IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT, 660 Pennsylvania Ave., SE Suite 302 Washington, DC 20003, **CENTER FOR FOOD SAFETY,** 660 Pennsylvania Ave., SE Suite 302 Washington, DC 20003, Plaintiffs, v. **TOMMY THOMPSON,** in his official capacity as Secretary, United States Department of Health and Human Services, 200 Independence Ave., SW Room 615-F Washington, DC 20201 **MARK MCCLELLAN,** in his official capacity as Commissioner, United States Food and Drug Administration, 14-71 Parklawn Building 5600 Fishers Lane Rockville, MD 20857 Defendants.	**Civil Action No.**

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This is an action for declaratory and injunctive relief challenging the Defendants' implementation of the New Animal Drug Application (NADA) provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 360b; the National Environmental Policy Act (NEPA), 42 U.S.C. § 4321 *et seq.*; the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.*,

and related regulations, with respect to the procedures by which Defendants have allowed the unregulated commercialization of genetically engineered ornamental fish.

2. This action also challenges the Defendants' failure to comply with NEPA while conducting programmatic actions with respect to the regulation of all genetically engineered animals under the NADA provisions of the FFDCA, including, but not limited to, ornamental fish.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (Federal question), 28 U.S.C. § 1346 (United States as defendant), 28 U.S.C. § 2201-02 (declaratory relief), and 5 U.S.C. § 706 (APA).

4. The relief requested is authorized pursuant to 28 U.S.C. § 2201 (declaratory relief) and 28 U.S.C. § 2202 (further relief), and the Plaintiffs have a right to bring this action pursuant to the APA.

5. Venue is properly vested in this Court pursuant to 28 U.S.C. § 1391(e) because the Defendants and Plaintiffs in this action reside and/or are based in this district and a substantial part of the events and omissions which gave rise to this action occurred in this district.

PARTIES

6. Plaintiff International Center for Technology Assessment (CTA) is located at 660 Pennsylvania Ave., S.E., Suite 302, Washington, DC 20003. Plaintiff is a tax-exempt, non-profit organization incorporated in the District of Columbia. Since its inception in 1994, the activities of CTA have been centered in several areas including addressing the environmental, economic, ethical and social concerns raised by the development and commercialization of agricultural, aquaculture, and related technologies.

7. To achieve its organizational goals, CTA participates extensively in the agency decision making process through petitions to various agencies, comments on agency rulemaking, calls for formal investigations, other administrative actions and appeals, and meetings with agency officials. As part of this work, CTA develops and disseminates to agencies, members of Congress and state governments, and the general public a wide array of educational and informational materials that address the environmental, economic, ethical and social impacts associated with use and release of genetically engineered animals. CTA's materials often analyze legal and regulatory means to address these impacts.

8. The interests of CTA are being, and will be, adversely affected by Defendants' actions complained of herein. In particular, the secretive, unaccountable way that Defendants have acted in their refusal to regulate genetically engineered ornamental fish and their failure to conduct NEPA compliance for their proposal-specific and programmatic actions with respect to the regulation of all genetically engineered animals injures CTA's ongoing operations by, *inter alia*, adversely affecting the organization's ability to disseminate information to the public, federal and state employees, policymakers, and others concerning the use and regulation of genetically engineered animal varieties.

9. Defendants' actions allowing the release of GE ornamental fish and other animal varieties into the environment also ensures that individuals serving on CTA's Board of Directors are, and will be, aesthetically, physically and recreationally injured. CTA's Board Members regularly visit parks, natural areas, and other places with native fish and natural habitat areas that are threatened by Defendants' actions allowing genetically engineered ornamental fish to be commercialized, distributed, and thereby released into freshwaters broadly around the nation without Federal regulation. Defendants' actions injure CTA Board Members by interfering, *inter*

alia, with their aesthetic enjoyment of native species and with their use and enjoyment of parks, natural areas, and other habitats with native fish, including, but not limited to, tropical and subtropical waters, warm springs around the nation, and the numerous others areas where ornamental fish may survive and outcompete or otherwise interfere with native species. The imminent appearance of genetically engineered ornamental fish in the nation's public and private waters further threatens CTA Board Members' ability to enjoy recreational fishing, swimming, snorkeling, warm spring bathing, and other aquatic activities.

10. Additionally, the imminent release of genetically engineered ornamental fish into the environment and the consumption of them by other carnivorous fish as part of the food chain means that such carnivorous fish will be caught or purchased and consumed by CTA Board Members. Such results compel their involuntary consumption of genetically engineered ornamental fish that have not been approved as safe for use as human or animal food.

11. Further, the ongoing and imminent release of genetically engineered ornamental fish into the environment will cause CTA Board Members to suffer from increased exposure to antibiotic-resistant bacteria and the health impacts therefrom as a result of the unsafe use of antibiotic-resistance genes and the exposure to viruses and other inserted constructs used in the engineering of the GloFish and other ornamental fish.

12. Finally, Defendants' ongoing failure to conduct NEPA compliance for their proposal-specific and programmatic actions with respect to the regulation of all genetically engineered animals causes CTA Board Members environmental, health, aesthetic, and other injuries resulting from the commercialization and use of such animals. These injuries include the consumption of genetically engineered animals resulting from their accidentally and/or purposefully use in the human food supply and aesthetic injury from viewing genetically

engineered of GloFish and other animals in aquaria and other captive situations.

13 Plaintiff Center for Food Safety (CFS) is located at 660 Pennsylvania Ave., SE, Suite 302, Washington, DC 20003. CFS is a national non-profit membership organization with members in almost every State across the country, including in the tropical and subtropical States of Hawai'i and Florida, and numerous States that contain warm springs. Since the organization's founding in 1997, the activities of CFS have been centered in several areas including addressing the environmental, economic, ethical, human health and social concerns raised by the development and commercialization of agricultural, aquaculture, and food processing technologies. Plaintiff CFS seeks to protect human health and the environment by ensuring that products of genetic engineering are thoroughly tested prior to any marketing; that such products are tested in a manner that minimizes any risk of contaminating food supplies or the environment; and that products created through genetic engineering, if on the market, are appropriately labeled.

14. To achieve these goals, CFS disseminates to its members, government agencies, members of Congress and state governments, and the general public, a wide array of educational and informational materials addressing the introduction of genetically engineered animals into the environment and food supply. These materials include, but are not limited to, reprints of news articles, policy reports, legal briefs, press releases, action alerts, and fact sheets. Collectively, the dissemination of this material has made CFS an information clearinghouse for public involvement and governmental oversight of the use of genetic engineering in our nation's food supply and in the environment.

15. Plaintiff CFS brings this action on behalf of itself and its members. The interests of CFS and its members are being, and will be, adversely affected by Defendants' actions

complained of herein. In particular, the secretive, unaccountable way that Defendants have acted in their refusal to regulate genetically engineered ornamental fish and their failure to conduct NEPA compliance for their proposal-specific and programmatic actions with respect to the regulation of all genetically engineered animals injures CFS' ongoing operations by, *inter alia*, adversely affecting the organization's ability to disseminate information to the public, federal and state employees, policymakers, and others concerning the use and regulation of genetically engineered animal varieties.

16. Defendants' actions allowing the release of GE ornamental fish and other animal varieties into the environment also injures CFS members. In particular, CFS members regularly visit parks, natural areas, and other places with native fish and natural habitat areas that are threatened by Defendants' actions in allowing genetically engineered ornamental fish to be commercialized, distributed, and thereby released into freshwaters broadly around the nation with no Federal regulation. Defendants' actions will injure CFS members by interfering, *inter alia*, with their aesthetic enjoyment of native species and their use and enjoyment of parks, natural areas, and other habitats with native fish, including, but not limited to, tropical and subtropical waters, warm springs around the nation, and the numerous others areas where ornamental fish may survive and outcompete or otherwise interfere with native species. The imminent appearance of genetically engineered ornamental fish in the nation's public and private waters threatens CFS members' ability to enjoy recreational fishing, swimming, snorkeling, warm spring bathing, and other aquatic activities.

17. Defendants' failure to regulate genetically engineered ornamental fish also allows the imminent appearance of untested genetically engineered fish into the food supply where such fish species are produced for purported ornamental purposes but also used as food. Additionally, the

imminent release of genetically engineered ornamental fish into environmental and the consumption of them by other carnivorous fish as part of the food chain means that such carnivorous fish will be caught or purchased and consumed by CFS members. Such results compel CFS members' involuntary consumption of genetically engineered ornamental fish that have not been approved as safe for use as human or animal food.

18. Further, the ongoing and imminent release of genetically engineered ornamental fish into the environment will cause CFS members to suffer from increased exposure to antibiotic-resistant bacteria and the health impacts therefrom as a result of the unsafe use of antibiotic-resistance genes and the exposure to viruses and other inserted constructs used in the engineering of the GloFish and other ornamental fish.

19. Finally, Defendants' ongoing failure to conduct NEPA compliance for their proposal-specific and programmatic actions with respect to the regulation of all genetically engineered animals causes CFS members environmental, health, aesthetic, and other injuries resulting from the commercialization and use of such animals. These injuries include the consumption of genetically engineered animals resulting from their accidentally and/or purposefully use in the human food supply and aesthetic injury from viewing genetically engineered of GloFish and other animals in aquaria and other captive situations.

20. Defendant Tommie Thompson is sued in his official capacity as Secretary, United States Department of Health and Human Services (DHHS), with his principal place of business located at 200 Independence Avenue, S.W., Rm. 615-F, Washington, DC 20201. As Secretary, Defendant Thompson has the ultimate responsibility for the activities of the DHHS, including those actions complained of herein.

21. Defendant Mark McClellan is sued in his official capacity as Commissioner of the

DHHS Food and Drug Administration (FDA), with his principal place of business located at 14-71 Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. As Commissioner, Defendant McClellan is delegated the responsibility for activities of the FDA, including those actions complained of herein.

STATEMENT OF FACTS

22. The development and use of genetically engineered animals for food and ornamental purposes has expanded rapidly over the last several years. FDA has repeatedly asserted that inserted genetic constructs used in the creation of these animals and their expression products are "drugs" and will be regulated as "new animal drugs" under the NADA provisions of the FFDCA. Since at least 2001, FDA has acknowledged use of this NADA regulatory program as it considers the regulatory fate of a genetically engineered salmon developed by a company called AquaBounty Technologies.

23. Since 1998, FDA has also regulated the development of genetically engineered pigs designed to grower faster being developed by the University of Illinois at Urbana-Champaign under the NADA provisions of the FFDCA. In early 2003, FDA used this regulatory authority to investigate and determine that as many as 386 of these genetically engineered pigs were improperly sold to a livestock for slaughter and placed in the human food supply.

24. During a March 18, 2003, meeting with Defendants, and by follow up letter, FDA Deputy Commissioner Lester Crawford has acknowledged that at least 18 genetically engineered animal experiments and actions were being regulated under the FFDCA's NADA provisions.

25. These FDA's actions concerning the regulation of genetically engineered animals are consistent with other public pronouncements and actions. FDA, in a 2001 interagency effort with the White House's Council on Environmental Quality (CEQ) and Office of Science and

Technology Policy (OSTP) and other Federal agencies, later known as the Case Studies of Environmental Regulation for Biotechnology, made the legal determination in Sidebar No. I.A on Ornamental Fish, that the NADA provisions of the FFDCA apply to genetically engineered ornamental fish. FDA endorsed the statement therein that it would regulate them "similar" to the way it regulates genetically engineered salmon under the NADA requirements. Also, the genetically engineered salmon case study makes clear that whether a genetically engineered fish is intended as food or not is irrelevant to the applicability of FDA's NADA requirements.

26. Part of this action concerns a fluorescent genetically engineered variety of zebra danio (*Brachydanio rerio*), hereinafter referred to by its trademarked name GloFish. This fish is intended primarily for ornamental use in home aquariums but could be put to other uses and readily enter the animal and human food chains through accidental or intentional releases. The GloFish now being sold contains inserted genetic constructs including genes from a sea anenome that cause it to glow fluorescent red and which may result in other expression products. On information and belief, the genetic modification of the GloFish occurs by use of genes, promoters, and vectors that may cause potentially harmful environmental, animal health, and human health impacts. Green and yellow versions of the GloFish also are likely to be released soon; they will present the same or similar risks.

27. GloFish are genetically engineered with the aid of plasmids, specifically: *pdsRed-1* (for red coloration), *pEGFP-1* (enhanced green fluorescence protein), and *pEYFP-1* (enhanced yellow fluorescence protein). Each of these plasmids contain antibiotic resistance marker genes. Several scientists have cautioned about potential negative impacts from the wide use of antibiotic resistance marker genes, as they may result in long-term environmental, animal health, and human health impacts. GloFish also contain novel potentially mobilizing genetic sequences.

They are created utilizing a shuttle vector, which is a vector capable of replicating itself in other species as well as the host species. Further, the GloFish are engineered in such a way that they contain other potentially dangerous material, including, but not limited to, simian and human viruses.

28. On information and belief, in the Fall of 2003, Yorktown Technologies, LLP, apparently requested approval for the GloFish from the FDA under the NADA provisions of the FFDCA. The FDA has failed to review this application under the NADA provisions and has not undertaken any approval process to date. Defendants nevertheless have allowed the GloFish to be commercialized by Yorktown Technologies and other businesses, including but not limited to 5-D Tropical and Segrest Farms, both of which are ornamental fish farmers based in Florida. Defendants' action is major and unprecedented because the GloFish is the first ever retail GE animal available in the United States.

29. On December 10, 2003, Defendants' issued an "FDA Statement" stating:

> *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.*

30. As a result of actions and subsequent statements, FDA has asserted that it does not have authority under the FFDCA to regulate the GloFish or other genetically engineered ornamental fish.

31. As of December 11, 2003, the Yorktown Technologies website, www.GloFish.com, carried this announcement: "AVAILABILITY UPDATE: In response to extraordinary consumer demand, limited numbers of GloFish™ fluorescent fish will be made available immediately." This announcement indicates that the GloFish are being shipped nationwide. Part of Yorktown

Technologies' stated justification for this early release of the GloFish was FDA's December 10 Statement that it did not have authority under the FFDCA to regulate them. But for FDA's actions and omissions, this hasty, unregulated commercialization of the first ever retail genetically engineered animal in the United States would not have occurred.

32. Over the past several months, Plaintiffs have urged the FDA repeatedly in writing, and in a December 15, 2003, direct meeting with FDA staff, to take the required regulatory actions sought herein. The FDA has refused Plaintiffs' requests and reiterated that it does not have authority under the FFDCA to regulate the GloFish.

33. On information and belief, on December 15, 2003, just prior to its meeting with Plaintiffs, FDA sought to conduct ESA Section 7 compliance by consulting over the phone with the U.S. Fish and Wildlife Service (FWS), with respect to potential impacts of the GloFish on threatened and endangered species. This action occurred well after FDA had already issued its public statement that it lack statutory authority to regulate the GloFish. To date, the FWS still has not offered its opinion back to FDA under Section 7.

34. On January 5, 2004, Yorktown Technologies, 5-D Tropical, Segrest Farms, and other companies carried out their announced national "roll-out" date for broad commercialization of the GloFish. The product is selling rapidly in virtually every market in the United States. The exception is in California, where the GloFish was banned by a December 3, 2003, decision by the California Fish and Game Commission.

35. Ornamental fish, such as the variety of zebra danio used to create the GloFish, are routinely dumped into marine and fresh water bodies by aquarium owners who no longer wish to keep them. Virtually all fisheries experts agree that the unregulated commercial sale of any genetically engineered ornamental fish, such as the GloFish, guarantees that unauthorized

releases of that fish will occur. Numerous tropical and otherwise warm water bodies occur within the United States and its territories where the GloFish could invade. Zebra danios are non-native fish that already have invaded in their non-transgenic form in warmsprings and other warm water locations around the United States, including, but likely not limited to, California, Connecticut, Florida, New Mexico, and Wyoming. Numerous invasions of other non-native fish, including dozens of ornamental species, have occurred across the United States throughout its history and in many cases have caused serious economic and environmental damage. According to the FWS, ornamental fish have been major factors in the endangerment of rare, endemic, native U.S. species, including at least the Moapa dace, desert pupfish, White River spinedace, Hiko White River springfish, Independence Valley speckled dace, Ash Meadows Amargosa pupfish, and Railroad Valley springfish.

36. When released into the wild, intentionally or accidentally, the GloFish are likely to be consumed by predatory fish, birds, and mammals and thereby enter the animal and human food chains. FDA has not analyzed the potential human and animal food safety significance of this fact.

37. On information and belief, the GloFish is just the first of many such products. Defendants actions allow, and will continue to allow, the unregulated commercialization of several other announced, or unannounced but readily foreseeable, varieties of genetically engineered ornamental fish - flourescent, colored, and otherwise. Some of these fish primarily developed for ornamental purposes can also be used and marketed for human consumption. News articles, industry statements and websites, and admissions from FDA officials make clear that more genetically engineered ornamental fish are being developed. On information and belief, the genetic modification of these other ornamental fish will occurs by use of genes,

vectors, and promoters that may cause unanticipated effects, including potentially harmful environmental, animal health, and human health impacts.

38. Plaintiffs and members of the public may be exposed to antibiotic-resistant bacteria and suffer health impacts therefrom as a result of the unsafe use of antibiotic-resistance genes, in addition to exposure to viruses and other inserted constructs, in the engineering of the GloFish and other ornamental fish. Defendants have refused and failed to formally assess these constructs with respect to the safety of these risky engineering approaches.

39. In 2002, the National Academy of Sciences issued a contracted report on genetically engineered animals at FDA's specific request, entitled "Animal Biotechnology: Science-Based Concerns," which makes clear that the environmental impacts of genetically engineered fish could be serious and unpredictable. In addition, the UN Food and Agriculture Organization issued a report in 2003, entitled "Status of Genetically Modified Fish: Research and Application," which cautions specifically about fluorescent genetically engineered ornamental fish, stating that they could pose "additional environmental risk issues" if they are widely popular and sold into "into thousands or millions of households," rendering further monitoring of confinement "impossible". This scenario is occurring now with the flourescent GloFish and is imminent, or may even be ongoing, with other already-announced genetically engineered ornamental fish.

40. FDA's denial of authority under the FFDCA and failure to comply with NEPA are allowing, and will allow, piecemeal, unanalyzed commercialization of unlimited numbers of GloFish and other foreseeable genetically engineered ornamental fish or traditionally non-food animals to occur across the country and pose serious potential environmental, animal health, and human health risks as they are released into the environment and enter the animal and human food chains, harming Plaintiffs thereby.

41. This action also challenges the Defendants' failure to comply with NEPA as they have conducted their programmatic actions with respect to the regulation of all genetically engineered animals under the NADA provisions of the FFDCA, not limited to ornamental fish. On information and belief, Defendants have dozens of proposals before them to commercialize a broad variety of genetically engineered animals of several varieties, including wild and domestic animals, and food and non-food animals. In response, Defendants have taken such unprecedented programmatic actions as: participating in the CEQ/OSTP Case Studies; issuing warning letters to universities regarding the disposition of genetically engineered animals; contracting the report from the National Academy of Sciences on food, animal, and environmental safety issues with bioengineered animals "to help it develop its regulatory approach"; and made numerous public statements regarding its regulatory approach.

42. This concerted series of actions constitutes a new, distinctive, and unprecedented program for genetically engineered animals. Defendants' failure to conduct NEPA compliance for their programmatic actions with respect to the regulation of all genetically engineered animals exposes Plaintiffs to greater likelihood of suffering environmental, health, aesthetic, and other injuries resulting from unanalyzed risks of such animals. Such unanalyzed risks of Defendants' programmatic actions include: risks of genetically engineered animals being accidentally or purposefully allowed to enter the human food supply, which already has occurred; risks of genetically engineered animals being accidentally or purposefully released into the environment, which already has occurred, and causing ecological, health, and aesthetic injuries resulting from grotesque and offensive genetic engineering of animals contrary to accepted norms of animal welfare, which already has occurred.

43. The Introduction to the CEQ/OSTP Assessment states, at page 1:

> *As part of the generation of these case studies, agencies have been reviewing their own procedures and policies, and intend to continue to do so. Should an agency determine that major changes in policy or procedures are warranted, it would only do so through a notice and comment procedure to ensure full public participation.*

FDA actions with respect to the GloFish have contravened this commitment to make any major change in its programs with respect to genetically engineered ornamental fish only pursuant to a notice and comment procedure, and thereby denied any public participation in that process, including by the Plaintiffs herein.

CAUSES OF ACTION

CLAIM ONE

Refusal and Failure to Assert Regulatory Authority over the GloFish under the New Animal Drug Provisions of the Federal Food, Drug And Cosmetic Act

44. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 43, *supra*.

45. FDA repeatedly has asserted that inserted genetic constructs in animals and their expression products will be regulated as "new animal drugs" under the FFDCA. The FFDCA definition of new animal drug, at 21 USC § 321(v) specifically covers use in all animals, as follows:

> *The term new animal drug means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed* [with certain inapplicable exceptions as far as animal feed].

46. FDA's NADA authority applies to "any particular use or intended use" without exception and makes no distinction between new animal drugs used in animals for food and non-food uses. However, FDA now has inconsistently, and arbitrarily and capriciously, denied regulatory authority over the GloFish by distinguishing between food and non-food uses as it has

applied its NADA authority.

47. In light of the foregoing, the Defendants violated the NADA provisions of the FFDCA, 21 U.S.C. § 360b, have caused reasonably foreseeable direct and indirect impacts to Plaintiffs, and their actions are arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of the procedures required by law, in violation of the APA.

CLAIM TWO

Use of an Erroneous Standard for Regulation of the GloFish and other Genetically Engineered Ornamental Fish

48. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 47 *supra.*

49. The FDA's NADA authority, 21 USC § 360b, provides:

> *(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 351(a)(5) of this title and section 342(a)(2)(D) of this title unless-(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug, and (B) such drug, its labeling, and such use conform to such approved application.*

In the Fall of 2003, Yorktown Technologies, LLP, apparently requested approval for the GloFish from the FDA under the NADA provisions of the FFDCA. The FDA has failed to review this application under the NADA provisions and has not undertaken any approval process to date

50. FDA's NADA authority unambiguously requires that all new animal drugs shall be preliminarily "deemed unsafe." Nevertheless, in acting not to assert jurisdiction over the GloFish, FDA arbitrarily and capriciously decided to treat the GloFish NADA application pursuant to a different threshold regulatory standard, the "absence of a clear risk to the public health." That is not a regulatory standard recognized in any applicable provisions of the FFDCA.

FDA's use of that "absence" standard as a threshold for deciding whether to regulate the GloFish illegally reverses the threshold in its NADA authority requiring FDA to presume the GloFish to be unsafe and to regulate it pursuant to the detailed NADA requirements.

51. In light of the foregoing, the Defendants violated the NADA provisions of the FFDCA, 21 U.S.C. § 360b, have caused reasonably foreseeable direct and indirect impacts to Plaintiffs, and their actions are arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of the procedures required by law, in violation of the APA.

CLAIM THREE

Proposal-specific National Environmental Policy Act Requirements for Commercialization of the GloFish

52. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 51 *supra.*

53. Section 102(2)(C) of NEPA, (42 U.S.C. §4332(2)(C)), requires each Federal agency to prepare an environmental impact statement (EIS) with respect to each major action of such agency that may significantly affect the quality of the human environment. The FDA is required to prepare a full EIS or at least an environmental assessment (EA) for its major, unprecedented action allowing the proposed commercialization of the GloFish, the first ever retail genetically engineered animals in the United States.

54. Defendants have failed and refused to prepare any EIS or EA for their actions in deciding to allow the proposed commercialization of the GloFish. The Defendants' actions violate section 102(2)(C) of NEPA and the implementing regulations promulgated by the FDA, 21 C.F.R. Part 25, and by the CEQ, at 40 C.F.R. § 1500 *et seq.*

55. In light of the foregoing, Defendants have violated NEPA and the implementing

regulations, have caused reasonably foreseeable direct and indirect impacts to Plaintiffs, and their actions are arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the APA.

CLAIM FOUR

Programmatic National Environmental Policy Act Requirements with Respect to Regulation of All Genetically Engineered Animals

56. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 55 *supra*.

57. Section 102(2)(C) of NEPA, (42 U.S.C. §4332(2)(C)), requires each Federal agency to prepare an EIS with respect to each major action of such agency that may significantly affect the quality of the human environment.

58. Applicable regulations define very broadly the federal "actions" that are subject to NEPA's requirement, and include "[a]doption of programs, such as a group of concerted actions to implement a specific policy or plan; systematic and connected agency decisions allocating agency resources to implement a specific statutory program or executive directive." 40 C.F.R. § 1508.18(b)(3). Defendants' regulations implementing NEPA require that the agency undertake a full EIS or at least an EA for their programmatic actions, including with respect to their decisions regarding the GloFish and other genetically engineered ornamental fish, and with respect to genetically engineered animals generally.

59. Since 1998, the FDA Defendants' decisionmaking actions and policies with respect to the GloFish and other genetically engineered ornamental fish, and with respect to genetically engineered animals generally, have amounted to adoption of a "program" in that they are "a group of concerted actions to implement a specific statutory program or executive directive."

60. Defendants have failed and refused to prepare any EIS or EA for their

unprecedented programmatic actions with respect to genetically engineered animals, including their actions in allowing the unregulated commercialization of the GloFish pursuant to a changed and novel regulatory standard. Their failure and refusal to comply with NEPA's requirements for programmatic actions is allowing and will allow piecemeal, unanalyzed commercialization of unlimited numbers of GloFish and other foreseeable genetically engineered animals to occur across the country and pose serious potential environmental, animal health, and human health risks as they are released into the environment and enter the animal and human food chains.

61. In light of the foregoing, Defendants have violated NEPA and its implementing regulations, have caused reasonably foreseeable direct and indirect impacts to Plaintiffs, and their actions are arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the APA.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request this Court to,

(1). Declare that Defendants have authority under the New Animal Drug Application provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360b, to regulate all genetically engineered fish, including, but not limited to, ornamental fish;

(2). Declare that Defendants' actions in allowing the unregulated commercialization of the GloFish and any other genetically engineered ornamental fish based on the threshold standard of the "absence of a clear risk to public health" are arbitrary, capricious, an abuse of discretion, and not in accordance with law and a violation of the Federal Food, Drug and Cosmetic Act and the Administrative Procedure Act;

(3). Order the Defendants to require full consideration of the GloFish proposal and any other genetically engineered ornamental fish proposals under the New Animal Drug Application

provisions of the Federal Food, Drug and Cosmetic Act;

(4). Declare that Defendants' proposal-specific actions in allowing the commercialization of the GloFish failed to comply with the National Environmental Policy Act and the implementing regulations issued thereunder and are arbitrary, capricious, an abuse of discretion, and not in accordance with law;

(5). Declare that Defendants' programmatic actions with respect to the regulation of genetically engineered ornamental fish and other genetically engineered animals failed to comply with the National Environmental Policy Act and the implementing regulations issued thereunder and are arbitrary, capricious, an abuse of discretion, and not in accordance with law;

(6). Enjoin Defendants from allowing any further sales of the GloFish and from allowing any further proposals for commercialization of genetically engineered ornamental fish until Defendants have complied with the New Animal Drug Application provisions of the Federal Food, Drug and Cosmetic Act and with the National Environmental Policy Act;

(7). Enjoin Defendants from allowing any proposals for commercialization of any genetically engineered animals whatsoever until Defendants have prepared a programmatic environmental impact statement for their regulatory program for them under the National Environmental Policy Act;

(8). Direct Defendants to utilize their authority under 21 U.S.C. § 360b(e), and other relevant statutes, to immediately suspend and withdraw any approval of GloFish and to recall existing GloFish and any other genetically engineered ornamental fish that are in the commercial marketplace at the time of the Court's order,

(9). Retain jurisdiction of this action to ensure compliance with its decree;

(10). Award Plaintiffs' attorney's fees and other reasonable expenses occurred in this

action; *and*

(11). Grant such other relief as the Court deems just and proper.

Respectfully submitted,

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