IN THE UNITED STATES DISTRICT COURT
FOR THE 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,	)	11 CIV 3562 (THK) ECF Case
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.	)	

PLAINTIFFS' OPPOSITION TO THE GOVERNMENT'S BRIEF CONCERNING A SCHEDULE FOR COMPLIANCE WITH THE COURT'S ORDER

Mitchell S. Bernard (MB 5823)
Natural Resources Defense Council, Inc.
40 West 20th Street
New York, New York 10011
(212) 727-2700
(212) 727-1773 (fax)
mbernard@nrdc.org

Avinash Kar, *admitted pro hac vice*
Jennifer A. Sorenson, *admitted pro hac vice*
Natural Resources Defense Council, Inc.
111 Sutter Street, 20th Floor
San Francisco, California 94104
(415) 875-6100
(415) 875-6161 (fax)
akar@nrdc.org; jsorenson@nrdc.org

Counsel for Plaintiffs

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INTRODUCTION

On March 22, 2012, this Court granted plaintiffs' motion for summary judgment and ordered the U.S. Food and Drug Administration (FDA) to initiate and complete withdrawal proceedings for certain nontherapeutic uses of penicillin and tetracyclines in animal feed. Mem. Op. & Order (Order) 54, Mar. 22, 2012 (Dkt. 70). The Court requested further briefing on the "issue of a time-line for holding a hearing and issuing a final decision in the matter." *Id.* at 55 n.19.

A judicially imposed deadline is essential to ensure FDA's prompt compliance with the Court's order. The agency has repeatedly demonstrated its resistance to conducting withdrawal proceedings. FDA first issued notices proposing to withdraw approval for penicillin and tetracyclines in animal feed in 1977, on grounds that these drug uses have not been shown to be safe for human health. For more than thirty years, FDA failed to follow through on the notices, despite the growing evidence of a threat to public health. Now, in its brief on a compliance schedule, FDA asserts that the Court should not impose any deadline at all.

Alternatively, FDA proposes a protracted schedule for compliance with a statutory mandate it has defied for decades. Ignoring the substantial amount of effort the agency has already expended in studying the issue of antibiotic resistance in recent years, FDA avers that it will take eleven to seventeen months to search the scientific literature, evaluate the current science, and update the notices. Altogether, the agency wants five to five-and-a-half years to comply with the Court's order. Withdrawal proceedings need not, and should not, take nearly that long. Indeed, FDA's relaxed proposed schedule provides further evidence of the need for a prompt and enforceable set of deadlines.

BACKGROUND

Factual Background

As this Court has observed, for "over thirty years, the FDA has taken the position that the widespread use of certain antibiotics in livestock for purposes other than disease treatment poses a threat to human health." Order 2. This drug use promotes the development of antibiotic-resistant bacteria that can be transferred from animals to humans. *Id.* at 5. FDA first "became concerned" about this public health risk in the "mid-1960s." *Id.* at 6. After convening a task force to study the issue, in 1973 FDA issued a regulation "providing that the agency would propose to withdraw approval of all subtherapeutic uses of antibiotics in animal feed unless drug sponsors and other interested parties submitted data within the next two years 'which resolve[d] conclusively the issues concerning [the drugs'] safety to man and animals.'" *Id.* at 7-8 (quoting 21 C.F.R. § 558.15). FDA defined "subtherapeutic" uses to include "increased rate of [weight] gain, disease prevention[,] etc." 21 C.F.R. § 558.15(a).

After reviewing the submissions from drug manufacturers, FDA issued "notices of an opportunity for hearing . . . on proposals to withdraw approval of all subtherapeutic uses of penicillin in animal feed . . . and, with limited exceptions, all subtherapeutic uses of oxytetracycline and chlortetracycline in animal feed." Order 10. The agency found that these drug uses were "'not shown to be safe'" for human health. *Id.* at 11 (quoting Penicillin-Containing Premixes, 42 Fed. Reg. 43,772, 43,792 (Aug. 30, 1977)); *see id.* at 12 (quoting Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264, 56,288 (Oct. 21, 1977)). Under the Federal Food, Drug, and Cosmetic Act (Food and Drug Act), FDA is required, "after due notice and opportunity for hearing," to "issue an order withdrawing approval" of an animal drug if the agency finds that "new evidence . . . shows that such drug is not shown to be safe." 21 U.S.C. § 360b(e)(1)(B).

Following FDA's publication of the notices, "Congressional committees issued three reports that contained statements that the FDA interpreted as requests to postpone the withdrawal hearings pending further research." Order 13. Although the agency completed the requested research, "the FDA never held hearings on the proposed withdrawals." *Id.* at 13-15. Since the 1970s, "the scientific evidence of the risks to human health from the widespread use of antibiotics in livestock has grown, and there is no evidence that the FDA has changed its position that such uses are not shown to be safe." *Id.* at 3. At the same time, the use of antibiotics in livestock production has proliferated: between 1970 and 2009, the volume of antibiotics used annually in U.S. livestock quadrupled, from 7.3 million pounds to 28.8 million pounds. *See* Antibiotic and Sulfonamide Drugs in the Feed of Animals, 38 Fed. Reg. 9811, 9812 (Apr. 20, 1973), Ex. D to Decl. of Jennifer A. Sorenson (1st Sorenson Decl.), Oct. 5, 2011 (Dkt. 33-4); FDA, *2009 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, at tbl.1, 1st Sorenson Decl. Ex. P (Dkt. 33-16).

In 2010, FDA issued a nonbinding document, Draft Guidance No. 209, which concluded that "using medically important antimicrobial drugs for [livestock] production purposes is not in the interest of protecting and promoting the public health." FDA, Draft Guidance No. 209, at 13 (2010), 1st Sorenson Decl. Ex. O (Dkt. 33-15). The Draft Guidance recommended using medically important antibiotics in food-producing animals only when necessary to ensure the animals' health. *See id.* at 16. FDA finalized Guidance No. 209 in April 2012. The final Guidance summarizes forty years' worth of key scientific reports on the issue of antibiotic use in livestock production, including several recent peer-reviewed studies. *See* FDA, Guidance No. 209, at 5-17 (2012), Ex. A to 3d Decl. of Amy A. Barcelo, Apr. 16, 2012 (Dkt. 78-1). FDA notes

that the literature review presented in the Guidance is not exhaustive, but it asserts that the agency has "considered all available information" in reaching its conclusions. *Id.* at 5, 17.

Procedural Background

In May 2011, plaintiffs filed this action, seeking to compel FDA to complete withdrawal proceedings for penicillin and tetracyclines in animal feed. Contrary to FDA's assertion, plaintiffs brought suit not because they "disagreed with FDA's new regulatory strategy" of encouraging drug sponsors voluntarily to discontinue the marketing of medically important antibiotics for livestock production purposes. Br. in Supp. of the Government's Position on the Issue of Timing (Gov't Br.) 5, May 15, 2012 (Dkt. 85). Rather, plaintiffs believed that FDA had violated the law by failing to act on its own findings that penicillin and tetracyclines in animal feed were not shown to be safe for human health. *See* Pls.' 1st Am. Compl. ¶ 97, July 7, 2011 (Dkt. 11). Plaintiffs sought an order compelling "agency action unlawfully withheld" under the Administrative Procedure Act (APA), 5 U.S.C. § 706(1).

"On December 16, 2011, nearly [thirty]-five years after their initial publication and during the pendency of this action, the FDA rescinded the 1977 [notices of opportunity for a hearing]." Order 17. The agency "did not rescind its findings" that the drug uses at issue were not shown to be safe. *Id.* at 50. On the contrary, it explained that the withdrawal of the notices "'should not be interpreted as a sign that FDA no longer has safety concerns or that FDA will not consider re-proposing withdrawal proceedings in the future, if necessary.'" *Id.* at 17-18 (quoting Withdrawal of Notices of Opportunity for a Hearing, 76 Fed. Reg. 79,697, 79,698 (Dec. 22, 2011)). Nonetheless, FDA argued that plaintiffs' action was now moot. *See* Reply Mem. in Supp. of the Government's Mot. for Summ. J. (Gov't Summ. J. Reply Br.) 9-10, Feb. 10, 2012 (Dkt. 55).

This Court disagreed. On March 22, the Court granted plaintiffs' motion for summary judgment on their first claim for relief.[1] The Court held that the "plain meaning" of the Food and Drug Act "requires the Secretary to issue notice and an opportunity for a hearing whenever he finds that a new animal drug is not shown to be safe," and "[i]f the drug sponsor does not meet his burden of demonstrating that the drug is safe at the hearing, the Secretary must issue an order withdrawing approval of the drug." Order 33-34. Finding that the agency "made the findings necessary to trigger mandatory withdrawal proceedings," *id.* at 46-47, the Court ordered FDA to conduct withdrawal proceedings for penicillin and tetracyclines in animal feed. *See id.* at 54. At the suggestion of the parties, the Court requested additional briefing on the "issue of a time-line for holding a hearing and issuing a final decision in the matter." *Id.* at 55 n.19.

ARGUMENT

I. A Judicially Imposed Schedule Is Necessary to Ensure FDA's Prompt Compliance with the Court's Order

A. This Court Should Disregard FDA's Attempts to Reargue the Merits

The Court should ignore FDA's uninvited attempts to reargue the merits of plaintiffs' underlying claim for relief. *See* Gov't Br. 1, 3-5, 8, 12-13. The Court ordered further briefing only on the "issue of a time-line," not on the question whether FDA violated the law and is required to conduct and complete withdrawal proceedings. Order 55 n.19. Thus, the agency's assertion that it needs time to "decide whether the science still supports the withdrawal" of the drug uses at issue is misdirected. Gov't Br. 12-13. The Court has already ordered FDA "to initiate withdrawal proceedings" by "re-issu[ing] a notice of the proposed withdrawals." Order

[1] In a separate claim, plaintiffs have challenged FDA's denial of two citizen petitions requesting that the agency withdraw approvals for several other nontherapeutic uses of medically important antibiotics in livestock production. *See* Pls.' 1st Supplemental Compl., Feb. 1, 2012 (Dkt. 53). That claim is pending.

54. Absent some revelation altering the scientific landscape, FDA is required to issue new notices of opportunity for a hearing.

The Court should likewise disregard FDA's complaint that, under any schedule, the "commitment of resources to Withdrawal Proceedings will detract from FDA's voluntary compliance program." Gov't Br. 16. That contention is irrelevant here. The Court has already held that FDA's pursuit of "'other ongoing regulatory strategies' . . . does not relieve it of its statutory obligation to complete withdrawal proceedings." Order 52-53. The sole legitimate subject of this remedy briefing is the deadline for FDA compliance with the Court's order.

B. This Court Has Authority to Impose a Schedule for Compliance

The Court has authority to impose a compliance schedule for FDA's withdrawal proceedings. In this case, it is necessary for the Court to do so.

District courts possess "broad equitable powers" to remedy violations of law. *Cobell v. Norton*, 240 F.3d 1081, 1108 (D.C. Cir. 2001). As the D.C. Circuit has concluded, "courts are presumed to possess the full range of remedial powers—legal as well as equitable—unless Congress has expressly restricted their exercise." *Id.* Here, the Court exercised its authority under the APA to compel an "agency action unlawfully withheld or unreasonably delayed." Order 18, 21, 54 (citing 5 U.S.C. § 706(1)). Courts granting relief under that provision, or issuing writs of mandamus under analogous circumstances, regularly set deadlines for agencies to act. They do so regardless of how they characterize the required action, i.e., as unlawfully withheld or unreasonably delayed. *See, e.g.*, *In re Core Commc'ns, Inc.*, 531 F.3d 849, 861-62 (D.C. Cir. 2008) (setting a deadline for the Federal Communications Commission (FCC) to respond to a court order enjoining it to explain the legal authority for rules it had issued); *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 420 (D.C. Cir. 2004) (ordering a response to plaintiffs' petition within forty-five days); *In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1150 (D.C.

Cir. 1992) (setting a deadline for the Occupational Safety and Health Administration (OSHA) to complete a rulemaking); *Pub. Citizen Health Research Grp. v. Brock*, 823 F.2d 626, 629 (D.C. Cir. 1987) (setting a deadline for OSHA to issue a final decision on a regulation); *Farmworker Justice Fund, Inc. v. Brock*, 811 F.2d 613, 633 (D.C. Cir.) (ordering the Secretary of Labor to issue a field sanitation standard within thirty days), *vacated as moot*, 817 F.2d 890 (D.C. Cir. 1987); *Potomac Elec. Power Co. v. Interstate Commerce Comm'n*, 702 F.2d 1026, 1035 (D.C. Cir. 1983) (setting a deadline for the Commission to reach a final decision in an administrative appeal); *Barnett v. Califano*, 580 F.2d 28, 32-33 (2d Cir. 1978) (upholding the district court's imposition of deadlines for the Social Security Administration to conduct hearings); *White v. Mathews*, 559 F.2d 852, 855, 859-60 (2d Cir. 1977) (same); *Ass'n of Am. R.R.s v. Costle*, 562 F.2d 1310, 1321-22 (D.C. Cir. 1977) (ordering the Environmental Protection Agency (EPA) to issue final regulations setting railroad noise emission standards within one year); *Natural Res. Def. Council, Inc. v. Train*, 545 F.2d 320, 322, 324, 328 (2d Cir. 1976) (upholding a district court order compelling EPA to list lead as a pollutant within thirty days), *aff'g* 411 F. Supp. 864 (S.D.N.Y.); *Families for Freedom v. Napolitano*, 628 F. Supp. 2d 535, 541 (S.D.N.Y. 2009) (ordering the Department of Homeland Security to respond to a petition within thirty days); *Pub. Citizen Health Research Grp. v. FDA*, 724 F. Supp. 1013, 1023 (D.D.C. 1989) (setting a deadline for FDA to issue a final tampon absorbency regulation); *Pub. Citizen v. Heckler*, 602 F. Supp. 611, 614 (D.D.C. 1985) (ordering FDA to issue a proposed rule reflecting its decision on plaintiff's citizen petition within sixty days); *see also Butts v. Barnhart*, 416 F.3d 101, 106 (2d Cir. 2005) (directing an administrative law judge on remand, in light of past delays, to complete proceedings to determine petitioner's eligibility for benefits within 120 days, provided petitioner was prepared to go forward with his case).

The cases FDA cites in arguing against a deadline are inapposite. In these cases, agency delay was either not at issue, or it was not sufficiently serious to warrant the imposition of a compliance schedule. *See Int'l Union, United Mine Workers of Am. v. Dep't of Labor*, 554 F.3d 150, 155 (D.C. Cir. 2009) (finding no need to impose a deadline on remand where the agency had remedied delay by issuing a rule); *Natural Res. Def. Council v. EPA*, 489 F.3d 1364, 1375 (D.C. Cir. 2007) (declining to set a deadline on remand in a case where delay was not at issue); *Qwest Commc'ns Int'l v. FCC*, 398 F.3d 1222, 1238-39 (10th Cir. 2005) (finding no unreasonable delay where the complexity of the task at hand justified the pace of the agency's action); *Baystate Med. Ctr. v. Leavitt*, 587 F. Supp. 2d 37, 41 (D.D.C. 2008) (declining to set a deadline on remand in a case where delay was not at issue).

Here, in contrast, FDA's "prolonged inaction" cries out for a compliance schedule. Order 51 n.16. FDA's mission is to protect the public health. *See* 21 U.S.C. § 393(b)(1)-(2) (setting forth FDA's mission to "protect the public health by ensuring that . . . human and veterinary drugs are safe and effective"). Since 1977, the agency has taken the position that penicillin and tetracyclines in animal feed pose a threat to human health. *See* Order 2-3, 45-47. For more than three decades, the agency has failed to act. *See id.* at 3. During that time, the scientific evidence affirming the public health threat has grown. *Id.* FDA's parent agency, the Department of Health and Human Services (HHS), has concluded that "the use of antimicrobials in food-producing animals has adverse human consequences." FDA, Draft Guidance No. 209, at 12 (internal quotation marks omitted). FDA's sister division within HHS, the Centers for Disease Control and Prevention (CDC), has cited the "compelling body of evidence" demonstrating the "adverse human health consequences" of antibiotic use in animals. Letter from Thomas R. Frieden, Director, CDC, to the Honorable Frank Pallone, Jr., Chairman, Subcommittee on Health, House

Committee on Energy and Commerce (July 13, 2010), 1st Sorenson Decl. Ex. W (Dkt. 33-23). And in 2010, FDA itself declared that using medically important antibiotics for livestock production purposes "is not in the interest of protecting and promoting the public health." FDA, Draft Guidance No. 209, at 13. Yet the agency continues to resist withdrawal proceedings, as its brief on a compliance schedule illustrates. *See infra* p. 12-13. In these circumstances, as demonstrated by the cases cited above, *supra* pp. 6-7, setting a deadline for agency action is both routine and appropriate.

FDA also relies on cases in which courts declined to impose a more intrusive remedy than a deadline for agency action. In *Sierra Club v. Army Corps of Engineers*, 701 F.2d 1011 (2d Cir. 1983), the Second Circuit upheld the district court's decision invalidating a construction permit and enjoining the agency from taking further action on the project without complying with the applicable environmental laws. The appellate court reversed the portion of the district court's order appointing a special master—an extraordinary remedy—but it found the agency's transgressions sufficiently serious to warrant the imposition of a rigorous recordkeeping requirement. *Id.* at 1048-49. The district court had appointed the special master with an eye toward resolving "in a timely fashion" any problems arising in the remand proceedings. *Id.* at 1043. But the question of a *deadline* for the agency to act was not at issue, because the plaintiffs sought to prevent, not to compel, agency action. Thus, *Sierra Club* is inapposite.

Similarly, *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 546 (1978), dealt with the question whether courts may require agencies to employ "extra procedural devices" beyond those called for in the governing statute, and *Federal Power Commission v. Transcontinental Gas Pipe Line Corp.*, 423 U.S. 326, 333 (1976), held that a reviewing court, after finding that additional evidence is needed to facilitate review,

ordinarily may not dictate the "methods, procedures, and time dimension" of the agency's efforts to supplement the record. Neither case precludes the imposition of a deadline for compliance with a court order remedying unlawful agency action.

FDA points to no case holding that it is inappropriate, or even unusual, for a court to set a compliance schedule when compelling an agency to take an action that it has unlawfully withheld or unreasonably delayed. The Court plainly has authority, and reason, to do so here.

C. FDA's Intransigence Demonstrates the Need for a Court-Ordered Schedule

A judicially imposed schedule is essential to ensure FDA's prompt compliance with the Court's order. The agency argues that, prior to the order, it did not believe itself to be under a legal duty to conduct withdrawal proceedings for penicillin and tetracyclines in animal feed. Gov't Br. 1, 5, 8. Now that the Court has ruled, the agency says there is "no reason to assume that [FDA] will not proceed expeditiously." *Id.* at 8 (internal quotation marks omitted). In fact, there are compelling reasons to believe that FDA will not act promptly without an enforceable deadline. The agency has acknowledged the threat posed by these drug uses for decades, but it has consistently neglected its statutory mandate to protect the public health. FDA's "prolonged inaction" on this critical issue, Order 51 n.16, the agency's conduct in response to this litigation, and the content of its remedy brief all demonstrate the agency's deep-seated resistance to conducting withdrawal proceedings, pointing to the need for a tight, Court-imposed compliance schedule.

FDA's concern about potential "threats to human and animal health" posed by the "long-term use of antibiotics, including penicillin and tetracyclines, in food-producing animals" dates to the "mid-1960s." Order 6. In the early 1970s, the agency took several steps to address the issue, including convening a task force and requesting additional safety information from drug manufacturers. *Id.* at 6-10. Ultimately, in 1977, FDA concluded that subtherapeutic uses of

penicillin and tetracyclines in animal feed were not shown to be safe for human health, and it issued notices of opportunity for a hearing on proposals to withdraw approval of these drug uses. *Id.* at 10-12.

"Although the notices were properly promulgated and over twenty drug sponsors requested hearings on the matter, the FDA never held hearings or took any further action on the proposed withdrawals." Order 3. Since 1970, the use of antibiotics in U.S. livestock production has quadrupled. *See supra* p. 3. At the same time, "the scientific evidence of the risks to human health from the widespread use of antibiotics in livestock has grown . . . ." Order 3. For example, in 1997, a World Health Organization expert committee report "recommended that the use of antimicrobial drugs for growth promotion in animals be terminated if these drugs are also prescribed for use as anti-infective agents in human medicine or if they are known to induce cross-resistance to antimicrobials used for human medical therapy." Order 16 (internal quotation marks omitted). FDA's prolonged—and illegal—inaction in the face of a growing public health crisis underlines the need for an enforceable deadline for the Court-ordered withdrawal proceedings.

FDA's response to this litigation has been marked by evasion and delay. After receiving an initial extension of time to answer plaintiffs' complaint, *see* Endorsed Letter, July 8, 2011 (Dkt. 12), FDA requested an additional two-month delay the day before its response to plaintiffs' motion for summary judgment was due. Government counsel represented that FDA needed the extension so that it could take "a significant administrative action that should moot plaintiffs' . . . claim." *See* Letter from Amy A. Barcelo to Hon. Theodore H. Katz, at 2 (Nov. 7, 2011), Ex. A to 3d Decl. of Jennifer A. Sorenson (3d Sorenson Decl.), May 25, 2012. FDA then withdrew the 1977 notices of opportunity for a hearing, "on the grounds that they were outdated," Order 3, but

it "did not rescind its findings" that penicillin and tetracyclines in animal feed were not shown to be safe. *Id.* at 50. Nonetheless, the agency contended that it had mooted plaintiffs' claim. Gov't Summ. J. Reply Br. 9-10. This Court rejected FDA's maneuvering, observing that if the notices were outdated, it was only because FDA's "prolonged inaction" had made them so. Order 51 n.16.

Now, in its brief on a compliance schedule, the agency says it withdrew the notices "to ensure that there was no confusion about its regulatory strategy going forward." Gov't Br. 5. There was no such confusion. Rather, the chronology of events compels the inference that FDA withdrew the notices in a disingenuous, last-ditch attempt to avoid adjudication of plaintiffs' claim for relief. The agency's game of "administrative keep-away" warrants a deadline for prompt action on remand. *Am. Rivers*, 372 F.3d at 420.

FDA's brief raises additional reasons to doubt that, absent a deadline, the agency will comply expeditiously with the Court's order. The agency attempts to reargue the merits, *see* Gov't Br. 1, 3-5, 8, 12-13; resists the imposition of any compliance schedule, *see id.* at 6-10; insists on prioritizing its voluntary program, *see id.* at 3-5, 16; complains that withdrawal proceedings will divert resources from other agency work, including responses to hypothetical emergencies, *see id.* at 15-17; proposes a relaxed, unreasonable schedule for the mandated withdrawal proceedings, *see id.* at 6; and nowhere acknowledges the urgency of addressing a threat to public health that, in other contexts, the agency itself has clearly and consistently articulated. *See, e.g.*, Mem. in Supp. of the Government's Mot. for Summ. J. on Pls.' 1st Supplemental Compl. (Gov't Summ. J. Br. on Supplemental Compl.) 2, Mar. 21, 2012 (Dkt. 64).

FDA's stubborn insistence on prioritizing its voluntary program betrays the agency's reluctance to accept the import of the Court's order. Throughout this litigation, the agency has

contended that it has discretion to decide how best to address the public health threat posed by the use of antibiotics in livestock production. *See* Mem. in Supp. of the Government's Mot. for Summ. J. 10-11, 16-18, Jan. 9, 2012 (Dkt. 41); Gov't Summ. J. Reply Br. 5, 8, 10; Hr'g Tr. 14-15, 29-31, 35-36, 42-48, Feb. 23, 2012, Ex. B to 3d Sorenson Decl. The Court disagreed, admonishing FDA that its pursuit of "'other ongoing regulatory strategies' . . . does not relieve it of its statutory obligation to complete withdrawal proceedings." Order 52-53. Despite that admonition, the agency protests that the mandated withdrawal proceedings might delay implementation of its voluntary program, which "may lessen drug sponsors' willingness to engage in the voluntary withdrawal process." Gov't Br. 16. The conflict that FDA perceives between the remedy ordered by the Court and the agency's preferred, extrastatutory program provides a disincentive for prompt compliance with the Court's order.

During this litigation, FDA has recognized that antibiotic resistance is "a mounting public health problem of global significance," and that "[p]reserving the effectiveness of current antimicrobials . . . [is] vital to protecting human . . . health against infectious microbial pathogens . . . ." Gov't Resp. to Pls.' Statement of Facts ¶¶ 6-7, Jan. 9, 2012 (Dkt. 45). The agency has found specifically that penicillin and tetracyclines in animal feed are not shown to be safe for human health. Order 10-12. Nowhere in its brief, however, does the agency acknowledge the imperative to comply speedily with the Court's order to address this public health threat. The depth and immediacy of that threat, coupled with the agency's demonstrated aversion to completing the Court-ordered withdrawal proceedings the statute requires, underscore the need for a Court-imposed compliance schedule.

II. FDA's Proposed Schedule Is Leisurely

A. Eleven to Seventeen Months to Issue Updated Notices Is Excessive

For its timing projections, FDA relies on the declaration of Dr. William T. Flynn, an official at FDA's Center for Veterinary Medicine (CVM). Dr. Flynn asserts that issuing new notices of opportunity for a hearing will require five steps. He estimates the number of employees and the total amount of time that will be needed to complete each step. These estimates are vague because they do not specify how much time or effort each employee will devote to each of the identified tasks. The estimates are also excessive, given the amount of time FDA already has spent studying the drugs at issue.

1. Time to Search CVM's Files

The first step Dr. Flynn identifies is a search of CVM's "official files for relevant information." Decl. of William T. Flynn (Flynn Decl.) ¶ 11, May 15, 2012 (Dkt. 86). Dr. Flynn estimates that it will take a team of "10 to 14 Agency employees . . . approximately 60 days" to complete this file search. *Id.* He does not specify how much time each employee will commit to this task, except to say that the time commitment will be "substantial." *Id.*

The vagueness of Dr. Flynn's estimate allows for tremendous variation: Assuming ten employees spend two hours per day on this task, and assuming there are forty-three workdays in sixty calendar days, then the estimate is 860 hours (10 times 2 times 43), or 86 hours per employee. The same ten employees working full-time could finish the file search in just over two weeks, assuming a forty-hour workweek. On the other hand, assuming fourteen employees work full-time on this task for the entire sixty-day period, then the estimate is 602 workdays (14 times 43 workdays). To put this in perspective, assuming 240 workdays per year, it would take a single employee working full-time 2.5 years to complete this search of CVM's own files. That estimate is not credible.

FDA's generous estimate for the time required to search its own files is suspicious in light of the time the agency says it has invested in researching the drug uses in question. In 2008, an FDA official reported to a Senate committee that the agency had made substantial progress in evaluating the safety of approved uses of penicillin and tetracyclines in animal feed. Answering a question about a $3 million line item in CVM's budget for studying the resistance implications of already approved antibiotics, Admiral Linda Tollefson, Assistant Commissioner for Science at FDA, and former Deputy Director of CVM, testified that the agency had been looking at currently approved penicillin and tetracycline products "in great detail," which included reviewing "the files . . . for each of those products." *Emergence of the Superbug: Antimicrobial Resistance in the United States, Hearing before the S. Comm. on Health, Education, Labor, and Pensions* (Senate Hearing), S. Hrg. No. 110-989, at 21 (2008), 3d Sorenson Decl. Ex. C. Following the hearing, in response to the Senators' questions for the record, FDA stated that, for penicillin-containing products, the agency had "reviewed *all information contained in the administrative files*, looking specifically for microbial food safety information that can be used to assess any potential human health risks." *Id.* at 74 (emphasis added). The agency reported that a "similar review process is being applied to other 'older' approved antimicrobial products (e.g., tetracyclines)." *Id.* This testimony suggests that FDA has already devoted significant time and resources to searching its files for information that would be relevant to withdrawal proceedings for penicillin and tetracyclines in animal feed.

Considering the work FDA has already done, it should take the agency no longer than two weeks to search its own files for relevant information, particularly if ten to fourteen employees are spending substantial amounts of time on this task.

2. Time to Search Publicly Available Literature

Second, Dr. Flynn states that "CVM would need to conduct an in-depth search for publicly available literature and other information (*e.g.*, scientific reports) on the scientific topics that would be addressed at the hearings." Flynn Decl. ¶ 12. He estimates that it will take six to ten agency employees ninety days to "complete the necessary literature search." *Id.*

Again, the declaration is vague because it does not specify how much time each employee will spend on the search. Assuming six employees spend two hours a day, and assuming there are sixty-five workdays in ninety calendar days, then the estimate is 780 hours (6 times 2 times 65), or 130 hours per employee. The same six employees working full-time could finish the literature search in just over three weeks, assuming a forty-hour workweek. On the other hand, assuming ten employees work full-time on this task for the ninety-day period, then the estimate is 650 workdays (10 times 65 workdays). Assuming 240 workdays per year, it would take a single employee working full-time 2.7 years to search the publicly available literature. Once again, this estimate is not credible.

Dr. Lance Price, a microbiologist who studies the public health impact of antibiotic use in food animal production and is familiar with the body of scientific literature on the topic, has provided an estimate of the amount of time he would expect to spend on such a literature search. Decl. of Lance Price, Ph.D. (Price Decl.) ¶¶ 1, 4, 6, May 23, 2012. For purposes of the estimate, he assumes he would search the literature from 1977 to the present, without having done any previous searches or analyses. *Id.* ¶ 6. Dr. Price projects that if he were to spend 20 percent of his time guiding two graduate-level research assistants in conducting the search, it would take thirty days to complete. *Id.* Dr. Price's estimate suggests that if CVM were to devote even four employees and 20 percent of a supervisor's time to the literature search, the agency should be able to finish the search in two weeks.

The agency has the benefit of its previous literature searches on this topic. Just last month, FDA published its Guidance for Industry No. 209, entitled *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*. In Part III, "Key Reports and Peer-Reviewed Scientific Literature on the Issue," FDA summarizes the "findings and recommendations" from some of the "notable reports" by "recognized international, governmental, and professional organizations" that have studied "the use of antimicrobial drugs in food-producing animals." FDA, Guidance No. 209, at 5. The agency also presents summaries of "some of the more recent scientific research related to the use of antimicrobial drugs in animal agriculture and the impact of such use on antimicrobial resistance." *Id.* FDA acknowledges that the review of the literature presented in Guidance No. 209 is not exhaustive. *Id.* At the conclusion of the review, however, the agency states that "the public health concerns associated with the use of medically important antimicrobial drugs in food-producing animals have been the subject of scientific interest for the past 40 years," and "FDA has considered *all available information*." *Id.* at 17 (emphasis added).

Additionally, Admiral Tollefson testified before the Senate committee in 2008 that the agency had "undertaken an extensive literature search to look to see if there's any new information on either the penicillins or the tetracyclines." Senate Hearing 21. In its follow-up responses to the committee, FDA confirmed that the agency had "searched and reviewed scientific literature for microbial food safety information for penicillin-containing products," and that it was applying a "similar review process" to tetracyclines. *Id.* at 74.

In light of these facts, it should take FDA no longer than two weeks to update its literature search.

3. Time to Review the Evidence and Frame Arguments

Third, Dr. Flynn estimates that it will take eight months to "review," "analyz[e]," and "evaluat[e]" the documents collected and "identify whether the available scientific data supports the withdrawal" of the penicillin and tetracycline products at issue. Flynn Decl. ¶ 13. Dr. Flynn describes two stages of work: (1) six months for six to ten agency employees to review the available evidence and (2) an additional sixty days for eight to twelve agency employees "to identify whether the . . . data supports . . . withdrawal . . . , and to frame the legal and scientific arguments that may be included" in the reissued notices. *Id.* Once again, Dr. Flynn does not specify the amount of time each employee will devote to these tasks. If FDA has its way, this eight-month step in the process would consume nearly half of the seventeen months the agency claims is required to update the notices.

For the first stage, Dr. Flynn's six-month estimate is excessive, considering the time and resources FDA has already devoted to reviewing the evidence. By FDA's own account, the agency "has been actively involved in the area of antimicrobial resistance for over 40 years," and "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 [CVM]." Gov't Summ. J. Br. on Supplemental Compl. 2. Last month, in its Guidance No. 209, FDA reported that the agency "has considered *all available information* and believes that the *weight of scientific evidence* supports the recommendations outlined in this guidance document." FDA, Guidance No. 209, at 17 (emphasis added). One of FDA's recommendations is that "medically important antimicrobial drugs" should not be used in food-producing animals for "production purposes," "[i]n light of the risk

that antimicrobial resistance poses to public health." *Id.* at 21.[2] Similarly, in 2010 FDA pronounced that "the *overall weight of evidence available to date* supports the conclusion that using medically important antimicrobial drugs for [livestock] production purposes is not in the interest of protecting and promoting the public health." FDA, Draft Guidance No. 209, at 13 (emphasis added).

Moreover, FDA has recently conducted updated risk assessments for several, if not all, of the drug products at issue. In 2003, CVM reported that it had "completed microbiological food safety reviews for five out of seven approved penicillin and penicillin combination products, and the first of several tetracycline products." CVM, *Annual Report, Fiscal Year 2003*, at 20, 3d Sorenson Decl. Ex. D. By 2004, the agency had "completed microbiological food safety reviews of the last of seven approved penicillin and penicillin combination products," and "[r]eview of several approved tetracycline products [was] underway." CVM, *Annual Report, Fiscal Year 2004*, at 30, 3d Sorenson Decl. Ex. E. The same year, FDA sent letters to several manufacturers of approved animal feed products containing penicillin and tetracyclines, reporting that the agency had conducted a qualitative risk assessment and concluded that the products fell into a "high" risk category. Gov't Resp. to Pls.' Statement of Facts ¶ 65.

Given the amount of attention the agency says it has already devoted to this issue, the assertion that CVM now needs six months to review the available evidence is not credible. Thirty days should be sufficient.

Dr. Flynn begins from a faulty premise when he says the agency needs another sixty days to "identify whether the available scientific data supports . . . withdrawal." Flynn Decl. ¶ 13.

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[2] FDA considers penicillin and tetracyclines to be medically important. Gov't Resp. to Pls.' Statement of Facts ¶ 22.

Based on the record before it, this Court has already ordered FDA "to initiate withdrawal proceedings" by "re-issu[ing] a notice of the proposed withdrawals." Order 54. The agency found in 1977 that subtherapeutic uses of penicillin and tetracyclines in animal feed "had not been proven to be safe," Order 2, and there is "no evidence that the FDA has [since] changed its position that such uses are not shown to be safe." *Id.* at 3. The agency's findings "trigger[ed] mandatory withdrawal proceedings." *Id.* at 46-47. The agency reinforced its findings last month in FDA's Guidance No. 209, the premise of which is that these drug uses are not safe or shown to be safe for human health. *See supra* pp. 18-19. Barring some revelation that changes the scientific landscape, FDA is required to issue new notices of opportunity for a hearing.

It should not take more than a week to validate the position FDA has held for more than thirty years, *see* Order 2, and to frame the legal and scientific arguments for the reissued notices.

4. Time to Draft, Review, Edit, and Publish the Updated Notices

Fourth, Dr. Flynn estimates that it will take ten to fourteen employees approximately sixty days to draft the updated notices, and, fifth, he estimates an additional sixty days for senior agency management to "review and clear" the notices, and for the notices "to be edited and published in the Federal Register." Flynn Decl. ¶¶ 14-15. Once again, given the work FDA says it has already done, *see supra* pp. 18-19, 120 days to update and finalize the notices is too long. The agency is well versed in the issues, and it will already have completed a thorough analysis of the recent scientific literature. It should not take more than sixty days to draft, review, and publish the updated notices.

* * *

It need not, and should not, take eleven months—much less seventeen months—to reissue the notices, for the reasons described above. Dr. Flynn suggests that his total time estimate could be shortened if the agency "is able to conduct certain of the . . . tasks

simultaneously," but he makes no attempt to find or incorporate such economies in the timeline he has proposed. Flynn Decl. ¶ 16. Plaintiffs see no reason why the agency cannot, for example, begin to review immediately the scientific evidence it has on hand. Simultaneous execution of tasks could shorten considerably the time required to reissue the notices.

The vagueness of Dr. Flynn's declaration is further evidence of the agency's resistance to comply expeditiously with the Court's order. A judicially imposed deadline is essential to ensure compliance. Plaintiffs propose the following schedule for reissuing the notices:

- 2 weeks to search CVM's files;
- 2 weeks to update the agency's literature search;
- 30 days to review the available evidence;
- 1 week to validate FDA's position and to frame the legal and scientific arguments for the reissued notices;
- 60 days to draft, review, and publish the updated notices.

Under this schedule, the agency would reissue the notices within 125 days.

B. This Court Should Direct FDA to Conduct Any Required Hearing with All Reasonable Speed

This Court can and should direct FDA to conduct any required hearing expeditiously. (A hearing will occur only if drug sponsors request one and FDA grants the request. 21 C.F.R. § 514.200(c).) Dr. Flynn describes two main stages in the hearing process: (1) issuing a notice of hearing (following a review of any requests for a hearing received in response to the reissued notices of opportunity for a hearing) and (2) conducting the hearing. He estimates that the first stage will take eight months, and the second, forty-one months. Flynn Decl. ¶¶ 21, 25; Gov't Br. 14. Both estimates are bloated.

After FDA issues a notice of opportunity for a hearing on a proposal to withdraw approval of an animal drug product, drug sponsors have thirty days to request a hearing. *See* 21 C.F.R. § 514.200(a). Dr. Flynn projects that it would take nine to thirteen agency employees

ninety days to review any requests for a hearing; it would take four agency employees an additional sixty days "to develop a recommendation . . . on whether to grant a hearing"; and, if a hearing were granted, it would take sixty more days to publish a notice of hearing in the Federal Register. Flynn Decl. ¶¶ 18-21. Again, Dr. Flynn does not specify how much time each employee would spend on these tasks. Nor does he explain why it would take the agency seven months to review any requests for a hearing (which themselves would have been prepared in under thirty days), determine whether a hearing was warranted, and publish a notice of hearing. Given the agency's long familiarity with the issues and its obligation to act promptly to comply with the Court's order, it should not take longer than sixty days for FDA to review any requests for a hearing and issue a notice of hearing.

Contrary to FDA's assertion that "it is not advisable for this Court to cabin the ALJ's scheduling discretion in advance," Gov't Br. 10, the Court can and should direct the Administrative Law Judge (ALJ) to conduct any required hearing with all reasonable speed, and to issue an initial decision by a reasonable deadline. To remedy agency inaction and delay, the Second Circuit has repeatedly imposed or upheld deadlines for an ALJ to complete an administrative hearing. *See Butts*, 416 F.3d at 106 (setting a deadline of 120 days for an ALJ to complete proceedings to determine petitioner's eligibility for benefits); *Barnett*, 580 F.2d at 32-33 (upholding the district court's imposition of deadlines for the Social Security Administration to conclude hearings); *White*, 559 F.2d at 855, 859-60 (same).

Here, there is good reason for the Court to set a schedule for the ALJ to complete any hearing promptly. The Court has ordered FDA to conduct withdrawal proceedings, including any required hearing, to remedy the agency's "prolonged" and unlawful inaction. Order 51 n.16, 54. The reason for the proceedings is to address a serious public health threat that FDA has

acknowledged, but failed to confront, for more than three decades. The agency has indicated its reluctance to comply with the Court's order, particularly in light of the conflict it perceives between the mandated withdrawal proceedings and its preferred voluntary program. Additionally, history suggests that FDA, as a party to any hearing, will seek an extended schedule. During the withdrawal proceedings for another animal drug, fluoroquinolones used in poultry, the ALJ chided the parties for proposing a hearing schedule in April 2002 that provided "for an unduly prolonged process that would extend this proceeding well into the year 2004." *In re: Enrofloxacin for Poultry* (Scheduling Order) 1, FDA Dkt. No. 00N-1571 (Apr. 10, 2002), 3d Sorenson Decl. Ex. F; *see also* FDA, *Update: FDA's Proposed Withdrawal of Approval of Poultry Fluoroquinolones* 1, http://www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals/ucm042012.htm, 3d Sorenson Decl. Ex. G (noting that the parties were required to propose a schedule). The ALJ ordered a revised schedule under which the oral portion of the hearing would conclude by early May 2003. Scheduling Order 2.

FDA's regulations give the ALJ "all powers necessary to conduct a fair, expeditious, and orderly hearing." 21 C.F.R. § 12.70. If this Court directed the ALJ to issue an initial decision by a reasonable deadline, the ALJ would have authority to expedite the hearing, if necessary, to comply with the Court's schedule. Plaintiffs propose that the Court direct the ALJ to issue an initial decision within twelve months of the publication of the notice of hearing.

Following an initial decision by the ALJ, parties have sixty days to appeal to the Commissioner of Food and Drugs by filing exceptions, and sixty days to reply to exceptions filed by other parties. *See* 21 C.F.R. § 12.125(a), (c). The Commissioner "may invite the participants to file briefs or present oral argument on the matter." *Id.* § 12.125(f). FDA's regulations direct the Commissioner to issue a final decision "[a]s soon as possible after the filing of briefs and any

oral argument." *Id.* § 12.130(c). Plaintiffs propose that the Court order the Commissioner to resolve any appeal within sixty days of the expiration of time for replying to exceptions.

In summary, plaintiffs propose the following schedule for the hearing process:

- 30 days for drug sponsors to request a hearing, following the issuance of revised notices of opportunity for a hearing;
- 60 days for FDA to determine whether a hearing is warranted and issue a notice of hearing;
- 12 months for the ALJ to conduct the hearing and issue an initial decision;
- 60 days for the parties to file exceptions;
- 60 days for the parties to reply to exceptions; and
- 60 days for the Commissioner to resolve any appeal.

Under this schedule, the Commissioner would issue a final decision within twenty-one months of the publication of the revised notices of opportunity for a hearing. Allowing 125 days for FDA to issue the revised notices, the agency would complete the withdrawal proceedings, including any administrative appeal, in just over two years.

III. This Court Should Not Countenance FDA's Scare Tactics

FDA indulges in scare tactics, raising the specter of "'the deaths of dogs and cats'" if the schedule imposed by the Court is not "'flexible enough that CVM can respond to public health and animal health crises as they may arise.'" Gov't Br. 16 (quoting Flynn Decl. ¶ 29). But the agency provides no specifics about its ability to respond to crises while attending to its other obligations. CVM's Office of New Animal Drug Evaluations (ONADE) employs 216 people, and its Office of Research (OR), 85. *See* HHS, Employee Directory, http://directory.psc.gov/employee.htm (search for employees in CVM/ONADE), 3d Sorenson Decl. Ex. H; HHS, Employee Directory, http://directory.psc.gov/employee.htm (search for employees in CVM/OR), 3d Sorenson Decl. Ex. I. An agency can always argue that complying with a court order will require it to expend resources that it would otherwise spend differently. But that does not

diminish the agency's obligation to remedy its violation of the law when a court orders it to do so. "[T]hough the agency's decision of how to allocate its resources is entitled to deference, *In Re Barr*, 930 F.2d at 76, such deference yields when the statutory violation (here an excruciatingly long delay) is egregious and ceases to be reasonable." *Sandoz, Inc. v. Leavitt*, 427 F. Supp. 2d 29, 40 (D.D.C. 2006) (citing *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)).

FDA's violation of law is egregious. For more than three decades, the agency defied the Food and Drug Act—and its mission to protect the public—by failing to act on its own findings that penicillin and tetracyclines in animal feed have not been shown to be safe for human health. During this long period of agency neglect, the use of antibiotics in livestock production proliferated, as did the scientific evidence of the threat to public health. A judicially imposed schedule will ensure that FDA acts promptly, at long last, to right this wrong.

CONCLUSION

For the foregoing reasons, plaintiffs respectfully request that this Court impose the following schedule for FDA to comply with the Court's March 22, 2012 Order: (1) CVM must issue revised notices of opportunity for a hearing within 125 days of the Court's scheduling order; (2) CVM must issue any notice of hearing within 60 days of the deadline for requesting a hearing; (3) the ALJ must issue an initial decision within 12 months of the publication of the notice of hearing; and (4) the Commissioner must resolve any appeal within 60 days of the expiration of the period prescribed by regulation for replying to exceptions to the ALJ's decision.

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Respectfully submitted,

Mitchell S. Bernard (MB 5823)
Natural Resources Defense Council, Inc.
40 West 20th Street
New York, New York 10011
(212) 727-2700
(212) 727-1773 (fax)
mbernard@nrdc.org

s/ Jennifer A. Sorenson
Avinash Kar, admitted *pro hac vice*
Jennifer A. Sorenson, admitted *pro hac vice*
Natural Resources Defense Council, Inc.
111 Sutter Street, 20th Floor
San Francisco, California 94104
(415) 875-6100
(415) 875-6161 (fax)
akar@nrdc.org; jsorenson@nrdc.org

Counsel for Plaintiffs

Of Counsel for Plaintiff Center for Science in the Public Interest:

Stephen Gardner (SG 3964)
Center for Science in the Public Interest
5646 Milton Street, Suite 211
Dallas, Texas 75206
(214) 827-2774
(214) 827-2787 (fax)
sgardner@cspinet.org