

INTERNATIONAL CENTER FOR
TECHNOLOGY ASSESSMENT *et al.*,

V.

Defendants.

Document No.: 18

The development and use of genetically engineered animals for food and ornamental purposes has become a fast-growing industry in recent years. Am. Compl. ¶ 31. Genetically

engineered animals are subject to a wide array of regulatory authority. Defs.’ Mot. to Dismiss at 6-9. Under the New Animal Drug Application (“NADA”)¹ provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA”), the Food and Drug Administration (“FDA”) is responsible for approving new animal drug products. 21 U.S.C. § 360b.

At least one manufacturer, Yorktown Technologies, L.P. (“Yorktown”), has developed a line of genetically engineered ornamental or “pet” fish, hereinafter referred to by its trademarked name GloFish. Am. Compl. ¶ 35. The GloFish is a bright red fluorescent zebra fish that contains inserted genetic constructs from a sea coral, which cause the fish to glow under certain kinds of light. *Id.* Although GloFish are intended for use in home aquariums, the plaintiffs allege that they “could be put to other uses and readily enter the animal and human food chains through accidental or intentional releases.” *Id.*

In the fall of 2003, Yorktown’s CEO, Alan Blake, allegedly contacted one of the defendants, John Matheson, Program Officer at the FDA’s Center for Veterinary Medicine, to ask about the FDA’s views regarding GloFish. Defs.’ Mot. to Dismiss at 11; Pls.’ Opp’n to Defs.’ Mot. to Dismiss at 4. In response to this inquiry, the FDA reviewed materials provided by Yorktown to the public through its website and consulted directly with staff at the Animal and Plant Health Inspection Service of the USDA. Defs.’ Mot. to Dismiss at 12; Pls.’ Opp’n to Defs.’ Mot. to Dismiss at 4-5. After considering the legal, scientific, and policy issues involved in the commercialization of GloFish, the FDA determined that regulation would be inappropriate.

¹ “The Food, Drug and Cosmetic Act (‘FDCA’) provides that any new animal drug is considered unsafe prior to receiving FDA approval for its intended use. 21 U.S.C. § 360b(a)(1)(A). To secure such approval, the FDCA requires the applicant to file a New Animal Drug Application (‘NADA’) that includes information demonstrating both the safety and the efficacy of the drug. *Id.* § 360b(d)(1)(A).” *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1486 (D.C. Cir. 1995).

Pls.’ Opp’n to Defs.’ Mot. to Dismiss at 5; Defs.’ Mot. to Dismiss at 12. Accordingly, on December 9, 2003, the FDA issued the following statement (the “GloFish Statement”):

Because tropical aquarium fish are not used for food purposes, they pose no threat to the food supply. There is no evidence that these genetically engineered zebra danio fish pose any more threat to the environment than their unmodified counterparts which have long been widely sold in the United States. In the absence of a clear risk to the public health, the FDA finds no reason to regulate these particular fish.

Am. Compl. ¶ 38; Defs.’ Mot. to Dismiss at 12. The next day, Yorktown announced on its website that in response to the FDA’s decision not to regulate GloFish and due to unprecedented demand, limited numbers of GloFish would be made available immediately, with nationwide sales commencing shortly thereafter. Am. Compl. ¶ 40.

B. Procedural History

On March 4, 2004, the plaintiffs, seeking declaratory and injunctive relief, filed an amended complaint. The amended complaint makes the claims that the FDA: (1) arbitrarily and capriciously distinguished between food and non-food uses in the GloFish Statement; (2) failed to review Yorktown’s request for approval of the GloFish under the statutorily-prescribed standards; (3) failed to prepare an environmental impact statement (“EIS”) or an environmental assessment prior to allowing the proposed commercialization of GloFish, in violation of NEPA; (4) failed to prepare an EIS or an environmental assessment with respect to genetically engineered ornamental fish, and other genetically engineered animals generally, in violation of NEPA; (5) failed to prepare a biological assessment and failed to consult with the Fish and

Wildlife Service (“FWS”) before allowing the proposed commercialization of GloFish, in violation of the ESA; and (6) violated the ESA through its actions with respect to genetically engineered ornamental fish, and other genetically engineered animals generally. Am. Compl. ¶¶ 56-79.

On April 19, 2004, the defendants responded to the complaint by filing a motion to dismiss. On March 30, 2005, the court granted the defendants’ motion to dismiss. The court dismissed the first two claims (the “NADA claims”) because the FDA’s decision not to regulate GloFish is committed to the agency’s discretion. Mem. Op. (Mar. 30, 2005) (“Mem. Op.”) at 17-25. The court dismissed the third and fourth claims (the “NEPA claims”) because the FDA has not taken a major federal action as required by NEPA. *Id.* at 25-29. Finally, the court dismissed the fifth and sixth claims (the “ESA claims”) because the FDA has not engaged in agency action as required by ESA. *Id.* at 29-32. The plaintiffs subsequently filed a motion to alter or amend the court’s judgment. Pls.’ Mot to Alter or Amend Judgment (“Pls.’ Mot”). The court now turns to that motion.

III. ANALYSIS

A. Standard of Review for Motion to Alter or Amend

Federal Rule of Civil Procedure 59(e) provides that a motion to alter or amend a judgment must be filed within 10 days of the entry of the judgment at issue. FED. R. CIV. P. 59(e); see also *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 357 U.S. App. D.C. 422, 336 F.3d 1094, 1098 (D.C. Cir. 2003). While the court has considerable discretion in ruling on a Rule 59(e) motion, the reconsideration and amendment of a previous order is an unusual measure. *Firestone v. Firestone*, 76 F.3d 1205, 1208 (D.C. Cir. 1996) (per curiam); *McDowell v.*

Calderon, 197 F.3d 1253, 1255 (9th Cir. 1999).

Rule 59(e) motions “need not be granted unless the district court finds that there is an intervening change of controlling law, the availability of new evidence, or the need to correct a clear legal error or prevent manifest injustice.” *Ciralsky v. Cent. Intelligence Agency*, 355 F.3d 661, 671 (D.C. Cir. 2004) (quoting *Firestone*, 76 F.3d at 1208). Moreover, “[a] Rule 59(e) motion to reconsider is not simply an opportunity to reargue facts and theories upon which a court has already ruled,” *New York v. United States*, 880 F. Supp. 37, 38 (D.D.C. 1995), or a vehicle for presenting theories or arguments that could have been advanced earlier. *Kattan v. Dist. of Columbia*, 995 F.2d 274, 276 (D.C. Cir. 1993); *W.C. & A.N. Miller Cos. v. United States*, 173 F.R.D. 1, 3 (D.D.C. 1997).

B. The Court’s Dismissal of the NADA Claims is Not in Clear Error

The plaintiffs’ first two claims allege that the FDA improperly refused to regulate the GloFish, and that the FDA’s failure to assert regulatory authority over the GloFish violates the NADA provisions of the FDCA. The court dismissed the two claims, argued in the alternative, because the FDA’s “enforcement decisions relating to unapproved new animal drug products are discretionary and are not subject to judicial review under the APA.” Mem. Op. at 18.

1. The FDA Properly Refused to Assert Regulatory Jurisdiction Over the GloFish

The plaintiffs’ first claim is that the FDA arbitrarily and capriciously denied regulatory jurisdiction over the GloFish. Am. Compl. ¶¶ 39, 58. In particular, the plaintiffs allege that the FDA “arbitrarily and capriciously advised Yorktown that no NADA was mandated” because the FDA mistakenly believed it lacked jurisdiction to regulate the GloFish. Pls.’ Mot. at 4. The court dismissed the plaintiffs’ first claim because this is not a case “where the agency refuses to

institute proceedings based solely on the belief that it lacks jurisdiction.”² Mem. Op. at 22 (quoting *Balt. Gas & Elec. v. Fed. Energy Reg. Comm’n*, 252 F.3d 456, 460 (D.C. Cir. 2001)).

The plaintiffs’ motion to alter or amend judgment simply reiterates the argument that the FDA refused to assert regulatory authority over the GloFish based on the FDA’s mistaken belief that it lacks jurisdiction. The plaintiffs, moreover, do not present any new factual evidence to indicate clear error in the court’s original conclusion that the FDA was not acting on the basis of a mistaken belief as to its regulatory jurisdiction.³ Indeed, the evidence available, the GloFish statement, states that the FDA “finds no reason to regulate” GloFish. Am. Compl. ¶ 38. Nowhere does the statement indicate that the FDA believed it did not have the authority to regulate GloFish. As the court previously stated, the “FDA is simply exercising its discretion not to take enforcement actions against these particular fish.” Mem. Op. at 22. In short, the plaintiffs do not present any new evidence indicating that the court’s conclusion that the FDA was not acting under the mistaken belief that it lacked jurisdiction is incorrect. *New York*, 880 F. Supp. at 38 (denying a motion to alter judgment because the moving party failed to identify new evidence or a clear error of law). Accordingly, the court denies the plaintiffs’ motion to alter the dismissal of their first claim.

² Generally, an agency’s decision not to prosecute or enforce is committed to the agency’s discretion and courts presumptively do not have subject-matter jurisdiction to review actions committed to agency discretion. *Heckler v. Chaney*, 470 U.S. 821, 831 (1985); *Balt. Gas & Elec. v. Fed. Energy Reg. Comm’n*, 252 F.3d 456, 459 (D.C. Cir. 2001). The presumption against judicial review may be overcome where the agency refuses to institute proceedings based on the mistaken belief that it lacks jurisdiction. *Balt. Gas & Elec.*, 252 F.3d 456 at 460 (quoting *Chaney*, 470 U.S. at 833 & n.4). See also Mem. Op. (Mar. 30, 2005) (“Mem. Op.”) at 18-19.

³ The plaintiffs’ only argument with respect to the dismissal of the first claim is a one-sentence statement that it was an error for this court to conclude that the plaintiffs will not be able to prove that the FDA believed it lacked jurisdiction. Pls.’ Mot. to Alter or Amend Judgment (“Pls.’ Mot.”) at 4.

2. The Plaintiffs Fail to Show Yorktown Submitted a NADA

The court also rejected the plaintiffs' second claim, which alleges, in the alternative, that Yorktown Technologies did submit a NADA, and that the FDA subsequently reviewed the NADA under the wrong regulatory standard. Mem. Op. at 17-18. The plaintiffs move this court to alter or amend the judgment by arguing that the court's dismissal is based on its assumption that Yorktown Technologies did not submit a NADA.⁴ The plaintiffs argue that the court was required to treat their allegation that Yorktown Technologies submitted a NADA as true for the purposes of analyzing the defendants' motion to dismiss. Pls.' Mot. at 2-3.

Because subject-matter jurisdiction focuses on the court's power to hear the claim, the court must give the plaintiffs' factual allegations closer scrutiny when resolving a Rule 12(b)(1) motion than would be required for a Rule 12(b)(6) motion for failure to state a claim. *Macharia v. United States*, 334 F.3d 61, 64, 69 (D.C. Cir. 2005); *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). Indeed, district courts are required to resolve factual disputes to its subject matter jurisdiction. *Phoenix Consulting, Inc. v. Republic of Angola*, 216 F.3d 36, 41 (D.C. Cir. 2000). Although the plaintiffs allege that Yorktown Technologies submitted a NADA for GloFish, nowhere in the pleadings do the plaintiffs allege any facts supporting such a conclusion. Rather, the plaintiffs urge the court to treat informal contacts between Yorktown and the FDA as a submission of a NADA. Looking at the evidence,

⁴ The court reasoned that because Yorktown did not submit a NADA, the defendants' decision not to regulate the FDA was "simply a decision not to exercise enforcement authority." Mem. Op. at 21. The court concluded that such a decision is beyond the reach of judicial review. *Id.* The plaintiffs do not dispute the court's legal conclusion. Rather, the plaintiffs assert that Yorktown submitted a NADA and that the defendants arbitrarily and capriciously approved the NADA.

such as the Matheson Declaration, this court determined Yorktown did not submit a NADA. Mem. Op. at 21 n.10; *see also* Defs.’ Mot. to Dismiss, Ex. A (“Matheson Decl.”) ¶ 26. Based on the court’s conclusion that the plaintiffs could not show that Yorktown submitted a NADA, the court determined that there were no statutory “guidelines for the agency to follow in exercising its enforcement power,” and accordingly, the court did not have jurisdiction to review the claim. Mem. Op. at 21 (citing *Chaney*, 470 U.S. 833 (1985))

Assuming *arguendo* that Yorktown submitted a NADA, the court still declines to alter or amend the judgment because the FDA has the discretion to decline to take any enforcement action once a NADA is approved.⁵ The FDA’s decisions not to prosecute or enforce are presumptively unreviewable by the court because such decisions are committed to the agency’s discretion. *Jerome Stevens Pharma., Inc. v. FDA*, 402 F.3d 1249, 1256-57 (D.C. Cir. 2005). Thus, assuming *arguendo* that Yorktown submitted a NADA and that the FDA approved the NADA, the FDA’s determination not to take any enforcement actions in connection with the GloFish NADA is discretionary and not subject to judicial review. In sum, the plaintiffs’ motion to alter or amend the judgment dismissing their second claim does not contain any new information or new arguments to support their contention that this court has jurisdiction. The court accordingly denies the plaintiffs’ motion to alter or amend the dismissal of the NADA claims.

⁵ The defendants make this precise argument in their opposition to the plaintiffs’ motion. Defs.’ Opp’n to Pls.’ Mot. to Alter or Amend Judgment at 5 n.4. The plaintiffs’ reply does not make any arguments regarding this court’s ability to review the FDA’s decision not to take an enforcement action.

C. The Court’s Dismissal of the NEPA Claims is Not in Clear Error

The plaintiffs also move the court to alter its dismissal of their allegations that the defendants failed to comply with the NEPA requirements. The plaintiffs contend that two FDA actions amount to “major” federal actions triggering NEPA. First, in their third claim, the plaintiffs assert that the defendants’ refusal to regulate GloFish constitutes major federal action. Am. Compl. ¶¶ 64-67. Second, in their fourth claim, the plaintiffs assert that the defendants’ broader refusal to regulate genetically engineered ornamental fish is major federal action triggering NEPA requirements. *Id.* ¶¶ 68-73. The court dismissed both of these claims finding that the FDA’s activities did not amount to major federal action. Mem. Op. at 23.

NEPA requires federal agencies to prepare an EIS if the agency plans to undertake a “major” federal action “significantly affecting the quality of the human environment.” 42 U.S.C. § 4332(C). If the agency has not engaged in a major federal action, NEPA requirements do not apply. *Macht v. Skinner*, 916 F.2d 13, 16 (D.C. Cir. 1990). To trigger NEPA’s requirement that an agency prepare an EIS, the agency must undertake an “irreversible and irretrievable commitment of resources to an action that will affect the environment.” *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 174 (D.D.C. 2000) (quoting *Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 49 (D.C. Cir. 1999)). Agency decisions that maintain the status quo do not constitute major federal actions. *Id.* Moreover, “NEPA applies only to agency actions ‘even if inaction has environmental consequences,’” *id.* at 174-75 (quoting *Defenders of Wildlife v. Andrus*, 627 F.2d 1238, 1243 (D.C. Cir. 1980)), because “[n]o agency could meet its NEPA obligations if it had to prepare an environmental impact statement every time the agency had power to act but did not do so,” *Defenders of Wildlife*, 627 F.2d at 1246.

1. The FDA's Refusal to Regulate GloFish is Not a Major Federal Action

The plaintiffs allege this court clearly erred in dismissing the third claim because the court looked beyond the pleadings in ruling against them. Pls.' Mot. at 6. Specifically, the plaintiffs allege that the court's dismissal of their third claim was based on the court's determination that no NADA was submitted. Because the plaintiffs' argument is based on a misunderstanding of the court's reasoning and of the applicable law, the court declines to alter its decision to dismiss the plaintiffs' third claim.

The court, in ruling on a motion to dismiss, need not accept "legal conclusions cast as factual allegations." *Warren v. Dist. of Columbia*, 353 F.3d 36, 39 (D.C. Cir. 2004); *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002). Therefore, assuming *arguendo* that the court was required to accept the plaintiffs' allegation that Yorktown submitted a NADA for the purpose of ruling on a motion to dismiss, the court was not required to accept the plaintiffs' legal conclusion that the FDA's refusal to regulate GloFish constituted a major federal action under NEPA.

According to the plaintiffs, the defendants have engaged in a "major federal action" triggering NEPA compliance because they have "authorized the sale of a genetically engineered fish that has the potential to significantly impact public health, animal health, and the environment." Pls.' Opp'n to Defs.' Mot. to Dismiss at 31. But, the FDA never authorized the sale of GloFish. Rather, the agency declined to initiate enforcement proceedings against the GloFish manufacturer. The FDA's decision not to regulate GloFish is not an agency action, but rather, an agency inaction. In addition, the FDA has not made an "irreversible and irretrievable commitment of resources" to the regulation of GloFish or the regulation of genetically engineered animals in general that would trigger NEPA's requirements. *Id.* at 174. To the

contrary, the FDA's GloFish statement indicates that no resources are being committed to regulate GloFish because the GloFish Statement explicitly states that the FDA "finds no reason to regulate these particular fish." *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 174. Because NEPA does not require the FDA to prepare an EIS, the declines to alter or amend its original ruling dismissing the third claim.

2. The FDA's Refusal to Regulate Genetically Engineered Animals is Not a Major Federal Action

The court dismissed the plaintiffs' fourth claim, which alleges that the FDA's failure to prepare an EIS with respect to genetically engineered animals violates the NEPA, because the court concluded that the FDA did not engage in a major federal action. Mem. Op. at 23. In moving the court to alter or amend its judgment, the plaintiffs charge the court with committing clear error for failing to interpret the facts liberally in their favor and for misapplying NEPA regulations. Pls.' Mot. at 10. The court's conclusion, however, remains unchanged because the plaintiffs do not present any new evidence or arguments showing that the court committed a clear error.

The court must "treat the complaint's factual allegations – including mixed questions of law and fact – as true and draw all reasonable inferences therefrom in the plaintiff's favor." *Macharia*, 334 F.3d at 64. The court, however, need not accept as true inferences unsupported by facts set out in the complaint or "legal conclusions cast as factual allegations." *Browning*, 292 F.3d at 242; *see also Warren*, 353 F.3d at 39. Here, the plaintiffs urge the court to accept their

legal conclusions that the FDA's activities constitute a major federal action as true. These legal conclusions are not binding on the court. Thus, the court declines to alter or amend its judgment.⁶

D. The Court's Dismissal of the ESA Claims is Not in Clear Error

The court dismissed the plaintiffs' fifth and sixth claims because they failed to sufficiently allege an agency action triggering ESA compliance. Mem. Op. at 29. The plaintiffs now argue that the court committed clear error in concluding that the FDA's actions concerning GloFish and other genetically engineered animals do not trigger ESA requirements. Pls.' Mot. at 6. Because the plaintiffs have not presented any new arguments or evidence showing that the court committed a clear error, the court denies the plaintiffs' motion to alter or amend the dismissal of the fifth and sixth claims.⁷

To trigger ESA requirements, an agency must have engaged in an agency action. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.03 (stating that the consultation requirement in Section 7 of

⁶ The plaintiffs also allege that the court committed clear error in applying the NEPA regulations. Pls.' Mot. at 9. Although the plaintiffs charge the court with ignoring 40 C.F.R. § 1502.4(b), the plaintiffs did not include this argument in their opposition to the defendants' motion to dismiss. District courts are not "required to unearth theories and precedents not cited by a party." *Buchheit v. Palestinian Liberation Org.*, 388 F.3d 346, 352 (D.C. Cir. 2004) (quoting *Ned Chartering & Trading, Inc. v. Republic of Pakistan*, 294 F.3d 148, 155 (D.C. Cir. 2002)). That responsibility is delegated to the party's attorneys. *Id.* Given the plaintiffs' failure to raise these challenges in the original motions briefing, the court need not address the arguments the plaintiffs present in the instant motion. *Turkmani v. Republic of Bol.*, 273 F. Supp. 2d 45, 50 (D.D.C. 2002) (citing *Segua Corp. v. GBJ Corp.*, 156 F.3d 136, 144 (2d Cir. 1998)). This court's decisions are "not intended as mere first drafts, subject to revision and reconsideration at a litigant's pleasure." *Id.* (citations omitted). Neither does a motion to alter or amend judgment provide the plaintiffs a second bite at the juridical apple. *Id.*; see also *All West Pet Supply v. Hill's Pet Prods. Div.*, 847 F. Supp. 858, 860 (D. Kan. 1994) (stating that "[a] party's failure to present his strongest case in the first instance does not entitle him to a second chance in the form of a motion to alter or amend"). Moreover, 40 C.F.R. § 1502.4(b) provides no support for the plaintiffs' argument that the FDA's inaction triggers the NEPA requirements. 40 C.F.R. § 1502.4(b) (stating that an EIS may be required "for broad Federal actions such as the adoption of new agency programs or regulations").

⁷ The court notes that a motion to alter or amend judgment "is not simply an opportunity to reargue facts and theories upon which a court has already ruled." *New York v. United States*, 880 F. Supp. 37, 38 (D.D.C. 1995).

the ESA is limited to agency “action in which there is discretionary Federal involvement or control”); *Natural Res. Def. Council v. Houston*, 146 F.3d 1118, 1125 (9th Cir. 1996). “The standard for ‘major federal action’ under NEPA and ‘agency action’ under ESA are much the same.” *Marbled Murrelet v. Babbitt*, 83 F.3d 1068, 1075 (9th Cir. 1996). “Agency action” is defined by the ESA as “any action authorized, funded, or carried out by” a federal agency. 16 U.S.C. § 1536(a)(2); see *Marbled Murrelet*, 83 F.3d at 1073. Examples of agency action “include, but are not limited to . . . actions intended to conserve listed species or their habitat; . . . the promulgation of regulations; . . . [and] actions directly or indirectly causing modifications to the land, water, or air.” 50 C.F.R. § 402.02.

The plaintiffs’ motion asserts that the court’s reasoning in dismissing their fifth and sixth claims is based on facts extraneous to the amended complaint. Pls.’ Mot. at 6. Specifically, the plaintiffs allege that the court’s ruling is based on its determination Yorktown did not submit a NADA. *Id.* at 6. The court, however, did not base its ruling on this determination. Mem. Op. at 29-30.

The court concluded that the FDA’s actions did not constitute agency action because the plaintiffs failed to allege that the defendants engaged in any type of action. Mem. Op. at 30. As the court stated, the FDA simply decided not to engage in enforcement activity. Mem. Op. at 30. The court, furthermore, was not required to accept the plaintiffs’ legal conclusion that the alleged inaction constitutes an agency action. *Warren*, 353 F.3d at 39; *Browning*, 292 F.3d at 242. As the court explained previously, the plaintiffs mischaracterized the FDA’s refusal to engage in enforcement activity as an affirmative action authorizing and approving Yorktown’s commercialization of GloFish. Mem. Op. at 30. Consequently, the defendants did not engage in

an “agency action” triggering ESA compliance. *Fund for Animals, Inc. v. Thomas*, 127 F.3d 80, 84 n.6 (D.C. Cir. 1997) (noting that promulgation of policy to refrain from regulating a particular subject matter “most probably would have been no ‘agency action’ to trigger the ESA consultation requirement”).

IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiffs’ motion to alter or amend its ruling granting the defendants’ motion to dismiss. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this 8th day of March, 2006.

RICARDO M. URBINA
United States District Judge