UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC.; CENTER FOR SCIENCE IN THE PUBLIC INTEREST; FOOD ANIMAL CONCERNS TRUST; PUBLIC CITIZEN, INC.; and UNION OF CONCERNED SCIENTISTS, INC.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration; CENTER FOR VETERINARY MEDICINE; BERNADETTE DUNHAM, in her official capacity as Director, Center for Veterinary Medicine; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services,

Defendants.

11 Civ. 3562 (THK)
ECF Case

MEMORANDUM OF LAW IN SUPPORT OF THE GOVERNMENT'S MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' FIRST SUPPLEMENTAL COMPLAINT AND IN OPPOSITION TO PLAINTIFF'S SECOND MOTION FOR SUMMARY JUDGMENT

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The above-captioned defendants (the "Government"), by their attorney, Preet Bharara, United States Attorney for the Southern District of New York, respectfully submit this memorandum of law in support of their Motion for Summary Judgment Pursuant to Federal Rules of Civil Procedure 56 on Plaintiffs First Supplemental Complaint and in Opposition to Plaintiffs' Second Motion for Summary Judgment, dated February 21, 2012 ("Plfs' Br.").

PRELIMINARY STATEMENT

Plaintiffs' challenge to the denial by the United States Food and Drug Administration ("FDA" or "Agency") of two citizen petitions brought by certain of the Plaintiffs (the "Citizen Petitions") is not subject to judicial review under Administrative Procedure Act ("APA"), 5 U.S.C. § 501 *et seq*. Moreover, even if FDA's responses to the Citizen Petitions (the "Petition Responses") were subject judicial review, because those responses are neither arbitrary nor capricious, there is no basis to remand them to FDA.

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, FDA may initiate formal proceedings to withdraw drugs from the market when it believes that they are "unsafe" or "not shown to be safe." 21 U.S.C. § 360b(e)(1). Determining whether a drug is safe requires FDA to balance a number of factors and make scientific decisions within its delegated area of expertise. Withdrawal proceedings are relatively uncommon, for drug companies often voluntarily remove products from the market when serious safety questions arise. Because withdrawal proceedings are expensive and time consuming, the Agency usually focuses on voluntary measures first, although it can and does initiate formal withdrawal proceedings in appropriate circumstances when needed.

With respect to antibiotics in livestock, FDA has acknowledged that it has significant concerns about the potential public health consequences of misusing and overusing such drugs.

In particular, FDA has recently made clear that it does not consider the use of medically important antibiotics[1] for "growth promotion" in animals to be in the interest of public health. Accordingly, as FDA explained in the Petition Responses, the Agency is pursuing a plan to obtain industry cooperation to reduce the uses of antibiotics in animals based on principles articulated in its guidance documents.

This case is *not* about whether the phenomenon of antimicrobial resistance exists, whether antimicrobial resistance poses a threat to public health, whether the overuse of antimicrobial drugs in food-producing animals can contribute to the development of antimicrobial resistance, or whether the FDA should be involved in mitigating the risks posed by antimicrobial resistance. The answer to each of these questions is yes, and it is for these reasons that FDA has been actively involved in the area of antimicrobial resistance for over 40 years. This is also why, since at least 2003, the issue of the overuse of antimicrobial drugs in food producing animals has been a particular focus of the work done by FDA' s Center for Veterinary Medicine.

Despite the general agreement between the parties on some important issues, however, Plaintiffs are not entitled to dictate FDA's policy judgments and enforcement priorities, particularly with respect to the Agency's choice of the appropriate process to accomplish a policy goal. The Agency's decision whether and when to proceed with administrative withdrawal proceeding rests firmly within FDA's discretion under the Supreme Court's decision in *Heckler v. Chaney*, 470 U.S. 821 (1985), and its progeny. As that case law reflects, the FDCA grants broad discretion to FDA to select from a number of regulatory options to address these

[1] The term "medically important antimicrobial drugs" generally refers to antimicrobial drugs that are important for therapeutic use in humans. *See* Declaration of Amy A. Barcelo dated January 9, 2012 (Jan. Barcelo Decl.") (Dkt. No. 44) Ex. C at 1.

concerns, and specifically grants FDA unreviewable discretion to determine whether and when to pursue the more formal enforcement proceedings that Plaintiffs request.

Even if the Petition Responses were subject to some judicial review (which necessarily would be very deferential), FDA's decision to work with drug sponsors to achieve voluntary compliance with FDA's goals in the first instance was neither "arbitrary nor capricious," but rather reasonable and entitled to deference by the Court. Because the Agency has provided a complete (and entirely rational) explanation for its determination to forego formal withdrawal proceedings at this time, there would be no basis to vacate and remand the Petition Responses, nor to compel FDA to further address the Citizen Petitions. Accordingly, the Court should enter judgment for the Government.

BACKGROUND

A. FDA's Regulation of New Animal Drugs and Statutory Provisions Governing Withdrawals of Drug Use Approvals

The FDCA prohibits the introduction into interstate commerce of any new animal drug,[2] unless it is the subject of an approved new animal drug application ("NADA"), or, with respect to generic animal drugs, an abbreviated NADA ("ANADA"). 21 U.S.C. § 360b(a)(1)(A).[3] The NADA or ANADA for each new animal drug specifies which uses (also known as "indications") have been approved by FDA (*i.e.*, which diseases the new animal drug has been approved to

[2] A new animal drug is defined, in part, as any drug intended for use in animals other than man, including any drug intended for use in animal feed but not including the animal feed, the composition of which is such that the drug is not generally recognized as safe and effective for the use under the conditions prescribed, recommended, or suggest in the labeling of the drug. *See* 21 U.S.C. § 321(v).

[3] A new animal drug may also be introduced into interstate commerce if there is a conditional approval in effect pursuant to 21 U.S.C. § 360ccc or there is an index listing in effect pursuant to 21 USC § 360ccc-1. Neither of these provisions is relevant here.

prevent or treat). *Id.* There is no allegation that any drugs at issue in this litigation are not new animal drugs that are currently sold lawfully pursuant to approved NADAs or ANADAs.

FDA will not approve a new animal drug application if the evidence does "not show that such drug is safe for use" under specified conditions of use. *See* 21 U.S.C. § 360b(d)(1)(B). Under the FDCA, the determination of "safety" involves a use-specific balancing of risks against benefits for each specific use of a drug. *See United States* v. *Rutherford*, 442 U.S. 544, 555 (1979) ("Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk."). For a new animal drug intended for use in food-producing animals, FDA will not find it to be "safe" unless the drug sponsor demonstrates that there is a "reasonable certainty of no harm to human health" with respect to the food produced from treated animals. *See* Jan. Barcelo Decl. Ex. N at 94-95. Furthermore, a new animal drug used in animal feed is unsafe as a matter of law unless there is in effect an approved NADA or ANADA by FDA with regard to the drug's use or intended use, and unless such drug, its labeling (reflecting approved uses), and actual use conform to the approved application.[4] *See* 21 U.S.C. §§ 360b(a)(1), (4).

New animal drugs fall into three classifications of approved uses: (1) over-the-counter, (2) prescription, or (3) veterinary feed directive ("VFD"). Most antimicrobial[5] new animal drugs are currently labeled as over-the-counter, which means they may be used by anyone, including a lay person, in accordance with the labeled direction. A VFD drug, like a prescription drug, may be used only at the direction of a licensed veterinarian. *See* 21 U.S.C. §§ 353(f)(1)(A); 354. The

[4] While most animal drugs may be used lawfully in an "extra-label" manner in accordance with 21 C.F.R. § 530, this exception does not apply to drugs used in animal feeds. *See* 21 C.F.R. § 530.11(b).

[5] "Antimicrobial drugs" are drugs that work against a variety of microorganisms, such as bacteria, viruses, fungi, and parasites. Antimicrobial drugs that work specifically against bacteria are called "antibacterial drugs" or "antibiotics." *See* Jan. Barcelo Decl. Ex. C at 1.

VFD classification was established pursuant to the Animal Drug Availability Act of 1996 (*See* Pub. L. 104-250, § 504, 110 Stat. 3151 (1996)), and FDA has described it as "critical to reducing unnecessary use of [] drugs in animals and to slowing or preventing any potential for the development of bacterial resistance to antimicrobial drugs." *See* Final Rule, 65 Fed. Reg. 76924 (December 8, 2000).

The FDCA also establishes procedures whereby the FDA can withdraw an approved NADA or ANADA. Specifically, under 21 U.S.C. § 360b(e)(1), "the [Commissioner][6] shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an [NADA] with respect to any new animal drug if the [Commissioner] finds" that any of the conditions or events enumerated in 21 U.S.C. § 360b(e)(1)(A) through (F) are shown to have occurred. 21 U.S.C. § 360b(e)(1)(B) provides the basis for such a finding by the Commissioner if "new evidence [obtained in certain circumstances] evaluated together with the evidence available to the [Commissioner] when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved."

Although FDA exercises its withdrawal authority when necessary, FDA's general approach is to encourage voluntary compliance whenever possible before initiating enforcement proceedings.[7] FDA has had success with this approach in the past,[8] which conserves Agency

[6]The authority of the Secretary of Health and Human Services to approve animal drugs has been delegated to the Commissioner of Food and Drug. *See* Jan. Barcelo Decl. Ex. A.

[7] *See, e.g.*, Center for Veterinary Medicine, Program Policy and Procedure Manual, Voluntary Compliance, Declaration of Amy A. Barcelo dated March 21, 2012 (Second Barcelo Decl.") Ex. A; *see also* FDA Regulatory Procedures Manual, § 4-1-1 ("[I]t is [FDA's] practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action"), Second Barcelo Decl. Ex. B; FDA Investigations Operations Manual, § 2.6.1,("FDA uses a blend of industry voluntary correction and regulatory actions to help achieve industry compliance."), Second Barcelo Decl. Ex. C.

resources and enhances FDA's ability to protect the public health by allowing it to focus its resources only where necessary.

B. FDA's Regulation of Antimicrobial Drug Products For Animals

The Government described the history of FDA's regulation of antimicrobial drug products in the background section of its Brief in Support of its First Summary Judgment Motion ("Govt's First S.J. Br.") (Dkt. No. 41), and will briefly highlight a few of those points here. Specifically, after FDA began to have concerns in the 1960s regarding whether the use of antibiotics in animal feed to promote growth of food producing animals caused "antimicrobial resistance" (*i.e.*, a decreased susceptibility of bacteria to an antimicrobial drug), FDA dedicated substantial resources to researching these issues over the following decades. *See id.* at 5-7. In 2003, FDA issued Guidance for Industry #152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern* ("GFI 152"), Jan. Barcelo Decl. Ex. H, which recommended a new approach for evaluating antimicrobial resistance associated with the use of antimicrobial new animal drugs in food-producing animals. *See* Govt's First S.J. Br. at 7 (describing GFI 152).

Following additional research and analysis, in 2010, FDA published a draft guidance titled, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*, draft Guidance for Industry #209 ("Draft Guidance 209"). Govt's First S.J. Br. at 8-9 (discussing Draft Guidance 209), Jan. Barcelo Decl. Ex. B. Draft Guidance 209 explains FDA's

[8] FDA's website reflects examples of instances in which drug sponsors have voluntarily agreed to suspend sales of new animal drugs. *See* http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm257540.htm (sponsor voluntarily suspended sales of Roxarsone); http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm084110.htm (sponsor voluntarily suspended sales of Proheart 6); *see also* http://www.gpo.gov/fdsys/pkg/FR-2001-04-30/html/01-10067.htm (reflecting voluntary withdrawal of sarafloxacin by drug sponsor).

position that use of antimicrobial drugs to promote growth or improve feed efficiency represents an injudicious use, and explains that the Agency's corresponding position that: "[t]he use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation," and only used for "prevention indications [that] are necessary and judicious." Jan. Barcelo Ex. B at 16-17.

C. The Citizen Petitions.

Prior to FDA's publication of GFI 152, on March 9, 1999, several of the Plaintiffs petitioned FDA pursuant to 21 C.F.R. § 10.30, and requested that the Agency "rescind approvals for subtherapeutic uses in livestock of any antibiotic used in (or related to those used in) human medicine." *See* Second Barcelo Decl. Ex. D at 1-2. On April 7, 2005, two of the Plaintiffs submitted a second petition requesting similar relief—*i.e.*, that FDA withdraw approval for "herdwide/flockwide" uses of seven classes of antibiotics in chicken, swine, and cattle for purposes of growth promotion, disease prevention, and disease control. *See* Second Barcelo Decl. Ex. E at 1. FDA estimates that together the Citizen Petitions cover approximately 161 individual approved drug products, including NADAs, ANADAs, and approved combination products (the "Citizen Petition Drugs").

FDA provided tentative, but substantive, responses to the Citizen Petitions on February 28, 2001, and October 4, 2005, respectively. Second Barcelo Decl. Exs. F, G (the "Tentative Responses"). In the Tentative Responses, FDA explained that the Agency would not grant the Citizen Petitions at that time because the statutory standards for the withdrawal of the relevant antimicrobial drugs set forth in 21 U.S.C. § 360b(e)(1) had not been satisfied, as the Commissioner has never rendered the findings required to proceed with a withdrawal. *See* Second Barcelo Decl. Exs. F at 2-4, Ex. G. However, FDA explained that it was not formally

denying the Citizen Petitions at that time because it recognized that it may decide to proceed with such withdrawals in the future. *See* Second Barcelo Decl. Exs. F at 4, G at 3.

Also in 2005, after an almost five-year process, FDA withdrew the approval for the use of the antimicrobial drug enrofloxacin in poultry on the ground that it had not been shown to be safe and could contribute to the emergence of antimicrobial resistance in humans. *See* Jan. Barcelo Decl. Ex. N. Otherwise, the status described in the Tentative Responses remains current—*i.e.*, the FDA has not pursued formal withdrawal proceedings pursuant to 21 U.S.C. § 360b(e)(1) in connection with the Citizen Petition Drugs.

On November 7, 2011, FDA issued the Petition Responses. *See* Jan. Barcelo Decl. Exs. I & J. The Petition Responses denied the request in the Citizen Petitions for "the immediate issuance by the FDA Commissioner of an order withdrawing the approvals of subtherapeutic uses of medically important antimicrobials in livestock feed" on the ground that the "formal evidentiary process that must be followed before new animal drug approvals may be withdrawn" had not transpired, and, accordingly, no statutory findings had been made. *See* Jan. Barcelo Decl. Ex. I at 2; *see also* Ex. J at 2.

To the extent that the petitioners sought for FDA to institute formal withdrawal proceedings for the Citizen Petition Drugs, the Petition Responses denied that request because the Agency "is currently pursuing other alternatives to address the issue of antimicrobial resistance related to the production use of antimicrobials in animal agriculture." Jan. Barcelo Decl. Ex. I at 3, Ex. J at 2. Specifically, FDA explained its belief that "the animal pharmaceutical industry is generally responsive to the prospect of working cooperatively with the Agency to implement the principles recommended in [Draft Guidance 209]." Jan. Barcelo Decl. Ex. I at 4, Ex. J at 3. Accordingly, for production indications, FDA stated that it "intends

to work with sponsors who approach FDA and are interested in working cooperatively with the Agency to phase out production uses of medically important antimicrobials." With regard to currently approved therapeutic indications (*e.g.*, for approved disease treatment or prevention indications), FDA plans to "transition medically important antimicrobials currently approved for over-the-counter use in food-producing animals to . . . VFD status for feed use drugs, and prescription status for drugs approved for use through other routes of administration." Jan. Barcelo Decl. Ex. I at 4, Ex. J at 3.[9]

FDA explained its expectation that the regulatory strategy it was pursuing would "achieve the same goals" as those for which Plaintiffs advocated in the Citizen Petitions, but in a more targeted and efficient manner. Jan. Barcelo Decl. Ex. I at 3, Ex. J at 3. The Agency explained its decision to initially pursue a voluntary strategy because its experience with contested, formal withdrawal proceedings demonstrated that the withdrawal process can consume extensive periods of time and Agency resources. Jan. Barcelo Decl. Ex. I at 3, Ex. J at 2-3 (citing examples). Finally, the Agency made clear that its strategy did "not foreclose initiating withdrawal proceedings in the future." Jan. Barcelo Decl. Ex. I at 4, Ex. J at 4.

D. Plaintiffs' Claims in This Action

Plaintiffs began this action by filing a Complaint on May 25, 2011, which they then amended on July 7, 2011. (Dkt. No. 11). Following litigation on the two claims contained in the First Amended Complaint, on February 2, 2012, Plaintiffs filed their First Supplemental Complaint. (Dkt. No. 53). The Supplemental Complaint alleges that the Petition Responses

[9] As part of the proposed strategy, FDA noted that it had "issued an advance notice of proposed rulemaking ("ANPRM") in March 2010 to seek public comment on whether and to what extent efficiency improvements should be made to the current VFD process as set forth in FDA's regulation at 21 CFR 558.6" and that "FDA received numerous public comments in response to the ANPRM and is taking those comments into consideration in drafting a revised rule." *See* Jan. Barcelo Decl. Ex. I at 4, Ex. J at 3-4; *see also* Jan. Barcelo Decl. Ex. K.

should be remanded to FDA as "arbitrary and capricious" on the grounds that "FDA's stated reasons for denying the [Citizen] Petitions . . . are not grounded in the [FDCA]." Supp. Compl. ¶ 36; *see also id.* at ¶¶ 37-38.

ARGUMENT

Plaintiffs are incorrect in asserting that FDA must initiate proceedings to withdraw approvals for the Citizen Petition Drugs at this time. The FDCA does not compel the Agency to engage in the one particular course of action that Plaintiffs advocate on Plaintiffs' timetable, but instead provides FDA with the discretion to select from a number of regulatory options. Plaintiffs cannot prevail in their efforts to compel FDA to initiate animal drug approval withdrawal proceedings because, as the Supreme Court has determined, FDA has unreviewable discretion to determine whether and when to initiate enforcement action. However, even if the presumption against judicial review established in *Heckler v. Chaney*, 470 U.S. 821 (1985), does not apply here, this Court should review this matter under the deferential standards of the APA. Because FDA's choice of regulatory pathways is reasonable, it is entitled to deference by the Court. Accordingly, the Court should enter judgment for the Government.

I. THE COURT LACKS SUBJECT MATTER JURISDICTION OVER FDA'S DENIAL OF THE CITIZEN PETITIONS BECAUSE THE DECISION WHETHER AND WHEN TO PURSUE THE WITHDRAWAL OF ANIMAL DRUG APPROVALS IS COMMITTED TO AGENCY DISCRETION BY LAW

A. Standard for Preclusion of Review under the APA and *Heckler v. Chaney*

Pursuant to 5 U.S.C. § 701(a)(2), a court may not judicially review agency action "'to the extent that' such action 'is committed to agency discretion by law.'" *Lunney v. United States*, 319 F.3d 550, 558 (2d Cir. 2003) (quoting *Lincoln v. Vigil*, 508 U.S. 182, 190-91 (1993)). Because the APA constitutes a limited waiver of sovereign immunity, if 5 U.S.C. § 701(a)(2) applies, then no subject matter jurisdiction exists over the challenge to such action. *Id.*

The bar to judicial review contained in 5 U.S.C. § 701(a)(2) applies both when the statute at issue is written in such broad terms that "there is no law to apply," *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 410 (1971), and when the language of the statute "'is drawn so that a court would have *no meaningful standard* against which to judge the agency's exercise of discretion.'" *Lunney*, 319 F.3d at 558 (quoting *Chaney*, 470 U.S. at 830) (emphasis in original). Accordingly, for subject matter jurisdiction to exist over their claim, Plaintiffs "must specify some statute or regulation that would limit [FDA's] discretion in this matter." *Id.*; *see also Chaney*, 470 U.S. at 830.

In *Heckler v. Chaney*, 470 U.S. 821 (1985), the Supreme Court expanded upon its prior holdings on the subject of agency discretion and held that where, as here, the agency decides not to undertake an enforcement action, there is a presumption that the agency's decision is not subject to judicial review. *Id.* at 838; *see also id.* at 831. The Second Circuit has made clear that *Chaney*'s presumption of non-reviewability applies not only to "pure" enforcement relief, but to all challenges seeking to compel an agency to "enforce the statutes and regulations under its authority . . . in the manner in which [a plaintiff] thought they should be enforced."[10] *Riverkeeper, Inc. v. Collins*, 359 F.3d 156, 166 n.11 (2d Cir. 2004).

In *Chaney*, inmates who had been sentenced to death by lethal injection petitioned FDA for relief, arguing that, pursuant to 21 U.S.C. § 355, FDA was "required" to take investigatory and enforcement action to prevent the use of drugs in executions that were not approved for such use. 470 U.S. at 824. FDA denied the petitions and explained that its decision to not undertake such actions fell within the scope of its enforcement discretion. *Id.* at 824-25. In subsequent

[10] Although *Riverkeeper* court also concluded that plaintiffs had waived their argument that the agency action at issue was not in the nature of "enforcement," the court nevertheless addressed whether the agency action at issue constituted enforcement action. 359 F.3d at 116 n.11.

litigation, the D.C. Circuit sided with the inmates, held that FDA had not "fulfill[ed] it statutory function," and remanded the action to the district court with instructions to require FDA to perform a "searching consideration" of the evidence submitted by the inmates in support of their petition. *Id.* at 827.

The Supreme Court then reversed the D.C. Circuit, holding that FDA's decision to not "investigate and enforce" was exempt from judicial review under the APA. *Id.* at 838. The majority reasoned that exercise of FDA's enforcement discretion is subject to a presumption of unreviewability (and was thus "committed to agency discretion by law" under 5 U.S.C. § 701(a)(1)) for three main reasons. First, the Court recognized that decisions implicating an agency's enforcement discretion "often involve[s] a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise." *Id.* at 831 (describing those factors as including: (1) where the agency's resources "are best spent," (2) the agency's chances of success in pursuing a particular action, (3) whether the particular enforcement action at issue "best fits the agency's overall policies," and, (4) "whether the agency has enough resources to undertake the action at all").

Second, the Court held that such a presumption of unreviewability is appropriate because "when an agency refuses to act it generally does not exercise its *coercive* power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect." *Id.* at 832. And finally, the Court explained that agencies are entitled to particular deference in their decisions not to enforce because those decisions are analogous to "the decision of a prosecutor in the Executive Branch not to indict," which traditionally involves executive control and judicial restraint. *Id.*

The *Chaney* court mentioned only two instances in which the presumption against judicial review might be overcome: (1) "where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers," *id.* at 833, or (2) perhaps when "the agency has 'consciously and expressly adopted a general policy' that is so extreme as to amount to an abdication of its statutory responsibility." *Id.* at 833 n.4.

B. FDA's Decision Not to Initiate Withdrawal Proceedings Is Not Subject to Judicial Review

As a preliminary matter, this Court need not determine if the *Chaney* presumption against judicial review applies in this case, because even without that presumption, 21 U.S.C. § 360b(b)(e)(1) does not provide any "law to apply" with respect to FDA's decision to not initiate proceedings that could result in a "finding" that an animal drug has not been shown to be safe, and should be withdrawn. *See, e.g.*, *Drake v. FAA*, 291 F.3d 59, 70-71 (D.C. Cir. 2002) (citing *Overton Park*, and comparing standards governing exercise of agency discretion set forth there and in *Chaney*). As discussed *infra* at pages 16-18, 21 U.S.C. § 360b(e)(1) does not provide any guidance for when FDA must initiate such proceedings, and like the FAA's decision in *Drake*, FDA's decision not to initiate withdrawal proceedings therefore has been committed to agency discretion. *See Drake*, 291 F.3d at 70-72.

Even if the Court reaches the *Chaney* presumption analysis, considering the striking similarities between the facts in *Chaney* and the instant case, the presumption against reviewability applies here with full force. Both cases address FDA's discretion to decline to pursue specific enforcement action regarding the approved use of drugs in response to a citizen petition—*i.e.*, a challenge to FDA's decision to not pursue proceedings that could lead to limitations on the specific uses for which already-approved drugs could be used. Indeed, the petitioners in *Chaney* sought essentially the same relief that Plaintiffs ultimately seek here.

Compare Chaney v. Schweiker, No. 81-2265, slip op. at 9 (D.D.C. Aug. 30, 1982), Second Barcelo Decl. Ex. H (*Chaney* petitioners sought "to compel the Secretary . . . to immediately hold evidentiary hearings designed to ascertain whether the lethal injection procedure authorized by [certain states] conforms to the requirements of the [FDCA]"); with Plaintiffs' Brief in Opposition to the Government's First Motion for Summary Judgment ("Plfs' First Opp. Br.") at 3 (conceding that FDA cannot pursue withdrawals of approvals for animal drugs without providing notice and opportunity for a hearing).

Moreover, FDA's decision to pursue voluntary reform for now, with the possibility of enforcement action in the future if such voluntary efforts are not successful, falls squarely within the types of FDA determinations that courts have held unreviewable under *Chaney*. The D.C. Circuit has held that "[t]he [FDCA] imposes no clear duty upon FDA to bring enforcement proceedings to effectuate either the safety of the efficacy requirements of the Act," *Cutler v. Hayes*, 818 F.2d 879, 893 (D.C. Cir. 1987), and declined to review FDA's decisions to postpone the review of drugs as within the Agency's enforcement discretion. *Id.*; *see also Jerome Stevens Pharm., Inc. v. FDA*, 402 F.3d 1249, 1258 (D.C. Cir. 2005) (FDA's decision to allow manufacturers of unapproved drugs two extra years to submit new drug applications was an "exercise of FDA's enforcement discretion" and immune to judicial review); *Schering Corp. v. Heckler*, 779 F.2d 683, 686 (D.C. Cir. 1985) (FDA's decision to abstain from action while it considered whether a product was a "new drug" is an exercise of the Agency's unreviewable discretion because "there are no statutory guidelines compelling the agency to investigate or pursue enforcement actions within any specified time frame"), *id.* at 687 (decision to abandon ongoing enforcement proceedings also within FDA's discretion); *Int'l Ctr. for Tech. Assessment*

v. Thompson, 421 F. Supp. 2d 1, 7 (D.D.C. 2006) (in declining to regulate genetically modified fish, "FDA is simply exercising its discretion not take enforcement actions.").

Even were this Court to find that the Citizen Petitions sought for FDA to initiate "enforcement" proceedings—whether "pure" or not, *see Riverkeepers*, 359 F.3d at 166 n.11—the presumption of unreviewability should apply here for the same reasons found in *Chaney*. This is first because the question of whether to enforce the FDCA against a particular drug involves precisely the "complicated balancing of a number of factors which are peculiarly within [the agency's] expertise" that the courts are not in a position to evaluate. *See Chaney*, 470 U.S. at 831.

Indeed, the Supreme Court's recognition that agencies have the discretion to allocate resources is particularly relevant here. *See Chaney*, 470 U.S. at 831. FDA has made the determination that its limited resources are "best spent" by pursuing voluntary reform in the first instance, rather than pursuing inevitably lengthy and expensive withdrawal proceedings. Jan. Barcelo Decl. Ex. I at 3, Ex. J at 2-3 (citing examples). In an era of diminishing funding for government agencies, proceedings to withdraw such a large number of products[11] could force FDA to defer and possibly scale back other regulatory efforts pertaining to the drug supply and human health, perhaps significantly. But the Agency cannot be forced to redirect appropriated funds in order to pursue Plaintiffs' own enforcement agenda. *See Lincoln*, 508 U.S. at 193 (an agency's allocation of lump-sum appropriations is "committed to agency discretion by law"); *see also Cobell v. Norton*, 428 F.3d 1070, 1076 (D.C. Cir. 2005) ("judgment about the allocation of scarce resources" is a "classic reason[ ] for deference to administrators"); *Sierra Club v.*

[11] As noted, *supra*, FDA currently estimates that approximately 161 individual drug approvals would have been affected had it granted the relief requested in the Citizen Petitions.

Whitman, 268 F.3d 898, 902-03 (9th Cir. 2001) (agency action unreviewable in part because of need for agency to focus resources where they might be most effective).

Furthermore, FDA is exercising its enforcement discretion (analogous to principles of judicial restraint, *see Chaney*, 470 U.S. at 832) by pursuing an alternative regulatory policy that it believes will yield public health benefits more quickly and efficiently than the case-by-case evaluation and possible withdrawal of each antimicrobial drug. Jan. Barcelo Decl. Ex. I at 4, Ex. J at 4.[12] *Chaney*'s presumption of no judicial review therefore clearly applies to the Petition Responses.

C. Plaintiffs Have Not Overcome *Chaney*'s Presumption of Unreviewability

No exception to the presumption against judicial review applies here because 21 U.S.C. § 360b(e)(1) does not provide any meaningful standard against which to judge FDA's decision not to initiate withdrawal proceedings. 470 U.S. at 833. That is, section 360b(e)(1) does not set forth guidelines for when the Agency must initiate investigations and withdrawal proceedings that might ultimately lead to a "finding" pursuant to section 360b(e)(1) that a drug is unsafe or not shown to be safe.[13] Govt's First S.J. Memo at 13-18 (statutory "finding" can only happen

[12] Also applicable is the second reason noted by *Chaney*, because by pursuing voluntary compliance in the first instance, the Agency is not "exercise[ing] its *coercive* power" over drug sponsors and "thus does not infringe upon areas that courts often are called upon to protect." 470 U.S. at 832.

[13] Plaintiffs take the position, as they did in their briefs in support of their first motion for summary judgment, that FDA has already made "findings" pursuant to section 360b(e)(1) for the penicillin and tetracycline class of drugs. Plfs' Br. at 9 n.1. That is the subject of the parties' first cross-motions for summary judgment. (*See* Dkts. Nos. 19-52; 55). Even if Plaintiffs were right that the two notices of opportunity for hearing that a subsidiary bureau in FDA issued in 1977 could have served as the basis for the Agency to move forward with formal withdrawal proceedings respect to the two classes of drugs at issue in those notices and the FDA had not since withdrawn those notices (it has, *see* Jan. Barcelo Decl. Ex. L), FDA's decision not to move forward with withdrawal proceedings with respect to the two classes of drugs at issue in those motions would also not be subject to judicial review as an exercise of the Agency's enforcement

after notice and opportunity for hearing); *see also* Plf's First Opp. Br. at 3 (Dkt. No. 5) (conceding that withdrawals of approvals can only happen after notice and opportunity for hearing). Rather, the decision whether to make such a finding is left to the Agency.

Indeed, the Second Circuit has found that a similar statute does not provide the meaningful standards necessary to review agency action. *New York Public Interest Research Group v. Whitman*, 321 F.3d 316, 331 (2d Cir. 2003) (agency's decision is "necessarily discretionary" and therefore unreviewable where the statute provides no more than that the agency will make a finding "whenever [the agency] makes it"); *see also Speed Mining, Inc. v. Federal Mine Safety & Health Review Comm'r*, 528 F.3d 310, 318 (4th Cir. 2008) (statute providing that "[i]f . . . the Secretary . . . believes that an operator of a coal or other mine subject to this chapter has violated this chapter, . . . he shall, with reasonable promptness, issue a citation to the operator" did not provide a meaningful standard against which to judge the Secretary of Labor's decision); *Sec'y of Labor v. Twentymile Coal Co.*, 456 F.3d 151, 157-58 (D.C. Cir. 2006) (same); *Drake*, 291 F.3d at 70-72 (FAA's decision to dismiss a complaint not subject to judicial review because the statute did not provide any "reference point" other than the "beliefs" of the Administrator of the FAA).

Rather, the decision on whether and when to initiate action to remove drugs from the market is left to the scientific expertise and judgment of FDA, and its judgment regarding drug approvals and conditions for use is entitled to the utmost deference. *See Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995) (FDA's "judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us."); *see also Henley v. FDA*, 77 F.3d 616, 620 (2d Cir. 1996) ("the FDA's determination

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discretion, for the same reasons that the Petition Responses are not subject to judicial review. *See infra* Part I.

of what labeling best reflects current scientific information regarding the risks and benefits of [the drug] involves a high degree of expert scientific analysis").

Nor have Plaintiffs proposed any other viable or meaningful standard against which to judge the Petition Responses. Because "all legislation has purposes and policies," general statements about the policy behind the FDCA, Plfs' Br. at 12, cannot provide such a standard. *Twentymile*, 456 F. 3d at 158 (citing cases). Thus, Plaintiffs' reliance on *Nutritional Health Alliance v. FDA*, 318 F.3d 92 (2d Cir. 2003), for the proposition that "[r]apid removal from the market of drugs not shown to be safe serves the [FDCA's] 'overriding purpose': 'protect[ing] the public health," Plfs' Br. at 12, is inapposite.[14] Indeed, in *Nutritional Health Alliance* the Second Circuit held that FDA could *not* rely on its broad mandate to protect the public health where Congress had delegated particular authority to another agency. 318 F.3d at 95.

The legislative history of the Drug Amendments of 1962, *see* Plfs' Br. at 12, likewise does not provide any such standards. Introductory language in the Senate Report stating that "[t]he bill also would improve the procedures employed in the advance approval of new drugs and would *permit* the prompt removal from the market of such drugs" in certain circumstances, S. Rep. No. 87-1744, at 1 (1962), *reprinted in* 1962 U.S.C.C.A.N. 2884, 2884, does not, (as Plaintiffs argue, Plfs' Br. at 12) create a "mandate," requiring FDA to take such action or provide a binding timeframe in which FDA must do so.

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[14] *Am. Horse Protection Ass'n v. Lyng*, 812 F.2d 1 (D.C. Cir. 1987), Plfs' Br. at 12-13, is also inapposite because that case pertained to the Department of Agriculture's refusal to promulgate rules banning a practice that was "flatly prohibit[ed]" by Congress. *Am. Horse Protection Ass'n*, 812 F.2d at 6. The *Am. Horse Protection Ass'n* court did not base its holding on vague references to overriding purposes and goals of the applicable legislation, as Plaintiffs would have this Court do with respect to the FDCA. Likewise, *Pub. Citizen Inc. v. Nat'l Highway Traffic Safety Admin*, 374 F.3d 1251 (D.C. Cir. 2004), *Public Citizen v. Nuclear Regulatory Comm.*, 901 F.2d 147 (D.C. Cir. 1990), and *NRDC v. EPA*, 595 F. Supp. 1255, 1257 (S.D.N.Y. 1984), Plfs. Br. at 11, each address agencies' obligations to promulgate rules that have been specifically required by Congress.

Furthermore, any argument that FDA has "abdicated" its statutory authority to regulate animal drugs would also fail. *Chaney*, 470 U.S. at 833 n.4. No court has ever found this exception to apply, and the mere fact that FDA' s regulatory strategy is different than Plaintiffs would prefer is no basis to invoke the exception for the first time here. *Riverkeeper*, 359 F.3d at 169 (jurisdiction cannot be premised on an "'abdication' basis every time an administrative agency declines to order demanded action on an asserted discrete, perceived problem within its area of statutory responsibility."); *see also Cutler*, 818 F.2d at 893-94 (FDA's decision to delay its review of certain drugs for efficacy requirements had not "abdicated its statutory duty").

Ultimately, as the Court explained in *Chaney*, "the decision as to whether an agency's refusal to institute proceedings should be judicially reviewable" is "essentially [left] to Congress and not to the Courts." 470 U.S. at 838. Over the years, bills have been offered in Congress that might have hastened the removal of certain antibiotic drugs from the marketplace, but none has become law.[15] Rather, although Congress clearly is well aware of FDA's approach to the regulation of antimicrobial drugs,[16] it has not passed any law that limits the discretion that, as the *Chaney* Court held, Congress granted to FDA through enactment of the FDCA. *See Rutherford*, 442 U.S. at 554 n.10 (finding acquiescence in congressional inaction and pointing to congressional hearings as evidencing congressional awareness of FDA policy).

D. *Massachusetts v. EPA* Does Not Apply

Massachusetts v. EPA, 549 U.S. 497 (2007), on which Plaintiffs base almost their entire argument, *see* Plfs' Br. at 6-11, is inapposite. As a preliminary matter, the Court in

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[15] *See* Preservation of Antibiotics for Medical Treatment Act of 2011, H.R. 965, 112th Cong. (1st Sess. 2011).

[16] *See, e.g.*, Statement of Joshua M. Sharfstein, M.D., Principle Deputy commissioner, FDA, before the Subcommittee on Health, Committee on Energy and Commerce, United States Congress (July 14, 2010), attached as Exhibit R to the Declaration of Jennifer Sorenson dated October 5, 2011. (Dkt. No. 33).

Massachusetts Court expressly recognized and endorsed the holding and analysis of *Chaney* and its progeny, 549 U.S. at 527, which apply to this case. *See supra* Part I.B-C. Moreover, *Massachusetts* principally involved EPA's decision that it would not regulate greenhouse gases *at all*. *See* 549 U.S. at 529-33. Here, on the other hand, FDA acknowledges and actively exercises its jurisdiction to regulate virtually every aspect of new animal drugs that are delivered or held for sale in interstate commerce. FDA has promulgated hundreds of pages of regulations that articulate the standards for making, distributing, and using animal drugs, *see* 21 C.F.R. §§ 500-589, and has in effect 122 guidances to industry providing information on how to comply with the FDCA and how FDA intends to enforce the law (including GFI 152 and Draft Guidance 209).[17] FDA specifically pursued the withdrawal of approval for the antimicrobial drug enrofloxacin in poultry because of concerns about antimicrobial resistance, Jan. Barcelo Decl. Ex. N, it brings civil and criminal actions in federal court when appropriate to ensure that animal drugs are used by veterinarians, farmers and others in accordance with FDA's approvals,[18] and it is currently taking steps to protect against the misuse and overuse of antibiotics in animals.

Indeed, the only discussion in *Massachusetts* addressing how EPA would regulate greenhouse gases (if it exercised its judgment to so do) confirmed the basic principle of the APA that the EPA would have "significant latitude as to the manner, timing, content, and coordination" of that regulation. 549 U.S. at 533. To the extent that the Petition Responses are

[17] A list of FDA's Animal & Veterinary Guidances is available at: http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm.

[18] *See, e.g., U.S. v. Rhody Dairy, L.L.C.*, 812 F. Supp. 2d 1239 (W.D. Wash. 2011); *U.S. v. Scenic View Dairy, L.L.C.*, Slip Copy, 2011 WL 3879490 (W.D. Mich. 2011); *see also, e.g., U.S. v. Vitek Supply Corp*., 144 F.3d 476 (7th Cir. 1998); *U.S. v. Undetermined Quantities of Bottles of an Article of Veterinary Drug*, 22 F.3d 235 (10th Cir. 1994); *U.S. v. Thomas*, 840 F. Supp. 106 (D.Kan. 1993).

subject to judicial review, that is the principle that this Court must apply, and it does not provide any basis to disturb the Petition Responses. *See infra* Part II.

The Court's holding in *Massachusetts* also does not apply here because (like the rest of the cases on which Plaintiffs principally rely) that case addressed an agency's decisions with respect to "rulemaking," rather than an "adjudicatory" decision like FDA's decision not to pursue formal withdrawal proceedings at issue here.[19] *E.g.*, 549 U.S. at 511. "Administrative action pursuant to the APA is either adjudication or rulemaking." *Assoc. of Nat. Advertisers, Inc. v. F.T.C.*, 627 F.2d 1151, 1160 (D.C. Cir. 1979)); *see also Friends of the Bow v. Thompson*, 124 F.3d 1210, 1214 (10th Cir. 1997) ("Under the APA, agency functions are characterized as either 'rulemakings' or 'adjudications.'"). In this case, proceedings to withdraw drug approvals under 21 U.S.C. § 360b(e)(1) are adjudications (and not rulemakings) because they are adversarial proceedings to revoke specific licenses that have been previously granted to manufacture and distribute drugs. 21 U.S.C. § 360b(e) (requiring "notice and opportunity for a hearing" prior to withdrawal of approval); *see also* 21 C.F.R. § 12.80 *et seq.* (FDA regulations setting forth "Procedures" for such a hearing, which includes motions practice, testimony, oral argument, and post-hearing briefing); *id.* at § 12.120 *et seq.* (providing post-hearing rights of appeal). Moreover, a decision to withdraw a drug approval is effectuated through issuance of an "order," *see* 21 U.S.C. § 360b(e), which is the hallmark of an adjudication under the APA.[20]

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[19] All of the cases on while Plaintiffs principally rely involve agency's decision not to issue rules. *See* Plfs' Br. at 11 (relying on *Nat'l Highway Traffic Safety Admin*, 374 F.3d 1251, *Nuclear Regulatory Comm.*, 901 F.2d, and *NRDC v. EPA*, 595 F. Supp. 1255), Plfs' Br. at 12 (relying on *Am. Horse Prot. Ass'n* 812 F.2d at 7).

[20] The APA defines an "adjudication" as an "agency process for the formulation of an order," (*see* 5 U.S.C. § 551(7)), and an "order" is "a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making *but including licensing*." *See id.* § 551(6) (emphasis added). A "license" is "an agency permit, certificate, *approval*, registration, charter, membership, statutory exemption or other form of permission.

A rulemaking, by contrast, is "essentially legislative in nature, not only because it operates in the future but also because it is primarily concerned with policy considerations." *See* 1947 Attorney General's Manual on the Administrative Procedure Act [21] at 14, Second Barcelo Decl. Ex. I. A withdrawal proceeding should not be construed as a rulemaking, because the function of such a proceeding is to apply the facts established at the hearing to existing law. An order issued after a withdrawal proceeding could never be a "rule" because it would have no direct bearing on any other drug or any other sponsor (*i.e.*, no prospective "legislative" effect), and because no "rule" could ever trump the requirements of section 360b, which assures each drug sponsor the opportunity for a hearing before a withdrawal is ordered. [22]

Due to the fundamental differences between rulemaking and adjudication, there are reasons to subject rulemaking decisions to judicial review that do not apply to an agency's decision to forego adjudicatory action. Indeed, as the Supreme Court noted in *Massachusetts*, the "legal" and "infrequent" nature of an agency decision to initiate rulemaking (which are akin to "legislation"), make them particularly appropriate to judicial review, 549 U.S. at 527; *see also Am. Horse Prot. Ass'n*, 812 F.2d at 400 (noting provisions of the APA that "suggest that

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See id. § 551(8) (emphasis added). By contrast, a "rule making" is an agency process for formulating, amending or repealing a rule (*see id.* § 551(5)), and a "rule" is, *inter alia*, "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law and policy." *See id.* § 551(4).

[21] That manual was drafted contemporaneously with the enactment of the APA, and the Supreme Court has repeatedly deferred to its contents in interpreting that the APA. *See Bowen v. Georgetown Univ. Hospital*, 488 U.S. 204, 218 (1988) (Scalia, J., concurring) (collecting cases).

[22] To the extent that Plaintiffs argue that a drug's approval or withdrawal is a "rulemaking" because the conditions and indications for each new animal drug are ultimately listed in (or delisted from) the Code of Federal Regulations, they are incorrect. *See* Plfs' Br. at 7 (citing 21 U.S.C. § 360b(i)). These listings, which follow after a drug's approval or an order withdrawing the drug, are meant only to provide public notice with regard to a drug's approved uses and have no bearing on the drug sponsor. Moreover, the requirement for these listings is mostly arcane, as its only continuing relevance in the FDCA is in connection with 21 U.S.C. § 360b(m)(1)(C), which requires that animal feeds containing new animal drugs be "manufactured and labeled in accordance with such regulations."

Congress expected that agencies denying rulemaking petitions must explain their actions"). The same cannot be said about the fact-specific focus of an adjudicatory decision. Second Barcelo Decl. Ex. I at 17 ("[T]he entire [APA] is based upon a dichotomy between rule making and adjudication.").

Finally, the differences between 21 U.S.C. § 360b(e)(1) and the statute at issue in *Massachusetts* provides yet another reason that that case does not control the outcome here. The governing statute in *Massachusetts*, 42 U.S.C. § 7521(a)(1), provides that EPA shall *promulgate regulations* in defined circumstances. 549 U.S. at 506. On the other hand, 21 U.S.C. § 360b(e)(1) provides for the withdrawal of a new animal drug only *after* the Commissioner has made a specific determination, which can only occur after the drug sponsor's procedural rights to a notice and opportunity for a hearing have been satisfied. Govt's First S.J. Br. at 13-18; Govt's Reply in Further Support of its First Motion for Summary Judgment ("Govt's First S.J. Reply Br.") (Dkt. No. 55) at 3-8. Importantly, the FDCA provides no guidance whatsoever to FDA regarding whether and when to initiate the withdrawal process. Moreover, even if the use of the word "shall" in the FDCA imposed a mandatory duty on FDA (which it does not, *see Chaney* 470 U.S. at 835), under 21 U.S.C. § 360b(e)(1), such duty would only be triggered only *after* the Commissioner's finding, which itself could occur only *after* FDA had decided, in its discretion, to issue a notice of opportunity for hearing.

II. FDA'S DENIAL OF THE CITIZEN PETITIONS WAS NOT ARBITRARY OR CAPRICIOUS

Even if they were reviewable, which they are not, FDA's reasonable denials of the Citizen Petitions are entitled to deference. Administrative decisions, when reviewable, may be disturbed under the APA only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is highly deferential to the Agency.

It starts with "a presumption in favor of the validity of the administrative action," *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 216 (D.D.C. 1996), and requires the Court to uphold the action so long as it is "rational, based on consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute." *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto Ins. Co*., 463 U.S. 29, 42 (1983). In applying this standard, a reviewing court has "no license to substitute [its] policy judgment for that of the agency." *Bellevue Hosp. Ctr. v. Leavitt*, 443 F.3d 163, 174 (2d Cir. 2006).

When an agency's decision is based on evaluation of scientific information within the agency's area of technical expertise, the degree of deference is even greater. *Riverkeeper*, 475 F.3d at 126-27 (judicial review is particularly deferential when "the agency's decision rests on an evaluation of complex scientific data within the agency's technical expertise"). Furthermore, courts afford a high degree of deference to an agency's prioritization of its duties and its choice of policies and procedures in discharge them. *See Vermont Yankee Nuclear Power v. NRDC*, 435 U.S. 519, 543 (1978) ("administrative agencies should be free to fashion their own rules of procedure and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties") (citations and quotation marks omitted); *Mobil Oil Exploration v. United Distrib. Cos*., 498 U.S. 211, 230 (1991) ("The agency enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures and priorities.") (citations omitted).[23]

[23] Even if the Citizen Petitions were requests for rulemakings (they are not, *see supra* pp 21-23), the applicable standard of review under the APA is highly deferential. *See Massachusetts*, 549 U.S. at 527-28 ("refusals to promulgate rules are [ ] susceptible to judicial review, though such review is extremely limited and highly deferential") (internal quotations and citation omitted); *Cellnet Commc'n, Inc. v. F.C.C.*, 965 F.2d 1106, 1111 (D.C. Cir. 1992) ("an agency's refusal to initiate rulemaking is evaluated with a deference so broad as to make the process akin to nonreviewability"). An agency's refusal to promulgate a rule "is to be overturned only in the

In light of FDA's clear statements with respect to its current approach to regulating antimicrobial drugs in animals, Plaintiffs' request that this Court deem the Petition Responses as "arbitrary," and vacate and remand the Petition Responses for FDA to *further* explain its approach to regulating antibiotics in animals, *see* Plfs' Br. at 1, 17, is pointless. Specifically, there is no basis to grant Plaintiffs' request for a remand to "address the petitions promptly on their merits," *see* Plfs' Br. at 1, or require FDA to provide a "factual basis" for the Petition Responses, *see id.* at 17, because FDA did explain the bases for its decision, and such bases are reasonable. FDA agrees that the injudicious use of antibiotics in animals should stop, it accurately perceives its regulatory authority, and it has developed a plan to rationally exercise that authority to reach this goal. To reject FDA's reasoning, and force it to follow the regulatory path preferred by a group of petitioners, would impinge on the Agency's ability to exercise judgment in choosing the best methods to discharge its duties. *See Vermont Yankee Nuclear Power*, 435 U.S. at 543; *Mobil Oil*, 498 U.S. at 230 (1991).

With respect to the substance of FDA's policies, there is nothing arbitrary about the decision to initially encourage industry to voluntarily withdraw growth promotion indications from their product labeling, and to reserve resource-intensive withdrawal proceedings for companies that refuse. Indeed, this is no more than a judicious and reasoned plan for achieving FDA's goals while deploying its limited resources in a more effective fashion.

Likewise, FDA's plans to regulate the Citizen Petition Drugs' remaining therapeutic indications by labeling them "VFD" for use only under the supervision of a licensed veterinarian (which Plaintiffs' do not even acknowledge in their Brief), could hardly be "arbitrary," particularly in light of FDA's scientific expertise on this topic. *Riverkeeper*, 475 F.3d at 126-27;

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rarest and most compelling of circumstances . . . which have primarily involved plain errors of law . . . ." *Am. Horse Prot. Ass'n*, 812 F. 2d at 5 (internal quotations and citations omitted).

Schering Corp., 51 F.3d at 399. Because the FDCA and FDA's implementing regulations contemplate that a new animal drug can be safe under some, but not other, possible conditions, transitioning antimicrobials to VFD status may render safe a drug that is not safe for over-the-counter use. *See supra* Background pp. 3-5.

Moreover, Plaintiffs' argument that "FDA's pronouncements convey agreement with the premise of the petitions," Plfs' Br. at 13-15, is true in a general sense, but that is no basis upon which to vacate and remand the Petition Reponses, where FDA has explained its reasoned judgment that it has selected the best path to pursue. Furthermore, Plaintiffs' insinuation that FDA's statements of public health concern equal a finding under the FDCA that that the Citizen Petition Drugs are "not shown to be safe" in a legal sense is a bridge too far. Govt's First S.J. Reply Br. at 8. "Not shown to be safe" is a statutory term that is assigned only *after* withdrawal proceedings are complete. *See* 21 U.S.C. § 360b(e)(1); Govt's First S.J. Br. at 13-18; Govt's First S.J. Reply Br. at 3-8. As FDA has explained, however, there is no reason to initiate expensive and time-consuming proceedings now to demonstrate that the Citizen Petition Drugs are "not shown to be safe," when voluntarily measures could eliminate the need for such proceedings altogether.[24]

[24] Plaintiffs' citations on page 15 of their brief do not illuminate any relevant point. In *Assoc. of Irritated Citizens v. EPA*, __ F.3d __, 2012 WL 251912 (9th Cir. 2012), the court held that EPA was subject to a mandatory duty to promulgate an environmental remediation plan (a State Implementation Plan), and that its refusal to do so was arbitrary and capricious in light of evidence that the preexisting plan was inadequate. *Id.* at *3-*6. In the instant case, not only does FDA not have a mandatory duty to initiate withdrawal proceedings, *see supra* pp. 16-17, 23, but the Petition Responses did not "ignore" relevant evidence, as the court held that the EPA did in that case. *Assoc. of Irritated Citizens*, 2012 WL 251912, at *6. Rather, FDA has considered the evidence on which Plaintiffs' rely and decided to do something different than what Plaintiffs would like. Plaintiffs' citation to *Am. Lung. Assoc. v. EPA*, 134 F.3d 388 (D.C. Cir. 1998), Plfs' Br. at 15, also does not help their argument because that case held no more than that an agency must adequately explain its decision making. *Am. Lung. Assoc.*, 134 F.3d at 392-

Finally, that FDA has not cited to specific "evidence" establishing the "the efficacy of voluntary measures," Plfs' Br. at 15-18, is also not a basis to hold that the Petition Responses are "arbitrary." That argument disregards FDA's description of its attempts at voluntary reform as only a first step. Jan. Barcelo Decl. Ex. I at 4, Ex. J. at 4. Even if some drug companies fail to voluntarily comply as requested, FDA will still have made substantial progress in reducing the number of companies that may be the targets of enforcement action in the future, thereby pursuing its priorities in a resource-efficient manner.

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93. Plaintiffs' disagreement with the Petition Responses is not enough is not sufficient to argue that FDA has not adequately explained the basis for its decision.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motion for summary judgment, and grant summary judgment in favor of the Government.

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Respectfully submitted,

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