IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, *et al.*,

Plaintiffs,

CV-05-0366 (ERK/VVP)

v.

MARGARET HAMBURG, in her official capacity as commissioner of the Food and Drug Administration,

Defendant.

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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR CIVIL CONTEMPT

INTRODUCTION

Plaintiffs respectfully submit this memorandum of law in support of their motion for civil contempt against Defendant (hereinafter "the FDA") based on the FDA's failure to make any meaningful efforts to comply with the portion of this Court's March 23, 2009 Order directing it to reconsider its denial of the Citizen Petition submitted by Plaintiffs (hereinafter "the Order").

In the Order, the Court found that the FDA acted "in bad faith and in response to political pressure" when it repeatedly and unreasonably delayed rendering a decision on Plan B and departed in significant ways from the agency's normal procedures concerning over-the-counter switches. *Tummino v. Torti*, 603 F. Supp. 2d 519, 544-48 (E.D.N.Y. 2009). The Court remanded to the FDA to reconsider its decision on the Citizen Petition, expressing trust that the newly appointed FDA leadership would "conduct a fair assessment of the scientific evidence." *Id.* at 549-50. The Order quotes several sources within the FDA stating that the agency had

sufficient evidence to approve Plan B for over-the-counter use by women of all ages. *See id.* at 526-35.

The FDA has patently ignored the Order and continued its administrative stall on the Citizen Petition. For the past one-and-a-half years, the FDA has not taken any steps to comply with the Court's command to reconsider the Citizen Petition. Indeed, the FDA recently indicated that it has no plans to rule on the Citizen Petition any time soon (and possibly not at all), but rather believes "the best way" for it to comply with the Order is to wait for and review a Supplemental New Drug Application ("SNDA") from the manufacturer of Plan B that may or may not be filed at some unknown point in the future. This repeated stance throughout this litigation—that the FDA may just ignore the Citizen Petition and rule only on SNDAs filed by manufacturers—was found insufficient by this Court and demonstrates the FDA is in contempt of the Order for failure to diligently attempt to comply with it in a reasonable manner.

The FDA's disregard of the Court's clear and lawful order harms women whose access to Plan B is hindered by substantial obstacles imposed by the FDA, particularly in light of the need to take the medication within 72 hours of sexual intercourse in order for it to be effective. Plaintiffs therefore respectfully request that the Court:

1. schedule oral argument on this motion;
2. adjudge the FDA in contempt of this Court's Order dated March 23, 2009, directing the FDA to reconsider its ruling on the Citizen Petition;
3. direct the FDA to issue a ruling on the Citizen Petition within forty-five days of the Court's ruling on Plaintiffs' motion; and
4. grant such other and further relief as may be just and proper.

STATEMENT OF FACTS

Plan B is an emergency contraceptive that can be used to reduce the risk of pregnancy after sexual intercourse. It is highly effective and has no documented serious side effects or long-term health effects. Recognizing the importance of timely and wide access to emergency contraceptive pills, Plaintiffs filed a Citizen Petition on February 14, 2001, asking the FDA to grant over-the-counter ("OTC") status to Plan B and other equivalent drugs eligible for abbreviated new drug applications because of their equivalence to Plan B. Parallel to the Citizen Petition, a Plan B manufacturer also filed an SNDA with the FDA requesting the OTC switch on April 22, 2003.

The OTC switch, without age or other point-of-sale restrictions, was recommended by an overwhelming 23-to-4 majority of the Advisory Committee formed to review the switch, *see Tummino*, 603 F. Supp. at 528, as well as *all* of the FDA staff who conducted scientific reviews, *see id.* at 531 ("FDA scientific review staff uniformly and strongly supported approval of Plan B for OTC sales without age or point-of-sale restrictions."). These scientists represented several different divisions and offices within the FDA. *See, e.g.*, 603 F. Supp. at 529 (quoting Deputy Director of the Division of OTC Drugs recommending approval and "concluding that Plan B has a 'low misuse and abuse potential' and is 'safe and effective'"); *id.* at 530 (quoting conclusion of Director of Office of Drug Evaluation V that the drug sponsor "adequately demonstrated that women of reproductive potential across relevant age subgroups can use the product appropriately"). FDA leadership expressed concerns that OTC access would negatively impact adolescents, but FDA staff found no evidence to support these concerns. *See e.g., id.* at 530 (quoting Director of Office of Drug Evaluation V saying that "[t]here is no basis on which to assume that young women of child bearing potential would suddenly become promiscuous

because of this product"); *id.* at 531 (quoting Deputy Director of Division of Reproductive and Urologic Drug Products saying "that there was no justification for 'restrict[ing] access to the benefit of this product on the basis of age'"); *id.* at 532 (quoting Director of Office of New Drugs saying that studies on adolescents dispelled management's concerns and that those studies included sufficient numbers of adolescent subjects); *see also id.* at 531 (quoting meeting minutes showing FDA staff from several offices and divisions responding to management's concerns about impact on adolescents with analysis of additional data; FDA staff concluded that "the benefits of timely access outweighed any risk for all women, including adolescents").[1]

Instead of approving the OTC switch in accordance with the scientific evidence, "the FDA repeatedly and unreasonably delayed issuing a decision on Plan B for suspect reasons, and, on two occasions, only took action on Plan B to facilitate confirmation of Acting FDA Commissioners." *Id.* at 523. Plaintiffs sued the FDA on January 21, 2005, after the agency had failed to act on the petition for four years. Throughout the litigation, the FDA consistently resisted all efforts to allow judicial scrutiny of its handling of the Plan B OTC switch application, and pursued "a litigation strategy dependent on the assertion of deliberative process privilege to prevent plaintiffs from obtaining conclusive evidence as to the merits of its claim." *Id.* at 548. In fact, it was more than five years after the Citizen Petition was filed, and only when Plaintiffs declared their intention to seek discovery of White House documents describing the White House's role in the FDA's review of Plan B, that the FDA finally announced its denial of the Citizen Petition on June 9, 2006, and quickly exploited that announcement to propose a halt to discovery. *See* Letter from F. Franklin Amanat to the Court (June 28, 2006) (ECF No. 160)

[1] The FDA used both the Citizen Petition records and the SNDA records in reviewing the Citizen Petition, *see* Def. Mem. in Supp. of Mot. to Dismiss, p. 8, n. 6 (ECF No. 247) ("Many but not all of [the SNDA] documents have also been incorporated into the administrative record for the Citizen Petition."); *Tummino*, 603 F. Supp. 2d at 537 ("[T]he FDA acknowledged that the issues presented by the SNDAs and the Citizen Petition were one and the same.").

(notifying the Court of the denial of the Citizen Petition and requesting, inter alia, a stay of discovery to prevent discovery outside the administrative record).

Soon thereafter, the FDA approved the manufacturer's SNDA for a partial OTC switch for Plan B, which contained four unique point-of-sale restrictions: (1) women younger than 18 were still required to have a prescription to obtain Plan B; (2) Plan B could be sold only at pharmacies and health clinics; (3) Plan B must be kept behind the counter at pharmacies; and (4) persons must present government-issued identification in order to obtain Plan B. *See* Press Release, FDA, FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older; Prescription Remains Required for Those 17 and Under (August 24, 2006) (ECF No. 248-4 at 24).

As the Court found, however, "the FDA's course of conduct regarding Plan B had departed in significant ways from the agency's normal procedures." *Tummino*, 603 F. Supp. 2d at 523. For example, the FDA acted against the Advisory Committee's recommendation, despite the fact that "in every such application in the last decade, the FDA has followed committee recommendations." *Id.* at 547. In addition, the FDA made its decision *before* the scientific reviews were completed, demonstrating that the decision was not based on evidence. *Id.* Another significant departure was "the FDA's refusal to extrapolate actual use study data from the older age group to the 16 and younger age group [despite] evidence in the record that the FDA routinely extrapolated such data when reviewing the safety and effectiveness of various other contraceptives." *Id.* Finally, the Court noted the role that ideological balance, as opposed to scientific expertise, played in decisions about the membership of the Advisory Committee and the White House's "unusual involvement" throughout the process of making the OTC switch decision. *Id.*

In view of the facts stated above, the Court found that the FDA's decision was "not the result of good faith and reasoned agency decision-making," *id.* at 544, and vacated the denial of the Citizen Petition. The Court ordered the FDA to make Plan B available to 17 year olds immediately and remanded to the agency reconsideration of the Citizen Petition, which necessarily entails reconsideration of whether to approve Plan B for OTC status for all women without age or point-of-sale restrictions. *Id.* at 550. It noted that FDA scientific review staff members, as well as directors, had already reviewed the information contained in the SNDA materials and overwhelmingly supported the OTC switch for Plan B without age or point-of-sale restrictions. *See id.* at 526-35 (quoting numerous FDA sources stating that the evidence supported the switch).

In 2009, concerned about media reports indicating that the FDA was not taking any action on the Citizen Petition, Plaintiffs initiated a series of letter exchanges with the FDA requesting confirmation that the FDA's understanding of the Order was in accord with that of the Plaintiffs and that the FDA intended to comply with the Order. *See* Decl. of Suzanne Novak in Supp. of Mot. for Civil Contempt (hereinafter "Novak Decl."), Ex. A. Through letters, the FDA confirmed that: (1) it had approved OTC use for 17 year olds; (2) it understood that the Court had vacated the denial of the Citizen Petition and had remanded to the agency for reconsideration; 3) the Order required it to consider—and it was considering—both the availability of Plan B OTC for women under 17 and the removal of the other point-of-sale restrictions on Plan B; and 4) its decision would cover generic drugs equivalent to Plan B. *See* Novak Decl., Ex. B; *id.*, Ex. D. The FDA also initially indicated that it was "actively engaged" in the matter, though it refused to provide any details regarding such "active engage[ment]." *Id.*, Ex. B, at 2.

Recently, however, the FDA switched course and appears to have adopted the position that the Order does *not* require it to rule on the Citizen Petition and that it need only concern itself with the age restriction. In July, 2010, Plaintiffs sent a letter to the FDA seeking assurance that it has taken specific steps to comply with the Order and that it intends to issue a decision on both the age and the other point-of-sale restrictions within a reasonable time. *See id.*, Ex. E. In August, the FDA responded, stating that the "FDA believes that, at this time, the best way for FDA to comply with the court's order is to review a supplemental new drug application expected to be submitted by the sponsor of Plan B One Step."[2] *Id.*, Ex. F, at 1. In this latest letter, the FDA stated that the drug sponsor has inquired about the data that would be required for a new SNDA regarding nonprescription use by women under 17 years of age and that the sponsor "has stated that it plans to file an application when it has gathered sufficient data to support it." *Id.* Thus, rather than reconsidering Plaintiffs' Citizen Petition as ordered by this Court, the FDA has chosen instead to wait for a third party to act, which could happen many years from now, if at all. Notably, according to the letter, the anticipated supplemental application applies only to the age restriction on Plan B; the agency does not claim to have taken any action, or have plans to take any action, regarding reconsideration of the other point-of-sale restrictions currently placed on the OTC sale of Plan B.

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[2] The manufacturer of Plan B no longer makes Plan B; it now makes Plan B One Step, which is a single pill containing 1.5 mg of levonorgestrel, whereas Plan B consists of two pills that each contain 0.75 mg of levonorgestrel. The FDA has imposed the same age and point-of-sale restrictions on Plan B One Step, Plan B, and all generics equivalent to Plan B. By responding to Plaintiffs' letter inquiring about Plan B with information about Plan B One Step, the FDA has acknowledged the equivalence of the two brands for the purposes of the action requested by the Citizen Petition. *See* Novak Decl., Ex. F; *see also* Citizen Petition (ECF No. 248-2 at 21-28) (requesting OTC status for Plan B "and any new drug eligible for filing an abbreviated new drug application because of its equivalence to . . . *Plan B*"). Because of this equivalence, the Order regarding Plan B applies equally to Plan B One Step and generics that are equivalent to Plan B: the FDA is required to reconsider age and point-of-sale restrictions regarding those drugs as well. For purposes of simplicity, this memorandum does not distinguish among these drugs and uses "Plan B" as shorthand for all the drugs that are governed by the FDA-imposed age-restricted, behind-the-counter regime.

ARGUMENT

I. Legal Standard

This Court possesses the "inherent power to enforce compliance with [its] lawful orders through civil contempt." *In re Martin-Trigona*, 732 F.2d 170, 173 (2d Cir. 1984) (quoting *Shillitani v. United States*, 384 U.S. 364, 370 (1966)). This power is "governed not by rule or statute but by the control necessarily vested in courts to manage their own affairs so as to achieve the orderly and expeditious disposition of cases." *Chambers v. NASCO, Inc.*, 501 U.S. 32, 43 (1991). A court may hold a party in civil contempt if "(1) the order the party allegedly has failed to comply with is clear and unambiguous, (2) the proof of noncompliance is clear and convincing, and (3) the party has not diligently attempted in a reasonable manner to comply." *N.Y. State Nat'l Org. for Women v. Terry*, 886 F.2d 1339, 1351 (2d Cir. 1989). Plaintiffs easily meet this test.

II. **This Court's Order is Clear and Unambiguous**

An order is "clear and unambiguous where it is specific and definite enough to apprise those within its scope of the conduct that is being proscribed or required." *Terry*, 886 F.2d at 1352 (quoting *In re Baldwin-United Corp.*, 770 F.2d 328, 339 (2d Cir.1985)). Here, the language of the Order is specific and definite. The Court ordered that "[t]he denial of the Citizen Petition is vacated and the matter is remanded to the FDA to reconsider its decisions regarding the Plan B switch to OTC use." *Tummino*, 603 F. Supp. 2d at 550. This Order required the FDA's reconsideration to include "whether to approve Plan B for over-the-counter status without age or point-of-sale restrictions." *Id.* at 524. The Citizen Petition was the only document at issue in the case and the vacatur and the matter remanded for consideration clearly referred to reconsideration of the petition.

The FDA initially confirmed in its correspondence with Plaintiffs that it very well understood the terms of the Order. It acknowledged its obligation to "reconsider[] the Citizen Petition on remand from the District Court," Novak Decl., Ex. B, and stated that it "can assure [Plaintiffs] that the agency has been and is actively engaged in considering this topic, and intends to make a final decision as to the prescription status of Plan B for women under the age of 17," *id.* The FDA further confirmed that point-of-sale restrictions will be part of the reconsideration of the Citizen Petition and that any generic version of Plan B will be eligible for approval under the same approval conditions and labeling that the FDA has approved for Plan B. *See* Novak Decl., Ex. D.

III. There Is Clear and Convincing Evidence of the FDA's Failure to Comply with the Order

In the context of civil contempt, clear and convincing evidence means "a quantum of proof adequate to demonstrate to a 'reasonable certainty' that a violation has occurred." *Levin v. Tiber Holding Corp.*, 277 F.3d 243, 250 (2d Cir. 2002). "[F]ailures in meaningful respects to achieve substantial and diligent compliance" provide sufficient grounds for civil contempt. *Casale v. Kelly*, __ F. Supp. 2d __, Nos. 08 Civ. 2173(SAS), 05 Civ. 5442(SAS), 2010 WL 1685582, at *6 (S.D.N.Y. Apr. 26, 2010) (quoting *Aspira of New York, Inc. v. Bd. of Educ. of New York*, 423 F. Supp. 647, 649 (S.D.N.Y. 1976)). It is not necessary to show "scorn" or "willful disobedience" in order to establish civil contempt. *Aspira of New York, Inc. v. Bd. of Educ. of New York*, 423 F. Supp. 647, 649 (S.D.N.Y. 1976); *see also Donovan v. Sovereign Sec. Ltd.*, 726 F.2d 55, 59 (2d Cir. 1984); *Cordius Trust v. Kummerfeld Assocs., Inc.*, 658 F. Supp. 2d 512, 515-16 (S.D.N.Y. 2009). Plaintiffs handily meet this burden.

The FDA's failure to achieve substantial compliance with the Order is clearly established by its failure to rule on the Citizen Petition. Furthermore, in response to Plaintiffs' request that it describe the specific steps it has taken to comply with the Order, the FDA expressly admitted that it does not plan to reconsider the Citizen Petition at all. Rather, the FDA plans to wait for an SNDA that may or may not be filed by the drug sponsor at some unspecified time in the future before it reassesses the age restrictions. *See* Novak Decl., Ex. F.[3] It has further failed to indicate that it has *any* plan—passive or not—for reconsideration of the other point-of-sale restrictions that it currently places on Plan B. Though not necessary to warrant a finding of civil contempt, the FDA's continued failure to comply and its stated intention to essentially disregard the Order reflect the "bad faith and improper behavior" that has pervaded the case. *See Tummino*, 603 F. Supp. 2d at 543.

IV. The FDA Has Not Attempted to Comply with the Order in a Reasonable and Diligent Manner

Once it has been established that the relevant order is clear and unambiguous and that proof of noncompliance is clear and convincing, a party may be found in civil contempt if it has not attempted to comply in a reasonable manner and done so diligently. *See Terry*, 886 F.2d at 1351. "Reasonable diligence, at the very least, requires a party to develop and execute reasonable methods of compliance." *Casale*, 2010 WL 1685582, at *6. Reasonableness here is an objective standard, and the mere assertion of good faith is not a defense to civil contempt. *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 191 (1949); *see also Fortin v. Comm'r of Mass. Dep't of Pub. Welfare*, 692 F.2d 790, 796 (1st Cir. 1982). Because the FDA's actions are neither reasonable nor diligent, it should be found in civil contempt.

[3] Not only does such inaction violate the Order, but it violates the FDA's own regulations. *See* 21 C.F.R. § 10.30(e)(1) ("The Commissioner shall . . . rule upon each petition filed . . . .").

Even the length of time alone that the FDA has failed to act demonstrates that it has not made a reasonably diligent attempt to comply. Considering that the Citizen Petition was originally filed on February 14, 2001, the total length of delay in this case is over nine-and-a-half years, and it has been over one-and-a-half years since the Court ordered the FDA to reconsider the Citizen Petition. Unreasonably long delay is a ground for a finding of contempt. In *Aspira of New York, Inc. v. Bd. of Educ. of New York*, the Southern District of New York found the defendant's sixteen months of delay in complying with a consent decree to be a "failure[] of diligence." *Aspira*, 423 F. Supp. at 651. The court was particularly troubled by the defendant agency's "steady and repeated" failure to take action and noted that:

> The court is not empowered to command, any more than it can pretend for itself to achieve, performance approximating perfection. *The court is obliged, however, to require substantial performance and due diligence.* It is in these vital respects that today's decision must go against the defendants. As will appear, they failed steadily and repeatedly to exercise their power and authority so that those they controlled would proceed promptly and in good faith to accomplish the tasks commanded by the consent decree. *This failure reflected their own lack of concentrated will to achieve substantial performance.*

Aspira, 423 F. Supp. at 651 (emphasis added). The facts of this case show the same pattern of an agency lacking will to accomplish substantial performance.

In *Weiser v. Sec'y of the Dep't of Health and Hum. Serv.*, 645 F. Supp. 602 (S.D.N.Y. 1986), the plaintiff had applied for disability benefits five years prior to the judgment. The defendant agency repeatedly delayed the proceedings and ultimately rendered a flawed decision that did not consider all of the plaintiff's disabilities. Even after the court issued a remand order, the defendant did not hold a hearing for another eight months. The court found the defendant's "unreasonable delay" in the case "little short of outrageous" and awarded interim benefits to plaintiff. *Id.* at 603-04. The length of delay involved in this case is no less outrageous, involving

nearly twice that involved in *Weiser*: over one-and-a-half years of delay since the Order was issued, and nine-and-a-half years of delay since the Citizen Petition was originally filed.[4]

But here, the FDA's delay is all the more unreasonable because, as the evidence presented in the litigation shows, the FDA possesses all the necessary information it needs to rule on the Citizen Petition. *See Tummino,* 603 F. Supp. 2d at 526-35, 538 (describing unrebutted evidence that data on Plan B was sufficient to approve OTC availability for all ages). The soundness of the data on Plan B contained in the SNDA records and thus in the FDA's possession was acknowledged by the FDA's scientific review staff members. In particular, the Deputy Director of the Division of OTC Drugs noted that "[i]n terms of OTC switch applications, this drug has more information available to allow us to predict consumer behavior than any drug in recent memory. *If this is not enough data upon which to base a decision, it is unclear what would constitute enough data or even if that is an obtainable goal.*" *Id.* at 531.

Thus, the FDA's position that "the best way for FDA to comply with the Court's order is to review a supplemental new drug application expected to be submitted by the sponsor of Plan B One Step," *see* Novak Decl., Ex. F, at 1, is unreasonable. *See Weiser*, 645 F.2d at 604 (finding defendant agency's delay "especially troubling" when the records before it contained all the requisite information, a significant amount of which suggested that the plaintiff was entitled to relief). The FDA has offered Plaintiffs no explanation as to why it believes, contrary to all the evidence, that it needs more data before it can rule on the Citizen Petition. The agency's last letter to Plaintiffs implies that it expects new data specific to use by adolescents. *See* Novak

[4] The FDA contends that "even if the Citizen Petition were to be granted on remand, that would merely lead to the commencement of rulemaking proceedings." Novak Decl., Ex. F, at 1. What might happen *after* the FDA complies with the Order and rules on the Citizen Petition is irrelevant for purposes of this motion, which concerns only whether the FDA is in civil contempt for failing to comply with the Order in the first instance. Moreover, the FDA's position is unsupported by statutory text and inconsistent with the legislative history of the FDA's regulations and the interpretation the FDA adopted at the time the regulations were enacted.

Decl., Ex. F, at 2 (referring to data that "would be required to support a supplemental application for the nonprescription approval of [Plan B One Step] for females under the age of 17"). But to insist on adolescent-specific data before ruling on the Citizen Petition would be to engage in one of the departures from agency practice upon which the Court based its order for reconsideration of the OTC switch decision in the first place. 613 F. Supp. 2d at 547 ("[T]he FDA routinely extrapolated such data when reviewing the safety and effectiveness of various other contraceptives."). The FDA's position is even more unreasonable considering that the anticipated SNDA would supposedly provide information relevant only to the age restriction and not the other point-of-sale restrictions that the FDA has acknowledged the Order requires it to reconsider.

Finally, the agency's passive stance with regard to the Citizen Petition and the information it supposedly "needs" shows a profound lack of diligence. If the agency believed that it needed more data, it should either have been actively engaged in gathering that data before now or it should have denied the Citizen Petition on those grounds. Passively waiting for third-party action that may come years from now or not at all is not an acceptable course of action in light of this Court's Order. In its letter informing Plaintiffs of its plan to wait for information that a drug sponsor may or may not submit, the FDA contended that the agency has "the discretion to collect and evaluate new data and evidence on remand from the district court[and] to select the best administrative process." Novak Decl., Ex. F, at 2. However, this proposition and the cases cited in the FDA's letter do not justify the agency's current inaction. The cases cited by the FDA hold only that courts should not dictate the methods and procedure the agency should use on remand to *gather additional evidence* or *investigate* further. *See, e.g., Fed. Power Comm'n v. Transcon. Gas Pipe Line Corp.*, 423 U.S. 326, 333 (1976); *Florida Power & Light v.*

Lorion, 470 U.S. 729, 744 (1985). The principle that the agency may select its own fact-gathering process does not mean that the agency may refuse to do anything at all to gather facts in the hopes that a private party may gather and submit facts instead. The FDA's plan to wait for another SNDA to be submitted, rather than simply ruling on the almost-ten-year-old petition, is the antithesis of diligence.

CONCLUSION

The Citizen Petition at issue was filed almost ten years ago; more than one-and-a-half years ago, the Court ordered the FDA to reconsider its denial of the Citizen Petition. The FDA has now had ample time, sufficient information, and countless opportunities to rule upon the petition. Not only has it failed to do so, but it has asserted that it is not taking any affirmative steps to rule on it and has no plans to do so in the near future. Because the FDA has clearly failed to comply with this Court's Order and has not diligently attempted to comply in a reasonable manner, Plaintiffs respectfully request that the Court find the FDA in contempt, direct the FDA to issue a decision on the Citizen Petition within forty-five days of the contempt finding, and order any other relief that the Court deems fair and appropriate.

Dated: November 16, 2010

Respectfully submitted,

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