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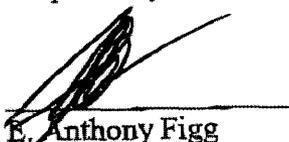
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Mr. Lyle Jaffe  
Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1061  
5630 Fishers Lane  
Rockville, Maryland 20852

Dear Mr. Jaffe,

In response to our telephone conversation of November 21, 2001, I enclose a statement claiming categorical exclusion from making an environmental impact statement under 21 C.F.R. § 25.31 (2000). Also enclosed is an Index to Exhibits A-E cited in the Citizen Petition. Please do not hesitate to call if you have further questions.

Respectfully submitted,



E. Anthony Figg  
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Enclosures  
LMZ:tbm

OIP-0529

CPI

**CITIZEN PETITION**

**C. Environmental Impact Statement**

Mylan Pharmaceuticals, Inc. claims categorical exclusion under 21 C.F.R. § 25.31 (2000).

As a result, an environmental impact statement is not necessary.

**Index of Exhibits to Mylan Pharmaceuticals Citizens Petition**

<b>Exhibit</b>	<b>Description</b>
<b>A</b>	<u>Mylan Pharmaceuticals v. Thompson</u> , 139 F. Supp.2d 1 (D.D.C. 2001)
<b>B</b>	<u>Mylan Pharmaceuticals, Inc. v. Thompson</u> , 2001 U.S. App. LEXIS 2178 (Fed. Circuit 2001)
<b>C</b>	Hearing Transcript: 10/30/2001 - In re: Buspirone Patent Litigation
<b>D</b>	Joint Motion of Watson and Mylan for Summary Judgment of Noninfringement or, in the Alternative, Invalidity of U.S. Patent No. 6,150,365 (Filed 11/07/01, U.S. District Court - Southern District N.Y.) w/ Exhibits A - F ( <i>please note Exhibit B has sub-sections B1 - B21 &amp; B21A - B21F, which is the patent prosecution history</i> )
<b>E</b>	Appeal from the United States District Court for the District of Columbia in 00-CV-2876, Judge Richard M. Urbina (Filed in re: Mylan Pharmaceuticals, Inc. v. Thompson v. Bristol-Myers Squibb Co., U.S. Court of Appeals - Federal Circuit)

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November 20, 2001

**VIA FEDERAL EXPRESS**

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**CITIZEN PETITION**  
**EXPEDITED DECISION REQUESTED**

The undersigned, on behalf of Mylan Pharmaceuticals, Inc. (hereinafter "Mylan"), submits this petition under 21 U.S.C. §355(j)(5)(B) and 21 C.F.R. §§10.25(a), 10.30 and 314.43 to request the Commissioner of Food and Drugs (hereinafter, the "Commissioner") to expedite review of this petition and pursuant to the exercise of his discretion, determine that the United States Food and Drug Administration ("FDA") will not re-list U.S. Patent No. 6,150,365 (the "'365 patent") in the Orange Book unless and until there has been a judicial adjudication either that such patent was properly listed in the Orange Book or that such a patent claims the product

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which is the subject of Mylan's Abbreviated New Drug Application ("ANDA") Nos. 75-272 and 76-008 (Mylan's "Buspirone Product").

The basis of this petition, as discussed in more detail below, is that there has already been a judicial adjudication that the '365 patent was improperly listed because: (a) the '365 patent does not claim methods of administering buspirone at all; and (b) even if the single claim of the '365 patent could be construed to cover some method of administering buspirone, that claim is not (and could not be) properly construed to claim the administration of buspirone according to the methods of use approved by the FDA. Mylan Pharms. v. Thompson, 139 F. Supp. 2d 1, 22-26 (D.D.C. 2001), rev'd on other grounds, No. 01-1257, 2001 U.S. App. LEXIS 21768 (Fed. Cir. Oct. 12, 2001). (Copies of the District Court and Court of Appeals decisions are annexed hereto as Exhibits A and B, respectively.) Although the United States Court of Appeals for the Federal Circuit reversed the District Court's decision in Mylan Pharms. v. Thompson on procedural grounds, it expressly declined to address the underlying merits of the case, leaving the District Court's claim construction undisturbed. Thus, the only judicial decision that has been rendered with respect to the '365 patent has expressly and unequivocally held that the '365 patent does not meet the statutory requirements for listing in the Orange Book.

Pursuant to Fed.R.App.P. 40, Mylan will shortly be filing a Petition for Rehearing and Suggestion for Rehearing *en banc*. If this petition is denied, the mandate of the Court of Appeals for the Federal Circuit (the "Mandate") could issue as early as December 3, 2001. Mylan

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expects that once that mandate issues, Bristol will request that the FDA re-list the '365 patent in the Orange Book and withdraw its approval of Mylan's ANDAs.<sup>1</sup>

In a patent infringement action brought by Bristol against Mylan in the United States District Court for the Southern District of New York (the "New York Action"), Mylan has filed a motion for summary judgment that its Buspirone Product does not infringe the '365 patent. Resolution of this motion in Mylan's favor would be relevant to the issue of re-listing and the status of Mylan's ANDA in two respects. First, if the District Court in the New York Action grants Mylan's motion for summary judgment that the Mylan product does not infringe the '365 patent, then there would be no basis for withdrawing the approval of Mylan's ANDAs since that ruling would constitute a "court decision" that the '365 patent is not infringed. See 21 U.S.C. § 355(j)(5)(B)(I). Second, if the District Court in the New York Action determines that the Mylan Buspirone Product does not infringe the '365 patent, that decision would necessarily establish (confirming the existing decision of the District Court in Mylan Pharms. v. Thompson), that the '365 patent does not meet the requirements for listing set forth in 21 U.S.C. § 355(c)(2). See Hoechst-Roussel Pharms. v. Lehman, 109 F.3d 756 (Fed. Cir. 1997).

When Mylan filed its motion for summary judgment in the New York Action, it asked that that motion be resolved on an expedited basis in light of the possibility that the Mandate

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<sup>1</sup> In a related judicial proceeding, when Judge Koeltl of the United States District Court for the Southern District of New York asked Bristol whether it intended to follow such a procedure, Bristol advised the Court that it was unwilling to represent that it would not seek re-listing of the '365 patent. See Exhibit C at 33.

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might issue as early as the first week of December. Over the opposition of Bristol, Judge Koeltl established the briefing schedule proposed by Mylan, observing that "there is a public interest involved, which is present there for me, in terms of deciding a motion that Mylan and Watson want to make now." Exhibit C at 34, 37-38.

It is therefore very likely that within three weeks, there will be an additional judicial decision construing the '365 patent and determining the legal issues that underlie the impropriety, vel non, of the listing of that patent in the Orange Book.<sup>2</sup>

Mylan therefore respectfully submits that under the FDA's long-standing policy of deferring to judicial adjudications regarding the scope of patents in the context of cases regarding the propriety of the listing of such patents, the FDA should rely upon the decision of the District Court in Mylan Pharms. v. Thompson in declining to re-list the '365 patent. At a minimum, the FDA should await the further decision of the United States District Court for the Southern District of New York on Mylan's already-filed motion for summary judgment of non-infringement.

As discussed below in Section II, there is an alternative basis upon which the FDA should determine not to re-list the '365 patent. In light of the decision of the United States Court of Appeals for the Federal Circuit in Mylan Pharms. v. Thompson that procedurally one may not challenge the listing of the patent in the Orange Book by bringing an action for declaratory

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<sup>2</sup> A complete copy of Mylan's motion papers is submitted herewith as Exhibit D.

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judgment against the entity listing the patent (except as a counterclaim in a Hatch-Waxman patent infringement litigation), the FDA's current policy of refusing to exercise its own judgment regarding whether a patent is properly listed is, as a matter of law, arbitrary and capricious and a violation of the Administrative Procedures Act. As discussed more fully below, in light of the ruling of the Court of Appeals in Mylan Pharms. v. Thompson, the FDA must independently examine the '365 patent in order to determine whether it is properly listed (or in this case, re-listed) in the Orange Book. In performing this analysis, the FDA is, of course, free to rely upon the only court decision which has construed the single claim of the '365 patent – that is, the decision of the District Court in Mylan Pharms. v. Thompson.

For each of these two independent reasons, Mylan respectfully requests that the Commissioner determine that the '365 patent should not be re-listed in the Orange Book and that it make this decision on an expedited basis in light of the possibility that the mandate may issue as early as the first week in December.

**BACKGROUND**<sup>3</sup>

Bristol Myers Squibb (hereinafter "Bristol") received U.S. Patent 4,172,763 (hereinafter "the '763 patent") covering the administration of buspirone to treat anxiety disorders in 1980 and obtained FDA approval of BuSpar® in 1986. Bristol received a two-year extension to its 17-

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<sup>3</sup> A more complete explanation of the facts which form the background of this petition may be found in the District Court's decision in Mylan Pharms. v. Thompson, 139 F. Supp. 2d at 3-11 (Ex. A), to which the Commissioner is respectfully referred.

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year patent term to compensate for delays in regulatory approval of BuSpar®. Bristol further extended its exclusivity rights with respect to buspirone for an additional six months under the pediatric exclusivity provisions of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §355 (a). Bristol's term of exclusivity was set to expire at 11:59 p.m. on November 21, 2000. Between 1986 and November 21, 2000, Bristol sold BuSpar® in the United States without any generic competition.

Mylan filed ANDA Nos. 75-272 and 76-008 with the FDA seeking permission to market buspirone hydrochloride tablets bioequivalent to BuSpar®. Mylan's ANDA's contained a Paragraph III certification stating that it would not market its Buspirone Product until the expiration of Bristol's '763 patent. The FDA tentatively approved Mylan's ANDA No. 75-272, with final approval for its 30 mg Buspirone Product contingent only upon the expiration of Bristol's '763 patent-based exclusivity on November 22, 2000.

On November 21, 2000 -- only 12 hours prior to Bristol's exclusivity was set to expire -- Bristol submitted that patent to the FDA for listing in the Orange Book. In its submission, Bristol advised the FDA that the '365 patent "is a method of use patent covering, among other things, a method of using BuSpar for all of its approved indications," and requested that the '365 patent be immediately listed in the Orange Book. The FDA listed the '365 patent in the Orange Book on November 21, 2000. Because of this listing, the FDA did not grant final approval to Mylan's ANDA No. 75-272.

Within days, Mylan moved in the United States District Court for the District of

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Columbia for a preliminary injunction requiring Bristol to request that the FDA de-list the '365 patent from the Orange Book. On March 14, 2001, Judge Urbina granted Mylan's motion for preliminary injunction and ordered Bristol to request the FDA to de-list the '365 patent from the Orange Book.

In his decision, Judge Urbina carefully and comprehensively reviewed the prosecution history of the '365 patent and held that "the '365 patent does not 'claim' a method of using BuSpar®." 139 F. Supp. 2d at 19. Specifically, the District Court found:

As Mylan correctly points out ... the prosecution history of the '365 patent shows that: (1) Bristol tried to claim the administration of buspirone as a prodrug; (2) the PTO would not allow it; and (3) Bristol surrendered that subject matter.

Mylan Pharms., 139 F. Supp. 2d at 21. Given this finding, the District Court held that under the decision of the United States Court of Appeals for the Federal Circuit in Hoechst, 109 F.3d 756, since the '365 patent "cannot claim the administration of buspirone", it did not satisfy the first statutory requirement under 21 U.S.C. §355(c)(2) (the patent must "claim the drug" or "a method of using" the drug) for listing in the Orange Book. Id.

The District Court also analyzed the '365 patent in order to ascertain whether it met the second statutory pre-requisite to Orange Book listing under 21 U.S.C. §355(c)(2): that is, that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the [approved] drug." Id. The District Court found that this statutory pre-requisite for listing in the Orange Book was not met for two reasons.

First, as discussed above, the District Court found that Bristol had "surrendered the claim

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coverage of the administration of buspirone during the prosecution of the '365 patent." Id. at 24-26. Thus, the patent did not cover the administration of buspirone at all.

Second, the District Court carefully examined the '365 patent itself and determined, as an alternative holding, that even if the '365 patent could be construed to claim the administration of buspirone, it "expressly disclaims coverage of the administration of buspirone in the manner currently approved." Id. at 22-24.<sup>4</sup>

The District Court noted, for example, that the specification of the '365 patent states in three different places that the patent does not cover currently-approved methods of using buspirone, stating that the claimed invention

- "improves upon and differs from the known standard method of oral administration of buspirone";
- "is in contradiction to currently-accepted methods of administration";
- "is directly counter to the past method of orally administering buspirone."

Mylan Pharms., 139 F. Supp. 2d at 23 (citing '365 patent, col. 12, lines 3-8, 17-18 and 58-59).

Bristol subsequently appealed the District Court decision to the Federal Circuit. On October 12, 2001, the Federal Circuit reversed on procedural grounds, holding that Mylan's declaratory judgment action to de-list the patent was not permitted under the patent laws or the Hatch-Waxman Act. See Mylan Pharms., Inc. v. Thompson, No. 01-1257, 2001 U.S. App.

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<sup>4</sup> The FDA's longstanding interpretation of 21 U.S.C. §355(c)(2) is that in order to be listed in the Orange Book "a method-of-use patent must claim an approved method of using the approved drug." See Exhibit E at 9-10. Mylan Pharms., 139 F. Supp. 2d at 23 n.15.

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LEXIS 21768 (Fed. Cir. Oct. 12, 2001) (Exhibit B).

In its ruling, the Federal Circuit did not address the propriety of Bristol's listing of the '365 patent and did not disturb in any way the District Court's claim construction analysis. The reversal of the District Court's ruling was solely on procedural grounds wholly unrelated to the District Court's construction of the '365 patent and its analysis regarding the appropriateness of that patent for listing in the Orange Book.<sup>5</sup>

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<sup>5</sup> A decision which is reversed on other grounds is still of precedential value as to those issues that were not the subject of the reversal. See Durning v. Citibank, N.A., 950 F.2d 1419, 1424 n.2 (contrasting a decision which is reversed on other grounds from one which has been vacated, and thus has no precedential value). Indeed, in a different context, the United States Supreme Court has observed that even when there has been a determination on appeal that there was an absence of subject matter jurisdiction of a case in the federal court,

"such a determination does not automatically wipe out all proceedings had in the district court at a time when the district court operated under the misapprehension that it had jurisdiction." In Chicot County Drainage Dist. v. Baxter State Bank, 308 U.S. 371, 60 S. Ct. 317, 84 L. Ed. 329 (1940), we held that a judgment rendered in a case in which it was ultimately concluded that the District Court was without jurisdiction was nonetheless *res judicata* on collateral attack made by one of the parties.

Willy v. Coastal Corp., 503 U.S. 131, 137 (1992).

Indeed, courts throughout the United States routinely treat decisions which have been reversed on other grounds as providing precedential support. See, e.g., Tanabe Seiyaku Co. v. United States ITC, 109 F.3d 726, 731 (Fed. Cir. 1997) ("Whether a product or process infringes the properly construed claims of a patent, literally or under the doctrine of equivalents, is a question of fact. Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1520, 35 U.S.P.Q.2d (BNA) 1641, 1647 (Fed. Cir. 1995) (*in banc*), *rev'd on other grounds*, 137 L. Ed. 2d 146, 117 S. Ct. 1040, 1997 WL 84999 (U.S. 1997)."); Lawson v. Kolender, 658 F.2d 1362 (9th Cir. 1981); Gonsalves v. Amoco Shipping Co., 733 F.2d 1020 (2d. Cir. 1984); Keller v. Merit Sys. Prot. Bd., 679 F.2d 220 (11th Cir. 1982); V-1 Oil Co. v. Wyoming, Dep't. Of Envtl. Quality, 902 F.2d 1482 (10th Cir. 1990); Beatrice Foods Co. v. U.S., 312 F.2d 29 (8th Cir.

(continued...)

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As previously indicated, Bristol has pending against Mylan and another ANDA holder (Watson Pharmaceuticals, Inc.) an action for infringement of the '365 patent. In that case (in which the suits against Mylan and Watson have been consolidated), Mylan has moved for summary judgment of non-infringement. Bristol's opposition to Mylan's motion is due on November 19, 2001, with reply papers due on November 26, 2001. The Judge handling the case, Judge Koeltl, directed (over Bristol's objections) that briefing take place under this schedule and specifically recognized the public interest in Mylan's summary judgment motion being resolved quickly. See Exhibit C at 33. Should the District Court in that action grant Mylan's motion for summary judgment of noninfringement, Mylan intends to then ask that Court promptly to issue an order requiring Bristol to refrain from re-listing the '365 patent in the Orange Book since such relief has been specifically recognized as appropriate by the Federal Circuit in its recent ruling in Mylan Pharms., Inc. v. Thompson, 2001 U.S. App. LEXIS 21768, at \*27 ("as part of its inherent power to give effect to a judgment, a Court may order the delisting of a patent in a context of a properly filed patent infringement suit").

**A. Action Requested**

This petition requests that the Commissioner rule, no later than December 3, 2001, that the FDA should exercise its discretion to not re-list the '365 patent in the Orange Book pursuant to 21 U.S.C. §§355(b) and (j) of the FFDCA in the event that the Mandate issues and Bristol

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<sup>5</sup>(...continued)

1963); John S. Doane Co. v. Martin, 164 F.2d 537 (1st Cir. 1947); Horne v. Owens-Corning Fiberglass Corp., 4 F.3d 276 (4th Cir. 1993).

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requests such re-listing.

**B. Statement of Grounds**

1. Since the only court decision construing the single claim of the '365 patent has held that the '365 patent covers neither the administration of buspirone nor any currently approved methods of using buspirone, and given that under this claim construction the '365 patent meets neither of the two statutory pre-requisites of 21 U.S.C. §355(c)(2) for listing a patent in the Orange Book, the FDA should rely on that ruling and refuse to re-list the '365 patent in the Orange Book.

2. In the alternative, in light of the ruling of the Court of Appeals in Mylan Pharms., Inc. v. Thompson, the FDA must independently evaluate the '365 patent to determine whether it is properly listable in the Orange Book. Failure to undertake such an analysis would be arbitrary and capricious and a violation of the APA. In undertaking this evaluation, the FDA is free to refer to (and defer to) the conclusions of the District Court in Mylan Pharms. v. Thompson.

**ARGUMENT**

**I.**

**BECAUSE THE FDA HAS CONSISTENTLY VIEWED ITS ROLE IN THE PATENT LISTING PROCESS AS ONE OF DEFERRING TO COURT DECISIONS, THE FDA, USING ITS DISCRETION, SHOULD REFUSE TO RE-LIST THE '365 PATENT IN THE ORANGE BOOK BASED ON THE DISTRICT COURT DECISION IN MYLAN V. THOMPSON**

The FDA has long taken the position that in deciding whether to publish patent information in the Orange Book, it will await the outcome of patent litigation. See Watson

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Pharms. v. Henney, No. S 00-3516, 2001 U.S. Dist. LEXIS 2477, at \*1 (D. Md. Jan. 18, 2001).

Moreover, the initial listing of the FDA of a patent in the Orange Book does not create any presumption that the patent was correctly listed. Id. Indeed, at least one court has explicitly recognized that the FDA's Orange Book listing, as it is not based (by statute, regulation, or practice) on any substantive evaluation of the patent, for which the FDA lacks the necessary expertise in the first place, is a matter to be settled in private litigation between the parties, not as part of an agency adjudication. Id. at \*3.

As discussed above, there has been a judicial adjudication of the proper construction of the '365 patent. The FDA is entitled to rely on that construction in refusing to re-list the patent.

## II.

### **IN THE ALTERNATIVE, THE FDA SHOULD EXERCISE ITS DISCRETION AND INDEPENDENTLY DETERMINE THAT THE '365 PATENT SHOULD NOT BE RE-LISTED**

"[A]gency action, findings, and conclusions -- including denial of citizen petitions -- are held to the 'arbitrary and capricious' standard." Henley v. FDA, 873 F. Supp. 776 (E.D.N.Y. 1995). The Federal Circuit held in Mylan Pharms., Inc. v. Thompson, 2001 U.S. App. LEXIS 21768 at \*2, that a declaratory relief action to delist against Bristol was not available to Mylan under the patent laws. If no court is competent to question whether Bristol properly submitted its patent for listing until the 45 day waiting period passes and Bristol then brings a patent infringement suit, then the FDA's current policy of refusing to exercise such judgment would, as a matter of law, be arbitrary and capricious and thus a violation of the APA. See Motor Vehicle

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Mfrs. Assoc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 44, (1983) (holding that an "agency's rule is arbitrary and capricious [under the APA] if the agency ... entirely failed to consider an important aspect of the problem").

Here, if the FDA refuses to make a determination as to whether the '365 patent is properly listed in the Orange Book, the FDA would be abdicating the authority that Congress has vested in it.

It would be particularly inappropriate for the FDA to refuse to evaluate the impropriety of re-listing the patent in the Orange Book since, in the past, the FDA has exercised its discretion to evaluate independently whether a patent should be listed in the Orange Book. For example, in Pfizer, Inc. v. Food & Drug Admin., 753 F. Supp. 171 (D. Md. 1990), the FDA refused to list a patent that claimed a tablet formulation of the drug nifedipine where the approved NDA was for a soft gelatin capsule. In denying Pfizer's petition, the FDA relied on its interpretation of the patent filing provisions in 21 U.S.C. §355 (b)(1) and (c)(2), which require information to be filed only on patents "which claim[] the drug for which the applicant submitted the application." Id. at 174.

In conducting its independent evaluation, the FDA is, of course, free to refer to (and even to defer to) the ruling of the District Court in Mylan Pharms. v. Thompson construing the '365 patent.<sup>6</sup>

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<sup>6</sup> Because the courts have ruled that the '365 patent does not cover the approved product and is thus not the type of patent that can be listed, if Bristol seeks to re-list the patent, Mylan  
(continued...)

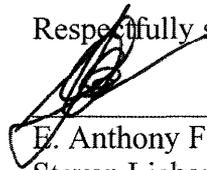
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**CERTIFICATION**

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition (including its attachments) includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



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<sup>6</sup>(...continued)

submits that the FDA may wish to take immediate action to withdraw approval of the Bristol NDA under 21 U.S.C. §505(e) since it would be necessary for Bristol to provide a statement in re-listing the patent that was untrue on its face. This would subject the application to withdrawal since it would contain an untrue statement of material fact.