all of the required information is proved by the ultimate arbiter of NDA requirements – FDA. FDA reviewed Synthon's data throughout the investigational new drug application process and the NDA review process, and determined that the NDA met the Act's requirements and the drug product should be approved for use as an antidepressant. As TorPharm knows, FDA is due special deference with respect to such science-based decisions within its particular expertise.[6] In the case of Pexeva, FDA used its particular expertise and judged the scientific data presented by Synthon – and ultimately approved the NDA. TorPharm has provided no scientifically-based theory to question FDA's approval, and no substantive reason why FDA should reverse itself and withdraw the Pexeva NDA.

E. FDA Cannot Withdraw An Approved NDA Without Providing Notice And An Opportunity For A Hearing To The NDA Sponsor

As noted above, TorPharm requests that FDA immediately withdraw the approval of Synthon's 505(b)(2) NDA for paroxetine mesylate, to stop the distribution and marketing of the product during TorPharm's 180-day exclusivity. It is unlawful, however, for FDA to use the Citizen Petition process to remove from the marketplace a product that is the subject of an approved NDA. The FDC Act, the Administrative Procedures Act ("APA") and the Due Process Clause of the U.S. Constitution obligate the agency to provide proper notice and an opportunity for a hearing prior to withdrawing or revoking an NDA. FDA's response to a Citizen Petition is not an available vehicle to bypass these protections.

Instead, FDA must adhere to the procedures and standards outlined in Section 505(e) of the FDC Act. Specifically, to reverse course with respect to the Pexeva NDA approval, FDA must

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[6] *See Troy Corp. v. Browner*, Nos. 96-5203, 96-5204 and 96-5188, 1997 WL 428500, at *5 (D.C. Cir. Aug. 1, 1997) (where an agency's decision "rests on an evaluation of complex scientific data within the agency's technical expertise," it is entitled to "considerable deference"); *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir.), *cert. denied*, 116 S. Ct. 274 (1995); *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995) (the court noted the "high level of deference" due "an agency's evaluations of scientific data within its area of expertise"); *Berlex Labs., Inc. v. FDA*, 942 F. Supp. 19, 25 (D.D.C. 1996) ("FDA's policies and its interpretation of its own regulations will be paid special deference because of the breadth of Congress' delegation of authority to FDA and because of FDA's scientific expertise"); *see also Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653-54 (1973) ("in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over.").

provide a reasoned analysis based on the relevant safety and efficacy data.[7] Section 505(e) unambiguously specifies the process that FDA must follow and the underlying findings that it must make before deciding to withdraw its approval of an NDA. The agency must satisfy two prerequisites. First, it must provide "due notice" to the applicant of the proposed action, including an explanation of its basis.[8] Second, FDA must make specific substantive findings supported by substantial evidence. Specifically, a withdrawal decision must be based on: (1) data demonstrating that the drug is unsafe under the approved conditions of use; (2) new data that was not available at the time of the application's approval, evaluated with the information that was available at the time of approval, revealing that the drug is unsafe under the approved conditions of use; or (3) new information, evaluated in conjunction with what was available at the time of approval, showing that there is insufficient evidence that the drug will have the effect claimed in the labeling.[9] TorPharm has failed to provide even a shred of scientific or other evidence as to any of these bases to support its claim that FDA should withdraw Synthon's NDA for paroxetine mesylate. As described above, TorPharm relies on mere administrative procedural issues and an alleged FDA misinterpretation of law. Because these issues are not a proper basis for NDA withdrawal and FDA is not permitted to ignore "the unambiguous command of a statute",[10] Synthon's product may be marketed and distributed lawfully under Section 505(a) unless and until the agency presents a basis to withdraw the NDA in accordance with Section 505(e).

In addition to the FDC Act requirements of Section 505(e), FDA is obligated under the APA and the Due Process Clause to provide notice and the opportunity for a hearing prior to the withdrawal or revocation of a license. 5 U.S.C. § 558(c). In particular, a party that may be subject to agency action is entitled to knowledge of both: (1) the issues upon which the agency's decision will be based; and (2) the facts and evidence on which the agency is relying to justify its proposed action so that the party can provide a rebuttal.[11] The granting of a third party's Citizen

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[7] *See Motor Vehicle Mfrs Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29 (1983); *see also Pearson v. Shalala*, 164 F.3d 650, 660 (D.C. Cir. 1999).

[8] *See* FDCA § 505(e); 21 C.F.R. § 314.200(a); *Brandenfels v. Heckler*, 716 F.2d 553, 555 (9th Cir. 1983).

[9] *See* 21 U.S.C. § 355(e); *see also Warner-Lambert Co. v. Heckler*, 787 F.2d 147, 151 (3d Cir. 1986).

[10] *TorPharm Inc. v. Shalala*, 1997 U.S. Dist. LEXIS 21983 (D.D.C. Sept. 15, 1997).

[11] *See Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 288 n.4 (1974); *Goldberg v. Kelly*, 397 U.S. 254, 264-70 (1970); *Hess & Clark v. FDA*, 495 F.2d 975, 983 (D.C. Cir. 1974).

Petition does not afford these rights to the NDA Sponsor.[12] Thus, withdrawal of an NDA pursuant to a Citizen Petition request denies the rights afforded under the APA and the Due Process clause and is unlawful.

F. Conclusion

For the foregoing reasons, FDA should deny the TorPharm Citizen Petition.

Sincerely,

Gary L. Yingling

Cc: Daniel Troy, FDA Office of Chief Counsel

[12] *See* 21 C.F.R. §§ 10.30(e), (h) (Citizen Petition procedures provide no notice requirement and afford FDA sole discretion to decide whether the applicant receives an opportunity for a hearing); *compare also* 21 C.F.R. § 10.30(b) *with* 21 U.S.C. § 355(e) (a withdrawal under Section 505(e) must be based only on the applicable statutory criteria, whereas petitioners in a Citizen Petition may set forth any basis for the requested action). A regulation cannot grant an agency any greater authority than it has under a statute. *Ass'n Am. Physicians & Surgeons v. FDA*, 226 F. Supp. 204, 216 n.17 (D.D.C. 2002) (citing *Office of Consumers' Counsel v. FERC*, 655 F.2d 1132, 1149 n.32 (D.C. Cir. 1980)).