Natural Resources Defense Council, Inc. et al v. United States Food and Drug Administration et al Doc. 77

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

REPLY MEMORANDUM OF LAW IN SUPPORT OF THE GOVERNMENT'S MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' FIRST SUPPLEMENTAL COMPLAINT

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PRELIMINARY STATEMENT

As FDA explained in the Petition Responses,[1] the Agency has concluded that pursuing the adversarial adjudications to withdraw the approximately 161 individual licenses at issue in the Citizen Petitions would not be an effective strategy to promote the public health. Because the duration and expense of such adjudication would be excessive, FDA is instead implementing a plan to encourage voluntary industry reform for a period of time, followed by appropriate further action under the FDCA, if necessary. FDA's determination is not subject to judicial review. But even if it were, the Court should defer to FDA's reasonable exercise of its authority to select the regulatory process that will most effectively use FDA's limited resources to protect public health.

FDA had been developing its enforcement strategy for the past several years, and, on April 11, 2012, took several important additional steps to implement it. First, FDA finalized Guidance #209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*, which recommends phasing out the growth promotion uses of medically important drugs, and phasing in veterinary oversight of therapeutic uses of these drugs. Third Barcelo Decl. Ex. A; 77 Fed. Reg. 22328 (Apr. 13, 2012). Second, FDA published a draft proposed Veterinary Feed Directive ("VFD") regulation, open for public comment, which will facilitate the needed veterinary oversight. Third Barcelo Decl. Ex. B; 77 Fed. Reg. 22247 (Apr. 13, 2012).

Third, FDA published a draft guidance entitled *New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use*

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[1] Abbreviations in this brief are the same as in the Government's opening brief dated March 21, 2012 (the "Govt's Opening Br.").

Conditions with GFI #209 ("Draft GFI #213"), which when finalized will assist drug companies in voluntarily removing growth-promotion uses of antibiotics from their FDA-approved product labels, and which asks drug sponsors to change their products' marketing status to "VFD" for remaining therapeutic uses. Third Barcelo Decl. Ex. C; 77 Fed. Reg. 22327 (Apr. 13, 2012). As Draft GFI # 213 explains, FDA expects that these labeling changes will take up to approximately three years from the date Draft GFI #213 is finalized, at which point the Agency "will consider further action as warranted in accordance with existing provisions of the [FDCA]," including, if necessary, initiating the process for involuntary drug withdrawals under 21 U.S.C. § 360b(e)(1). Third Barcelo Decl. Ex. C at 7.

For the reasons the Government explained in its Opening Brief, regardless of whether this Court determines that the decision whether to initiate adversarial administrative proceedings is unreviewable under *Heckler v. Chaney* and its progeny, or instead reviews the Petition Responses under the appropriately deferential arbitrary and capricious standards, the correct outcome here is the same: FDA should not be compelled to initiate adversarial administrative proceedings, particularly when the Agency believes that it can achieve the same goals more quickly and efficiently through other means.

ARGUMENT

I. THE PETITION RESPONSES ARE NOT SUBJECT TO JUDICIAL REVIEW

A. This Court's March 22 Order Does Not Control FDA's Discretion to Initiate Withdrawal Proceedings for the Remaining Citizen Petition Drugs

Plaintiffs are wrong to argue that this Court's Opinion and Order dated March 22, 2012 (the "March 22 Order") (Dkt. No. 70) held that the Petition Responses are subject to judicial review. Plfs' Opp. Br. at 3. As an initial matter, although Plaintiffs now seek to compel FDA to make a "finding" whether the Citizen Petition Drugs are not shown to be safe, the Citizen

Petitions themselves requested something different: that FDA *actually withdraw* approvals for the Citizen Petition Drugs. *See* Second Barcelo Decl. Exs. D at 1, E at 1. It was that request (and not a request for "findings") that FDA properly addressed (and denied) in the Petition Responses.

In any event, even if the Citizen Petitions had requested that FDA only make "findings" with regard to the Citizen Petition Drugs, neither 21 U.S.C. § 360b(e)(1) nor the March 22 Order addresses FDA's discretion in deciding whether and when to make such findings. Specifically, the March 22 Order held no more than that FDA made "findings" that certain uses of penicillins and tetracyclines in animals feed were "not shown to be safe," March 22 Order at 45-48, and that as a result of having made such "findings," FDA must now initiate formal withdrawal proceedings for those specific drugs. *See id.* at 54. Plaintiffs do not (and cannot) contend that FDA made any statutory "findings" with respect to the remaining (non-penicillin, non-tetracycline) Citizen Petition Drugs. Rather than speak to whether and when FDA must undertake the process of making a "finding" in the first place, the March 22 Order held specifically that Section 360b(e)(1) provides for what happens *after* "findings" are made. *See, id.* at 29-39.

Accordingly, this case is controlled by *New York Pub. Interest Research Group v. Whitman*, 321 F.3d 316 (2d Cir. 2003) ("*NYPIRG*"), in which the Second Circuit found a statute to impose a "nondiscretionary obligation" on an agency that "arises [only] after [the agency makes] a discretionary determination."[2] 321 F.3d at 331. In that case, the EPA was not under

[2] Plaintiffs argue that *NYPIRG* was overruled by decision in *Massachusetts v. EPA*, Plfs' Br. at 13 n.2, but as discussed *infra*, *Massachusetts* is easily distinguishable on the ground that itinvolved the denial of a petition for a rulemaking that was based on an agency's refusal to assert jurisdiction over the subject matter (*i.e.*, greenhouse gasses). Moreover, if *Massachusetts*

any obligation to perform the "nondiscretionary obligation" because it had declined to undertake the "discretionary" obligation. *Id*. Likewise, here, even if the Citizen Petitions had requested only that FDA make "findings," whether to undertake to reach such findings is within the Agency's discretion; FDA has no "nondiscretionary obligation" to proceed with withdrawal hearings unless the prerequisite findings are made. *See* Govt's Opening Br. at 13-19.

B. The Petition Responses Are Entitled to a Presumption Against Judicial Review as Decisions Not to Enforce

Withdrawal proceedings under 21 U.S.C. § 360b(e)(1) are *enforcement* proceedings within the meaning of *Heckler v. Chaney*, 470 U.S. 821 (1985). First, they are unmistakably adversarial, and often are high-stakes, resource-intensive litigations. *See, e.g.*, Jan. Barcelo Decl. Ex. N. To withdraw an animal drug when a hearing is requested and granted, FDA must hold a formal, contested proceeding in which the Agency's Center for Veterinary Medicine ("CVM") litigates against the drug sponsors, with CVM seeking and the sponsor opposing withdrawal of approval. *See* 21 C.F.R. §§ 514.115, 514.200(b); Jan. Barcelo Decl. Ex. N at 7. Like in *Chaney*, the FDA's decisions whether to initiate and prosecute such adversarial proceedings "involve[] a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise." *Chaney*, 470 U.S. at 831.

Indeed, the reasoning of *Chaney* applies with even greater force here because proceedings to withdraw drug approvals that result in a determination adverse to the application holder(s) would serve as a "prelude" to further enforcement action. In *Chaney*, the Supreme Court held that administrative proceedings to determine whether a drug product comports with the requirements of the FDCA are tantamount to enforcement proceedings, because they serve

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had actually overruled *NYPIRG*, the decisions of four other Circuits—the Third, Fifth, Eighth, and Ninth—would also have been overruled. *See NYPIRG*, 321 F.3d at 330 n.7.

"no purpose apart from serving as a prelude" to other enforcement actions. *Chaney*, 470 U.S. at 825 n.2; *see also Chaney v. Schweiker*, No. 81-2265, slip op. at 9 (D.D.C. Aug. 30, 1982), Second Barcelo Decl. Ex. H; Govt's Opening Br. at 15-16. And so it is here, for proceedings leading to the involuntary withdrawal of a mass number of NADAs and ANADAs would be meaningless if they did not serve as a "prelude" to further FDA enforcement.

Moreover, even if FDA's decision not to pursue formal drug withdrawal proceedings were not a traditional "enforcement" decision, *Chaney* is not limited to such decisions, but rather identifies factors counseling against judicial review, each of which is present here. Govt's Opening Br. at 15-16, n.12. For example, decisions about the allocation of agency resources indisputably are committed to the agency's discretion. Govt's Opening Br. at 12, 15 (citing *Lincoln v. Vigil*, 508 U.S. 182 (1993)); Plfs' Opp. Br. at 9. Plaintiffs' sole response, that this is not "a lump-sum appropriations case," Plfs' Opp. Br. at 9, avoids the issue, for Plaintiffs never dispute that drug withdrawal proceedings would consume considerable agency resources that would otherwise be available to carry out FDA's public health protection mission.

Plaintiffs' attempts to cabin the scope of *Chaney* are not supported by the case law. For example, the parallels between this case and *Riverkeeper, Inc. v. Collins*, 359 F.3d 156 (2d Cir. 2004), where the Second Circuit held that judicial review is barred, confirm that *Chaney* applies to this case. Plfs' Opp. Br. at 6. In *Riverkeeper*, plaintiffs challenged the denial by the Nuclear Regulatory Commission ("NRC") of a petition requesting that NRC "condition" an existing license for two nuclear power plants on the adoption of safety measures that plaintiffs believed were statutorily required. 359 F.3d at 158. Likewise, here, Plaintiffs petitioned FDA to revise or revoke existing approvals of the Citizen Petition Drugs based on contentions that the drugs do not comport with the requirements of the FDCA. *See* Second Barcelo Decl. Exs. D & E. Thus,

as in *Riverkeeper*, Plaintiffs seek to amend or revoke existing government-granted licenses. And, like the Second Circuit in *Riverkeeper*, this Court should find that the Citizen Petitions were a petition to enforce the law that is subject to *Chaney*.

Riverkeeper also disposes of Plaintiffs' argument that *Chaney* applies only with respect to enforcement actions against "third parties" engaged in "unlawful activity." Plfs' Opp. Br. at 6-7. The *Riverkeeper* plaintiffs did not allege that the power plant operator had violated the terms of its existing license, just as there is no allegation here that the sponsors of the Citizen Petition Drugs are operating outside the terms and conditions of their FDA-granted NADAs and ANADAs. Rather, like in *Riverkeeper*, Plaintiffs here are trying to force changes to the already-granted government licenses, with which the licensees (*i.e.*, sponsors) will then be required to comply. Moreover, because (unlike *Riverkeeper*) FDA could only withdraw approvals for the Citizen Petition Drugs if it prevails in adversarial proceedings against the drug sponsors, *see supra* at 4, drug withdrawal proceedings under the FDCA possess even more of the essential characteristics of enforcement proceedings under *Chaney* than the proceedings in *Riverkeeper*.

Decisions since *Chaney* have confirmed FDA's unreviewable discretion to decline to commence formal proceedings to enforce the safety and efficacy provisions of the FDCA. *See Jerome Stevens Pharms. 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 from judicial review);[3] *see also Schering Corp. v. Heckler*, 779 F.2d 683, 686 (D.C. Cir. 1985) (FDA exercised unreviewable

[3] *Jerome Stevens* likewise disposes of Plaintiffs' argument that the FDCA "separates the substantive provisions of the Act from its enforcement provisions," and that *Chaney* applies only to the latter. Plfs' Opp. Br. at 4. As the D.C. Circuit held, FDA's decisions regarding how to manage the drug approval process under 21 U.S.C. § 355, which Plaintiffs characterize as a "substantive" provision of the FDCA, Plfs' Opp. Br. at 4, are presumed to be unreviewable in connection with decisions not to enforce the FDCA. *See Jerome Stevens*, 402 F.3d at 1257.

discretion in deferring action while deciding whether product required premarket approval); *Int'l Ctr. for Tech. Assessment v. Thompson*, 421 F. Supp. 2d 1, 7 (D.D.C. 2006) (FDA's decision whether to require drug application held to be unreviewable exercise of discretion). Since FDA possesses the unreviewable discretion to allow a product to remain on the market while it considers whether it is a "drug" under the FDCA, *see Schering Corp.*, 779 F.2d at 686, or whether a drug is safe and effective, *see Jerome Stevens*, 402 F.3d at 1258, there is no reason in logic or law that the Agency does not also have the unreviewable discretion to defer extensive withdrawal proceedings (and making any formal "finding" whether a drug has not been shown to be safe) while the FDA engages with drug companies to bring about desired changes voluntarily.

Plaintiffs particularly mischaracterize the *Jerome Stevens* case in arguing that it pertained to the exercise of FDA's discretion to not bring an enforcement action against a company engaged in a "prohibited act" under subchapter III of the FDCA. 402 F.3d at 1258. There in fact was no allegation in *Jerome Stevens* relating to any "prohibited act," and there was no request for FDA to initiate an enforcement proceeding in court. Rather, the *Jerome Stevens* plaintiff alleged that FDA had unlawfully extended the deadlines for one of its competitors to submit a new drug application. *Id.* The D.C. Circuit rejected this argument, finding that the extension was an "exercise of FDA's enforcement discretion." *Id.*

Nor should the Court accept Plaintiffs' argument that withdrawal proceedings do not count as "enforcement" because they would "change the law." Plfs' Opp. Br. at 4. Simply because the terms and conditions of a government license (*i.e.*, the NADAs for the Citizen Petition Drugs) must be observed does not mean that the withdrawal of such license effects any change in the parameters or reach of the FDCA. Rather, proceedings to withdraw an NADA or an ANADA involve the application of *existing* law to facts adduced at the hearing. If a drug

approval is withdrawn entirely, it simply means that the drug may no longer be introduced into interstate commerce. Moreover, contrary to Plaintiffs' argument, Pls' Opp. Br. at 8-9, the fact that orders approving NADAs are listed in the Code of Federal Regulations to provide public notice of the approved uses of animal drugs does not convert drug approval proceedings into rulemakings or the NADAs into legislative rules. *See* Govt's Opening Br. at 22 n.22. Indeed, the FDCA already provides that animal drugs used in animal feed may be used only in strict accordance with the approved conditions of use as reflected on the product labels, *see id.* at 4 (*citing* 21 U.S.C. §§ 360b(a)(1), (4)).

Finally, Plaintiffs do not cite any new authority for their argument that the substance of the Petition Responses are subject to judicial review. Plfs' Opp. Br. at 8. *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484 (D.C. Cir. 1995), involved a challenge to FDA's *approval* of an NADA in the first instance, rather than the denial of a *request to withdraw approvals* at issue here. *A.L. Pharma*, 62 F.3d at 1492 (describing the issue in that case as whether "FDA's approval of [the application at issue] was . . . arbitrary and capricious."). Likewise, *Barnes v. Shalala*, 865 F. Supp. 550, 554 (W.D. Wis. 1994), is best understood as no more than a challenge to FDA's labeling decisions in connection with a drug approval. *See Barnes*, 865 F. Supp. at 554 ("Plaintiffs contend that defendants acted improperly in approving Monsanto Corporation's application for the use of [a drug] in dairy cows."). The plaintiffs in that case did not seek adversarial proceedings to withdraw approvals, but rather challenged FDA's conclusion that consumer warnings on products made from cows treated with a particular drug was not required. *Id.* at 557. The facts of that case have little relevance here, where Plaintiffs do not challenge FDA's original approval of the Citizen Petition Drugs, and instead now seek for FDA to institute formal adversarial proceedings to revoke drug approvals that have been in effect for decades.

C. There is No Other Law to Apply

Even if the Petition Responses were not subject to the *Chaney* presumption against judicial review, the Agency's decision to defer withdrawal proceedings would still be "committed to agency discretion by law" under 5 U.S.C. § 701(a)(2) because 21 U.S.C. § 360b(e)(1) does not provide a meaningful standard against which to review FDA's exercise of its discretion. Although Plaintiffs assert that the FDCA "provides clear standards by which to judge" the Petition Responses, Plfs' Opp. Br. at 11, they do not (and cannot) point to any such standards. Rather, Plaintiffs' rely exclusively on this Court's March 22 Order, which speaks only to what actions FDA must take *after* it has made statutory findings.[4] *See supra* pp. 2-3; Govt's Opening Br. at 13.

Furthermore, Plaintiffs are incorrect that the "committed to agency discretion by law" exception is limited to statutes that *expressly preclude* judicial review. Plfs' Br. at 10 (citing *Schneider v. Feinberg*, 345 F.3d 135, 148-49 (2d Cir. 2003)). Rather, agency decision making is "committed to agency discretion by law" if the statute, like the FDCA in the eyes of the Supreme Court, "is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Chaney*, 470 U.S. at 830 (*citing Overton Park v. Volpe*, 401 U.S. 402, 410 (1971)); Govt's Opening Br. at 13.

Nor are the Government's arguments undermined by *Christianson v. Hauptman*, 991 F.2d 59 (2d Cir. 1993), Plfs' Br. at 10-11, where the court held that the National Park Service's ("NPS") refusal to grant an exception to a rule was subject to arbitrary and capricious review under the APA. The statute (and degree of APA deference) at issue in *Christianson* has no

[4] Plaintiffs' reference to the general purpose of FDA and the FDCA also does not provide any basis to review the Petition Responses. Plfs' Opp. Br. at 12. Indeed, as FDA has explained, it expects that the approach that it is currently undertaking will more quickly and efficiently fulfill the aims that Plaintiffs invoke.

bearing on whether the *FDCA* contains provisions limiting the Agency's discretion as to whether to initiate drug withdrawal proceedings. Moreover, *Christianson*, like the most of the rest of the cases upon which Plaintiffs rely, *see* Govt's Opening Br. at 21 n.19 (listing cases), involved the review of agency *rulemaking*. *See Christianson*, 991 F.2d 5at 63 (reviewing decision not to "process a regulatory change" to an agency rule). That the APA unquestionably provides for the review of agency *rulemakings* and denials of *petitions for rulemakings* has no relevance at all in this case, which concerns agency discretion not to initiate and conduct a proceeding that is tantamount to enforcement.

D. *Massachusetts v. EPA* Does Not Apply Here

Massachusetts v. EPA, 549 U.S. 497 (2007) does not apply here, because that case held only that an agency cannot deny a petition for rulemaking based solely on the agency's incorrect assertion that it has no jurisdiction. *Id.* at 511; Govt's Opening Br. at 21-23. Here, FDA does not invoke any purported lack of jurisdiction to justify its decision not to act as Plaintiffs wish; rather, FDA has chosen to pursue a different regulatory strategy while retaining the ability to commence enforcement proceedings later if necessary. Meanwhile, although Plaintiffs claim, in error, that the Citizen Petitions were petitions to "change the law," Plfs' Opp. Br. at 4, Plaintiffs do not dispute that drug withdrawal proceedings under the FDCA are adjudications, and *Massachusetts* does not speak to denials of requests to initiate enforcement adjudications.

Indeed, *Massachusetts* supports the Government's position in this case; the Supreme Court there explained that agencies that are weighing the exercise of their jurisdiction have "significant latitude as to the manner, timing, content, and coordination" of its actions. 549 U.S. at 533; Govt's Opening Br. at 19-23. To the extent that the Petition Responses are subject to

judicial review, that would be the standard that applies here, and FDA's actions are well within that latitude. *Supra* II.

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

Even if the Petition Responses were subject to judicial review, the Court should defer to FDA's reasonable exercise of its authority to allocate its finite resources effectively and select the regulatory process that, in FDA's judgment, will best promote the public health. *See* Govt's Opening Br. at 23-27. As noted above, FDA has recently finalized Guidance for Industry 209 and published Draft GFI #213, which sets forth the Agency's plan to encourage the withdrawal of growth-promotion indications and transition the remaining therapeutic indications to "VFD" status. Third Barcelo Decl. Exs. A & C. Although the recommendations in Draft GFI #213 are now voluntary, FDA has made clear that, after a proposed three-year implementation period, the Agency "will consider further action as warranted in accordance with existing provisions of the [FDCA] for addressing matters related to the safety of approved new animal drugs." Third Barcelo Decl. Ex. C at 7. FDA believes that the draft guidance will encourage substantial progress towards the withdrawal of all growth promotion indications within the three-year period. FDA also anticipates that this progress would outpace that which could be made were the Agency to engage in product-by-product withdrawals under 21 U.S.C. § 360b(e)(1).

This Court should defer to FDA's preferred plan to achieve its public-health goals, which does not now include adversarial proceedings with respect to the approximately 161 individual applications covered by the Citizen Petitions. Jan. Barcelo Decl. Ex. I at 3, Ex. J. at 3 (explaining that the recent withdrawal of just one product consumed in excess of five years and three million dollars). As the Second Circuit recently emphasized, agencies' decisions on whether to initiate or compromise adversarial actions in exercise of their regulatory authority are,

at a minimum, entitled to substantial deference. *See S.E.C. v. Citigroup Global Markets, Inc.*, _ F.3d _, 2012 WL 851807, *4 (2d. Cir. Mar. 15, 2012) (noting that in light of the "numerous factors" that affect an agency's decision to compromise adversarial proceedings, "the scope of a court's authority to second-guess an agency's discretionary and policy-based decision to settle is at best minimal"); *see also Vermont Yankee Nuclear Power v. NRDC*, 435 U.S. 519, 543 (1978) ("[A]dministrative 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."); Govt's Opening Br. at 24.

Nor do Plaintiffs' criticisms of FDA's regulatory strategy diminish FDA's regulatory discretion or the deference that this Court must afford FDA's choices. Plfs' Opp. Br. at 17-19. As the Second Circuit has explained, 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). Plaintiffs are therefore incorrect to analogize the instant case to *Detsel by Detsel v. Sullivan*, 895 F.2d 58 (2d Cir. 1990), where an agency's assertion about the evidentiary basis of a rule issued more than 40 years earlier was deemed to be an "educated guess," *id.* at 64. Plfs' Opp. Br. at 17. Rather, FDA's ongoing effort to reduce the use of antibiotics for promoting growth is based on a real, present-day expectation that its strategy will succeed, and that judgment is one that FDA is entitled to make in its substantial discretion.

Even if the Court were improperly to consider Plaintiffs' purported "evidence" that FDA's strategy is unlikely to succeed, that "evidence" is irrelevant, and insufficient to support disturbing the Petition Responses. Specifically, Alpharma, LLC's 2010 reaction to Draft Guidance 209, Bernard Decl. Ex. D, is irrelevant because that company no longer exists. *See* Third Barcelo Decl. Ex. D. Comments from the American Farm Bureau Federation also from

2010, Bernard Decl. Ex. E, have no bearing on the likelihood that drug sponsors will comply with FDA's latest recommendations, especially because that organization represents farmers, and not drug companies. *See* Third Barcelo Decl. Ex. E. And, although the 2010 comments by the Animal Health Institute ("AHI") do reflect some concerns with FDA's planned approach, the AHI at the same time expressed "general agreement" with FDA's proposed criteria for using antimicrobial drugs in animal feed, and it "agree[d] [that] veterinary involvement is important in assuring these uses are judicious." Bernard Decl. Ex. C at 8. Last week, moreover, in response to FDA's publication of the new guidance documents and the proposed VFD regulation, AHI issued a statement announcing its continued support for FDA's approach, and in particular, stated that "[i]mplementation of [FDA's] policy means all medically-important antibiotics used in animal agriculture will be used only for therapeutic purposes—disease treatment, control and prevention—under the supervision of a licensed veterinarian." Third Barcelo Decl. Ex. F.

Finally, as noted, FDA's current strategy to encourage voluntary compliance is only a first step. If some drug companies fail to voluntarily withdraw growth-promotion indications from their products, FDA reasonably expects that its current approach at a minimum will 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, and permitting FDA to prioritize deployment of its limited enforcement resources to products or sponsors that prove unresponsive to the voluntary initiative, and that, in FDA's judgment, are appropriate targets of withdrawal proceedings. Govt's Opening Br. at 27.

CONCLUSION

For the foregoing reasons, the Court should grant summary judgment in favor of the Government.

Dated: New York, New York
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Respectfully submitted,

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