UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC., et al.,	
Plaintiffs,	11 Civ. 3562(THK)
-against-	**MEMORANDUM OPINION AND ORDER**
UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,	
Defendants.	

THEODORE H. KATZ, UNITED STATES MAGISTRATE JUDGE.

Plaintiffs Natural Resources Defense Council, Inc. ("NRDC"), Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, and Union of Concerned Scientists, Inc. (collectively "Plaintiffs") bring this action against the United States Food and Drug Administration ("FDA"), Margaret Hamburg, in her official capacity as Commissioner of the FDA, the Center for Veterinary Medicine ("CVM"), Bernadette Dunham, in her official capacity as Director of the CVM, United States Department of Health and Human Services ("HHS"), and Kathleen Sebelius, in her official capacity as Secretary of HHS, alleging that the FDA withheld agency action in violation of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360b(e)(1), and the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(1). The parties have consented to trial

before this Court, pursuant to 28 U.S.C. § 636(c). Presently before the Court are the parties' cross-motions for summary judgment. For the reasons that follow, Plaintiffs' motion is granted and Defendants' motion is denied.

BACKGROUND[1]

I. Overview

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. In 1977, the FDA issued notices announcing its intent to withdraw approval of the use of certain antibiotics in livestock for the purposes of growth promotion and feed efficiency, which the agency had found had not been proven to be safe. The FDA issued the notices pursuant to 21 U.S.C. § 360b(e)(1), which states that

> [t]he Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . . with respect to any new animal drug if the Secretary finds . . . (B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application

[1] Except where otherwise noted, the following facts, derived from the parties' Statements Pursuant to Local Civil Rule 56.1, are undisputed.

> 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 . . . .

21 U.S.C. § 360b(e)(1)(B). 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.

In the intervening years, 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. In May 2011, after the FDA failed to respond to two Citizen Petitions urging the agency to follow through with the 1977 notices, Plaintiffs filed this action seeking a court order compelling the FDA to complete the withdrawal proceedings for antibiotics included in the 1977 notices. In December 2011, the FDA withdrew the original notices on the grounds that they were outdated, and it now argues that Plaintiffs' claim is moot.

II. Use of Antibiotics in Food-Producing Animals

Antibiotics, also known as antimicrobials, are drugs used to treat infections caused by bacteria. Although antibiotics have saved countless lives, the improper use and overuse of antibiotics has led to a phenomenon known as antibiotic resistance.

Specifically, the misuse of antibiotics creates selective evolutionary pressure that enables antibiotic resistant bacteria to increase in numbers more rapidly than antibiotic susceptible bacteria, increasing the opportunity for individuals to become infected by resistant bacteria. People who contract antibiotic-resistant bacterial infections are more likely to have longer hospital stays, may be treated with less effective and more toxic drugs, and may be more likely to die as a result of the infection. The FDA considers antibiotic resistance "a mounting public health problem of global significance." (First Amended Complaint ("First Am. Compl.") ¶ 38; Answer ¶ 38.)

In the 1950s, the FDA approved the use of antibiotics to stimulate growth and improve feed efficiency in food-producing animals, such as cattle, swine, and chickens. Antibiotics used for growth promotion are typically administered through animal feed or water on a herd- or flock-wide basis. The approved doses of antibiotics for growth promotion are typically lower than the approved doses for disease treatment. The administration of "medically important"[2] antibiotics to entire herds or flocks of

[2] The term "medically important antibiotics" refers to antibiotic drugs that are important for therapeutic use in humans.

food-producing animals, at "subtherapeutic"[3] levels, poses a qualitatively higher risk to public health than the administration of such drugs to individual animals or targeted groups of animals to prevent or treat specific diseases. (See Answer ¶ 34.) Research has shown that the use of antibiotics in livestock leads to the development of antibiotic-resistant bacteria that can be – and has been – transferred from animals to humans through direct contact, environmental exposure, and the consumption and handling of contaminated meat and poultry products. Consequently, the FDA has concluded that "the overall weight of evidence available to date supports the conclusion that using medically important antimicrobial drugs for production purposes [in livestock] is not in the interest of protecting and promoting the public health." (Guidance No. 209, attached as Exhibit B ("Ex. B") to Declaration of Assistant United States Attorney Amy A. Barcelo ("Barcelo Decl.") at 13.)

III. Penicillin and Tetracyclines

The present action pertains to the use of three different

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[3] The term "subtherapeutic" was commonly used in the 1960s and 1970s to refer to any use of antibiotics for purposes other than disease treatment and prevention, including growth promotion and feed efficiency in animals. Although FDA no longer uses the term, in this Opinion the Court uses the term "subtherapeutic" to refer to the use of antibiotics in food-producing animals for growth promotion and feed efficiency.

antibiotics in animal feed: penicillin and two forms of tetracycline – chlortetracycline and oxytetracycline ("tetracyclines"). Pursuant to the FDCA, any "new animal drug"[4] that is introduced into interstate commerce must be the subject of an FDA approved new animal drug application ("NADA") or, with respect to generic drugs, an abbreviated NADA ("ANADA"). See 21 U.S.C. § 360b(b)-(c). Drug companies that submit NADAs/ANADAs are typically referred to as "applicants" or "sponsors." The FDA lawfully issued NADAs and ANADAs for penicillin and tetracyclines in the mid-1950s. Since that time, penicillin has been used to promote growth in chickens, turkeys, and swine, and tetracyclines have been used to promote growth in chickens, turkey, swine, cattle, and sheep.

In the mid-1960s, the FDA became concerned that the long-term use of antibiotics, including penicillin and tetracyclines, in food-producing animals might pose threats to human and animal health. As a result, in 1970, the agency convened a task force to study the risks associated with the use of antibiotics in animal feed. The task force was composed of scientists from the FDA, the National Institutes of Health, the U.S. Department of Agriculture,

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[4] A new animal drug is defined, in part, as "any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed . . . ." See 21 U.S.C. § 321(v).

the Center for Disease Control, as well as representatives from universities and industry. In 1972, the task force published its findings, concluding that: (1) the use of antibiotics in animal feed, especially at doses lower than those necessary to prevent or treat disease, favors the development of antibiotic-resistant bacteria; (2) animals receiving antibiotics in their feed may serve as a reservoir of antibiotic pathogens, which can produce human infections; (3) the prevalence of bacteria carrying transferrable resistant genes for multiple antibiotics had increased in animals, and the increase was related to the use of antibiotics; (4) antibiotic-resistant bacteria had been found on meat and meat products; and (5) the prevalence of antibiotic resistant bacteria in humans had increased. See Antibiotic and Sulfonamide Drugs in Animal Feeds, 37 Fed. Reg. 2,444, 2,444-45 (Feb. 1, 1972). The task force made several recommendations, including that (1) antibiotics used in human medicine be prohibited from use in animal feed unless they met safety criteria established by the FDA, and (2) several specific drugs, including penicillin and tetracyclines, be reserved for therapeutic use unless they met safety criteria for non-therapeutic use. See id. at 2,445.

In response to the findings of the task force, the FDA, in 1973, 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 . . . under specific criteria" established by the FDA. Antibiotic and Sulfonamide Drugs in the Feed of Animals, 38 Fed. Reg. 9,811, 9,813 (Apr. 20, 1973) (codified at former 21 C.F.R. § 135.109; renumbered at 21 C.F.R. § 558.15). One of the most important of the human and animal health safety criteria that the FDA established for drug safety evaluations under the regulation involved the transfer of antibiotic resistant bacteria from animals to humans. The FDA regulation required that "[a]n antibacterial drug fed at subtherapeutic levels to animals must be shown not to promote increased resistance to antibacterials used in human medicine." Penicillin-Containing Premixes Notice ("Penicillin Notice"), 42 Fed. Reg. 43,772, 43,774 (Aug. 30, 1977). The other health safety criteria involved showing that use of antibiotics would not increase salmonella in animals, would not increase the pathogenicity of bacteria, and would not increase residues in food ingested by man, which may cause "increased numbers of pathogenic bacteria or an increase in the resistence of pathogens to antibacterial agents used in human medicine." See id.

Over the next two years, the Bureau of Veterinary Medicine

("BVM"),[5] a subdivision of the FDA, reviewed the data submitted by drug sponsors to support the subtherapeutic use of antibiotics. By April 20, 1975, all data concerning the safety and efficacy criteria for antibiotic drugs had been received. See id. at 43,774. The BVM was assisted by a sub-committee of the FDA's National Advisory Food and Drug Committee ("NAFDC") in its review of the data. The NAFDC sub-committee issued a report and recommendations on the subtherapeutic use of penicillin in animal feed, which the NAFDC adopted in 1977. See id. The NAFDC "recommended that FDA immediately withdraw approval for the subtherapeutic uses of penicillin, i.e., growth promotion/feed efficiency, and disease control." Id. Similarly, the NAFDC sub-committee made certain recommendations regarding the use of tetracyclines in animal feed. Specifically, for tetracyclines, the sub-committee recommended that the FDA "(1) discontinue their use for growth promotion and/or feed efficiency in all animal species for which effective substitutes are available, (2) permit their use for disease control where effective alternate drugs are unavailable . . ., and (3) control the distribution of the tetracyclines through . . . a veterinarian's order to restrict their use." Tetracycline (Chlortetracycline and Oxytetracycline)-Containing

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[5] The BVM was renamed the Center for Veterinary Medicine ("CVM") in 1984.

Premises; Opportunity for Hearing ("Tetracycline Notice"), 42 Fed. Reg. 56,264, 56,266 (Oct. 21, 1977). The NAFDC rejected the first two recommendations, but adopted the third recommendation. See id.

IV. The 1977 NOOHs

After carefully considering the recommendations of the NAFDC and the NAFDC sub-committee, the Director of the BVM issued notices of an opportunity for hearing ("NOOHs") on proposals to withdraw approval of all subtherapeutic uses of penicillin in animal feed, see Penicillin Notice, 42 Fed. Reg. at 43,772, and, with limited exceptions, all subtherapeutic uses of oxytetracycline and chlortetracycline in animal feed, see Tetracycline Notice, 42 Fed. Reg. at 56,264. In the Penicillin Notice, the Director reported that "[n]one of the specified human and animal health safety criteria [for the subtherapeutic use of antibiotics in animal feed] have been satisfied. . . ." Penicillin Notice, 42 Fed. Reg. at 43,775. With respect to the transfer of antibiotic-resistant bacteria, the Director surveyed the available data and found that (1) the pool of bacteria carrying transferrable resistance genes was increasing; (2) the increase was due in part to the subtherapeutic use of penicillin in animal feed; and (3) antibiotic-resistant bacteria were transferred from animals to humans as a result of direct human-animal contact, the consumption of contaminated food, and the widespread presence of resistant

bacteria in the environment. See id. at 43,781. Studies submitted by penicillin applicants and sponsors had failed to rebut theses findings. See id. Based on this evidence, the Director of the BVM proposed to withdraw approval of all NADAs/ANADAs for the use of penicillin in animal feed on the grounds "that the[se] drug products are not shown to be safe. . . ." Id. at 43,792. The Director further cautioned that "[t]he evidence, in fact, indicates that such penicillin use may be unsafe . . . ." Id.

Similarly, the Director of the BVM announced health and safety concerns regarding the subtherapeutic use of tetracyclines in animal feed. The Director explained that "[e]vidence demonstrates that the use of subtherapeutic levels of the tetracyclines . . . in animal feed contributes to the increase in antibiotic resistant E. Coli and in the subsequent transfer of this resistance to Salmonella. Further, some strains of E. Coli and Salmonella infect both man and animals. . . . Thus, the potential for harm exists . . . ." Tetracycline Notice, 42 Fed. Reg. at 56,267. The Director also noted that, in response to the 1972 FDA regulation announcing the health safety criteria for use of antibiotics in animal feed, the studies submitted by the holders of tetracyclines NADAs/ANADAs "were inconclusive because the studies were inappropriate." Id. The Director concluded that he "is unaware of evidence that satisfies the requirements for demonstrating the safety of

extensive use of subtherapeutic tetracycline-containing premixes . . . ." Id. at 56,288. Based on this evidence, the Director proposed to withdraw approval of certain NADAs/ANADAs for the subtherapeutic use of tetracyclines "on the grounds that they have not been show to be safe. . . ." Id.

In response to the 1977 NOOHs, approximately twenty drug firms, agricultural organizations, and individuals requested hearings. See Penicillin and Tetracycline in Animal Feeds Hearing, 43 Fed. Reg. 53,827, 53,828 (Nov. 17, 1978). On November 9, 1978, the Commissioner of the FDA granted the requests for hearings, stating that "there w[ould] be a formal evidentiary public hearing on [the proposed withdrawals]." Id. at 53,827. The Commissioner stated that a date for the hearing would be set "as soon as practicable." Id. at 53,827-28. According to the statutory and regulatory scheme, at the hearing, the drug sponsors would have the burden of proving that the drugs were in fact safe. (See FDA, Final Decision of the Commissioner, Withdrawal of Approval of the New Animal Drug Application for Enrofloxacin in Poultry ("Enrofloxacin Decision"), attached as Ex. N to Barcelo Decl. at 8-9.)

V. The FDA's Actions Following the Issuance of the 1977 NOOHs

The Commissioner never set a date for the hearings on the BVM's proposal to withdraw approval of the use of penicillin and

tetracyclines in animal feed. In the late 1970s and early 1980s, Congressional committees issued three reports that contained statements that the FDA interpreted as requests to postpone the withdrawal hearings pending further research. Specifically, in 1978, the House Committee on Appropriations "recommend[ed]" that the FDA conduct research regarding "whether or not the continued subtherapeutic use of [penicillin and tetracyclines] would result in any significant human health risk" before revoking such approval. H.R. Rep. No. 95-1290, at 99-100 (1978). In 1980, the House Committee on Appropriations requested that the FDA "hold in abeyance any implementation" of the proposed revocation pending further research. H.R. Rep. No. 96-1095, at 105-06 (1980). In 1981, the Senate Committee on Appropriations made a similar request. See S. Rep. No. 97-248, at 79 (1981). Importantly, none of these recommendations was adopted by the full House or Senate, and none was passed as law.

Regardless of the legal effect of these Congressional statements, the FDA never held hearings on the proposed withdrawals, and instead engaged in further research on the risks associated with the subtherapeutic use of antibiotics in food-producing animals. Soon after the initial House Appropriations Committee request, the FDA contracted with the National Academy of Sciences ("NAS") to assess the human health consequences of the

subtherapeutic use of penicillin and tetracyclines in animal feed by evaluating existing data, and to recommend areas for additional research. The NAS issued its report in 1980, drawing no conclusions about the safety of the subtherapeutic use of antibiotics in animal feed and recommending additional epidemiological studies. The FDA then contracted with the Seattle-King County Department of Public Health ("Seattle-King County") and the Institute of Medicine for further research. In 1984, Seattle-King County published its study, finding support for FDA's concerns about the risks posed by antibiotics in animal feeds. For example, the study found that Campylobacter bacteria were likely transferred from chickens to humans through the consumption of poultry products; samples of such bacteria taken from poultry products and humans exhibited "surprisingly high" rates of tetracycline resistance; and drug-resistant Campylobacter could transfer resistant genes to other bacteria. (See Excerpt from Seattle-King County Department of Public Health 1984 Report, attached as Ex. G to Declaration of Jennifer A. Sorenson ("Sorenson Decl.") at 3, 169.) The Institute of Medicine issued its report in 1988. Like the NAS, it could not conclude that the subtherapeutic use of antibiotics in animal feed was safe. However, it found several sources of "indirect evidence implicating subtherapeutic use of antimicrobials in producing resistance in infectious bacteria that

causes a potential human health hazard." (See Excerpt from Institute of Medicine 1988 Report, attached as Ex. H to Sorenson Decl. at 194.)

After the publication of the Seattle-King County and the Institute of Medicine studies, the FDA took little action on the still-pending 1977 NOOHs. In 1983, the Commissioner denied requests from several drug sponsors to rescind the 1977 NOOHs. See Penicillin and Tetracycline in Animal Feeds, 48 Fed. Reg. 4,554, 4,556 (Feb. 1, 1983). The Commissioner explained that the 1977 NOOHs "represent[ed] the Director's formal position that use of the drugs is not shown to be safe" and that the Commissioner "concur[red]" with the decision of the Director. Id. In 2003, the FDA published a proposed rule that referenced the risks to human health from the subtherapeutic use of antibiotics in animal feed. See New Animal Drugs; Removal of Obsolete and Redundant Regulations, 68 Fed. Reg. 47,272, 47,272 (Aug. 8, 2003). The FDA referenced the NAS and Institute of Medicine reports, as well other relevant studies. See id. at 47,275. The FDA "(1) [c]oncluded that the risks were neither proved nor disproved, (2) did not deny there was some degree of risk, and (3) did not conclude that the continued subtherapeutic use of penicillin and tetracyclines in animal feed is safe." Id. In 2004, the BVM, now known as the Center of Veterinary Medicine ("CVM"), sent letters to several

manufacturers of approved animal feed products containing penicillin and tetracyclines, explaining that "[t]he administrative record does not contain sufficient information to alleviate the CVM's concerns about the use of [these] product[s] and [their] possible role in the emergence and dissemination of antimicrobial resistance." (FDA Letters to Drug Sponsors (2004), attached as Ex. N to Sorenson Decl. at 2.) The FDA invited manufacturers to meet with the agency to discuss the agency's findings. (See id.)

On June 28, 2010, the FDA released a non-binding Draft Guidance entitled The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals ("2010 Draft Guidance"). (See Guidance No. 209, attached as Ex. B to Barcelo Decl. at 1.) In the Draft Guidance, the FDA reviewed recent scientific studies on the risks posed by the subtherapeutic use of antibiotics in animal feed, including a 1997 World Health Organization expert committee report that "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." (See id. at 8.) After reviewing the scientific evidence, the FDA concluded that "the overall weight of evidence available to date supports the conclusion that using medically important

antimicrobial drugs for production purposes is not in the interest of protecting and promoting the public health." (Id. at 13.) The FDA announced two non-mandatory principles to guide the use of antibiotics in animal feed: (1) "[t]he use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health[;]" and (2) "[t]he use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation." (Id. at 16-17.)

On December 16, 2011, nearly twenty-five years after their initial publication and during the pendency of this action, the FDA rescinded the 1977 NOOHs. See Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed ("NOOH Withdrawals"), 76 Fed. Reg. 79,697, 79,697 (Dec. 22, 2011). The FDA explained that it was rescinding the NOOHs because the "FDA is engaging in other ongoing regulatory strategies developed since the publication of the 1977 NOOHs" and that if the FDA were to move forward with the NOOHs it would need to "update the NOOHs to reflect current data, information, and policies" and "prioritize any withdrawal proceedings." Id. The FDA noted that "although [it] is withdrawing the 1977 NOOHs, FDA remains concerned about the issue of antimicrobial resistance." Id. at 79,698. The FDA

explained that the withdrawal of the NOOHs "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 79,698.

VI. The Present Action

Plaintiffs filed the present action on May 25, 2011, alleging that the FDA's failure to withdraw approval of the subtherapeutic use of penicillin and tetracyclines pursuant to the 1977 NOOHs constituted an agency action unlawfully withheld or unreasonably delayed in violation of the APA, 5 U.S.C. § 706(1), and the FDCA, 21 U.S.C. § 360b(e)(1).[6] Plaintiffs seek a Court order compelling

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[6] The First Amended Complaint contained an additional claim pertaining to two Citizen Petitions submitted by Plaintiffs to the FDA in 1999 and 2005. (See First Amended Compl. ¶¶ 99-101.) In those Citizen Petitions, Plaintiffs petitioned the FDA to immediately withdraw approval for certain uses of penicillin and tetracyclines in livestock given the evidence of the risks posed to human health. (See id. ¶¶ 82-87.) The FDA never issued a final response to these petitions. On November 7, 2011, the FDA issued final responses to both Citizen Petitions, denying the requested action. (See Stipulation and Order, dated Jan. 6, 2012). Consequently, Plaintiffs withdrew their claim as to the Citizen Petitions as moot, and the Court dismissed the claim without prejudice. (See id.) On January 9, 2012, Plaintiffs filed a motion for leave to file a supplemental complaint, which the Court granted on January 31, 2012. (See Scheduling Order, dated Jan. 31, 2012.) Plaintiffs filed their Supplemental Complaint on February 1, 2012, which added a claim that the FDA's final responses to the 1999 and 2005 Citizen Petitions were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the [FDCA], 21 U.S.C. § 360b, and the APA, 5 U.S.C. § 706(2)." (Supplemental Compl. ¶ 38.)

the FDA to withdraw approval for the subtherapeutic use of penicillin and tetracyclines in animal feed, unless, after a hearing, the drug uses at issue are determined to be safe. (See Amended Compl. ¶ 101(C).) Plaintiffs further request that the Court set a deadline by which the FDA must hold hearings and issue a final decision on the withdrawals. (See id.) Plaintiffs maintain that under the FDCA,[7] 21 U.S.C. § 360b(e)(1), once the FDA found that the subtherapeutic use of penicillin and tetracyclines in animal feed was not shown to be safe to humans, the agency was statutorily obligated to withdraw approval of those uses, unless the drug sponsors demonstrated the safety of the drugs. Defendants contend that withdrawal was not legally required, and, in any event, the issue is now moot because the 1977 NOOHs have been withdrawn. Plaintiffs reply that the recent withdrawal of the NOOHs was in response to this litigation and has no bearing on the FDA's obligation to act.

DISCUSSION

I. Legal Standard

A. Summary Judgment

A motion for summary judgment may not be granted unless the Court determines that there is no genuine issue of material fact to

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[7] Within the internal numbering of the FDCA, the statute at issue in this case is § 512.

be tried, and that the facts as to which there is no such issue warrant judgment for the moving party as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 106 S. Ct. 2548, 2552-53 (1986); Patterson v. Cnty. of Oneida, 375 F.3d 206, 219 (2d Cir. 2004); Shannon v. N.Y. City Transit Auth., 332 F.3d 95, 98 (2d Cir. 2003). The burden of demonstrating the absence of any genuine dispute as to a material fact rests upon the party seeking summary judgment, see Adickes v. S. H. Kress & Co., 398 U.S. 144, 157, 90 S. Ct. 1598, 1608 (1970), but once a properly supported motion for summary judgment has been made, the burden shifts to the nonmoving party to make a sufficient showing to establish the essential elements of that party's case on which it bears the burden of proof at trial. See Hayut v. State Univ. of N.Y., 352 F.3d 733, 743 (2d Cir. 2003) (citing Celotex, 477 U.S. at 322, 106 S. Ct. at 2552). Where, as here, a court considers cross-motions for summary judgment, the court applies the same legal principles and "must evaluate each party's motion on its own merits, taking care in each instance to draw all reasonable inferences against the party whose motion is under consideration." Make the Road by Walking, Inc. v. Turner, 378 F.3d 133, 142 (2d Cir. 2004) (citations omitted).

Here, the parties do not dispute the essential facts. The only issue before the Court is the legal conclusion resulting from those facts.

B. The Administrative Procedure Act

"The APA authorizes suit by "'[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute." Norton v. S. Utah Wilderness Alliance ("SUWA"), 542 U.S. 55, 61, 124 S. Ct. 2373, 2378 (2004) (quoting 5 U.S.C. § 702). Under the APA, an "agency action" includes the "failure to act." 5 U.S.C. § 551(13).[8] Section 706(1) provides relief for an agency's failure to act by empowering reviewing courts to "compel agency action unlawfully withheld or unreasonably delayed[.]" 5 U.S.C. § 706(1); see SUWA, 542 U.S. at 62; 124 S. Ct. at 2378. The Supreme Court has made clear that § 706(1) applies only when an "an agency failed to take a discrete agency action that it is required to take." SUWA, 524 U.S. at 64, 124 S. Ct. at 2379 (emphasis in original); see also Benzman v. Whitman, 523 F.3d 119, 130 (2d Cir. 2008). The limit to discrete actions precludes a court from authorizing "broad programmatic attack[s]" on agency policy, and the limit to legally required actions ensures that a court will not interfere with an agency's discretionary functions. See id. at 64-65, 124 S. Ct. at 2379-80. Accordingly, "when an agency is compelled by law to

[8] Specifically, the APA provides that "'agency action' includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act[.]" 5 U.S.C. § 551(13).

act within a certain time period, but the manner of its action is left to the agency's discretion, a court can compel the agency to act, but has no power to specify what the action must be." Id. at 65, 124 S. Ct. at 2380. The Court further explained that the purpose of the limitations under § 706(1) "is to protect agencies from undue judicial interference with their lawful discretion, and to avoid judicial entanglement in abstract policy disagreements which courts lack both expertise and information to resolve." Id. at 66, 124 S. Ct. at 2381.

II. Application

Here, the Director of the BVM, issued the penicillin and tetracyclines NOOHs pursuant to 21 U.S.C. § 360b(e)(1), which governs the withdrawal of approval of NADAs/ANADAs. Specifically, § 360b(e)(1) reads:

> The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . . with respect to any new animal drug if the Secretary finds . . . (B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary 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 . . . .

21 U.S.C. § 360b(e)(1)(B).[9] In order to obtain the relief they seek, Plaintiffs must establish that § 360b(e)(1) legally requires the FDA to take a discrete action.

A. Discrete Action

Plaintiffs maintain that § 360b(e)(1) prescribes a set of discrete actions to be taken by the FDA in the event that new evidence shows that a new animal drug has not been shown to be safe. The statute requires that prior to issuing an order withdrawing approval of a NADA/ANADA, the FDA must provide notice to the drug sponsors and an opportunity for a hearing. See 21 U.S.C. § 360b(e)(1). If a drug sponsor or other interested party timely requests a hearing, the FDA must hold a public evidentiary hearing prior to issuing a final withdrawal order.

The FDA has promulgated numerous regulations to guide the withdrawal process. First, the notice issued by the FDA "must contain enough information to provide the respondent a genuine opportunity to identify material issues of fact." Hess & Clark, Div. of Rhodia, Inc. v. Food & Drug Admin. ("Hess & Clark"), 495 F.2d 975, 983 (D.C. Cir. 1974); see also Rhone-Poulenc, Inc., Hess & Clark Div. v. Food & Drug Admin. ("Rhone-Poulenc"), 636 F.2d 750,

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[9] Section 360b(e)(1) lists six findings by the Secretary that prompt withdrawal. See 21 U.S.C. § 360b(e)(1)(A)-(F). The most relevant findings for the present action are those described in subsection (B).

752 (D.C. Cir. 1980); 21 C.F.R. § 514.200(a). If a NADA/ANADA applicant requests a hearing, he must submit, in writing, an explanation of why the NADA/ANADA "should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition to the [proposed withdrawal]." 21 C.F.R. § 514.200(c). If, in his application for a hearing, an applicant fails to raise a genuine and substantial issue of fact, the Commissioner may deny the request for a hearing and summarily withdraw approval for the NADA/ANADA based on the data presented in the original notice. See id.; Hess & Clark, 495 F.2d at 984-85 (approving the FDA's use of the summary judgment procedure where the NOOH presents a "prima facie case for withdrawal"). If a hearing is granted, "the issues will be defined, an Administrative Law Judge will be named, and he shall issue a written notice of the time and place at which the hearing will commence." 21 C.F.R. § 514.200(c). The purpose of the hearing is to provide a "fair determination of relevant facts consistent with the right of all interested persons to participate . . . ." 21 C.F.R. § 12.87. At the hearing, the FDA has the initial burden of producing evidence that the drug has not been shown to be safe, which is generally contained in the notice. See Rhone-Poulenc, 636 F.2d at 752; (Enrofloxacin Decision at 8.) However, the drug sponsor has the

"burden of persuasion on the ultimate question of whether [the drug] is shown to be safe." (Enrofloxacin Decision at 9); see also Rhone-Poulenc, 636 F.2d at 752. As soon as possible after a hearing, the presiding officer issues an initial decision that includes findings of fact, conclusions of law, a discussion of the reasons for the findings and conclusions, and appropriate citations. See 21 C.F.R. § 12.120 (a)-(b). A participant in a hearing may appeal an initial decision to the Commissioner. See 21 C.F.R. § 12.125(a).

Defendants argue that given the procedural complexity of issuing a notice and holding a hearing, which may take months or years to complete, the relief sought by Plaintiffs is not discrete. The Court disagrees. Upon a finding that a new animal drug has not been shown to be safe, § 360b(e)(1) and the accompanying regulations require the FDA to implement several related discrete actions: (1) provide notice of the FDA's finding and intent to withdraw approval; (2) provide an opportunity for a hearing to the relevant animal drug sponsors; (3) if an applicant timely requests a hearing and raises a genuine issue of fact, hold a hearing; and (4) if the applicant fails to show that the drug is safe, the Commissioner must issue an order withdrawing approval of the drug. The first three steps are statutory precursors to issuing the final withdrawal order. The APA defines "agency action" to include the

issuance of an order, see 5 U.S.C. § 551(13), and the Supreme Court has defined an order as a discrete agency action. See SUWA, 542 U.S. at 62, 124 S. Ct. at 2378. Moreover, the APA anticipates that an order will be preceded by a hearing or a similar process, as it defines "adjudication" as the "agency process for formulation of an order[.]" 5 U.S.C. § 551(7); see also 5 U.S.C. § 551(6) (defining "order" as "the whole or part of a final disposition . . . of an agency in a matter other than rulemaking but including licensing."). The fact that § 360b(e)(1) requires notice and an opportunity for a hearing prior to the issuance of a withdrawal order does not undermine the fact that the requested relief is a discrete agency action. See id. Plaintiffs are not launching a "broad programmatic attack" on the FDA's animal drug policies; rather, Plaintiffs have identified certain new animal drugs that the agency has publicly concluded are "not shown to be safe" and is requesting that the agency move forward with its statutory duty to hold the requested hearings and withdraw approval if the drug sponsors fail to show that the drugs are safe.[10] See SUWA 542 U.S. at 64, 124 S. Ct. 2379-80 (contrasting a "discrete" agency action with a "broad programmatic attack").

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[10] Plaintiffs have not asked the Court to direct the outcome of the requested hearings or to compel Defendants to issue a final withdrawal order.

B. Legally Required Action

The parties dispute whether, given the facts of this case, § 360b(e)(1) legally requires the Commissioner of the FDA to hold withdrawal proceedings for the relevant penicillin and tetracyclines NADAs/ANADAs. Defendants acknowledge that § 360b(e)(1) contains language mandating the Secretary to act ("[t]he Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . . if the Secretary finds . . ."). See Nat'l Ass'n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 661-62, 127 S. Ct. 2518, 2531-32 (2007) (interpreting the statutory language "shall approve" to impose upon the agency a mandatory duty); Lopez v. Davis, 531 U.S. 230, 241, 121 S. Ct. 714, 722 (2001) (noting Congress' "use of a mandatory 'shall' . . . to impose discretionless obligations"); Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26, 35, 118 S. Ct. 956, 962 (1998) ("[T]he mandatory 'shall' . . . normally creates an obligation impervious to judicial discretion."). However, Defendants disagree with Plaintiffs as to when and how the Secretary's duty to act is triggered. Defendants contend that the statute only requires the Secretary to withdraw approval of a NADA/ANADA if the Secretary makes a finding after a formal hearing. Since the FDA never held hearings and has now withdrawn the 1977 NOOHs, Defendants argue

that no findings have been made and no further action is required. Plaintiffs contend that under § 360b(e)(1) the Secretary makes a finding prior to a hearing, and that upon making such a finding, the Secretary is legally required to withdraw approval of a drug, unless the drug sponsor requests a hearing and shows that the drug is safe. They further argue that the FDA's recent withdrawal of the 1977 NOOHs does not disturb the agency's original findings and that the FDA is legally required to hold withdrawal proceedings for the relevant penicillin and tetracyclines NOOHs. The question before the Court is whether the FDA is legally required to proceed with the hearing and withdrawal process.

1. Statutory Interpretation

a. Legal Standard

In interpreting a statute, a court "must give effect to the unambiguously expressed intent of Congress." Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843, 104 S. Ct. 2778, 2781 (1984). "To ascertain Congress's intent, [a court] begin[s] with the statutory text because if its language is unambiguous, no further inquiry is necessary." Cohen v. JP Morgan Chase & Co., 498 F.3d 111, 116 (2d Cir. 2007) (citations omitted); see also Tyler v. Douglas, 280 F.3d 116, 122 (2d Cir. 2001) ("'If the statutory terms are unambiguous, [a court's] review generally ends and the statute is construed according to the plain meaning of

its words.'")(quoting Sullivan v. Cnty. of Suffolk, 174 F.3d 282, 285 (2d Cir. 1999)). Statutory interpretation must take into account the "structure and grammar" of the provision. See Bloate v. United States, -- U.S. --, --, 130 S. Ct. 1345, 1354-55 (2010). "If the statutory language is ambiguous, however, [a court] will 'resort first to cannons of statutory construction, and, if the [statutory] meaning remains ambiguous, to legislative history'" to determine the intent of Congress. Cohen, 498 F.3d at 116 (quoting Daniel v. Am. Bd. of Emergency Med., 428 F.3d 408, 423 (2d Cir. 2005)). If the intent of Congress remains unclear, a court will defer to an agency's interpretation of the statute, so long as it is "reasonable." See Chevron, 467 U.S. at 843-44, 104 S. Ct. at 2782.

b. Application: Findings Pursuant to § 360b(e)(1)

Here, the statute unambiguously commands the Secretary to withdraw approval of any new animal drug that he finds is not shown to be safe, provided that the sponsor of the animal drug has notice and an opportunity for a hearing. See 21 U.S.C. § 360b(e)(1). The statute does not explicitly state the order in which this process must occur. Defendants maintain that the Secretary can only issue a finding after a hearing, whereas Plaintiffs claim the Secretary makes a finding first, which then triggers the Secretary's obligation to provide notice and an opportunity for a hearing.

The Court finds that Plaintiff's interpretation provides a common sense reading of the statute based on its text and grammatical structure. The statute states that "[t]he Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of a[] [NADA/ANADA] . . . if the Secretary finds . . . [that a drug is not shown to be safe] . . . ." The "after due notice and opportunity for hearing" clause is setoff by commas and immediately precedes the words "issue an order withdrawing approval," indicating that the "notice" clause modifies the "issue an order" clause and not the findings clause. See United States v. Liranzo, 729 F. Supp. 1012, 1014 (S.D.N.Y. 1990) (interpreting a modifier to apply to the verb closest to it) (citing W. Strunk, Jr. & E.B. White, The Elements of Style 30 (3d ed. 1979)). Accordingly, the statute only requires the Secretary to give notice and provide an opportunity for a hearing before issuing an order of withdrawal and not before making findings. Under this reading, if the Secretary finds that an animal drug has not been shown to be safe, he is statutorily required to withdraw approval of that drug, provided that the drug sponsor has notice and an opportunity for a hearing. See Rhone-Poulenc, 636 F.2d at 752 ("[T]he Commissioner must withdraw his approval [of an animal drug] whenever he finds that 'new evidence . . . shows that such drug is not shown to be safe . . . .'")

(quoting 21 U.S.C. § 360b(e)(1)(B)). If, after a hearing, the drug sponsor has not met his burden of proving the drug to be safe, the Secretary must issue a withdrawal order.[11]

The text and grammar of other provisions within § 360b support this interpretation. For example, § 360b(d)(1) explicitly requires the Secretary to provide notice and an opportunity for a hearing before making findings regarding the approval or refusal of a NADA. See 21 U.S.C. § 360b(d)(1). Section 360b(d)(1) reads: "If the Secretary finds, after due notice to the applicant . . . and giving him an opportunity for a hearing, . . . he shall issue an order refusing to approve the application." By placing the "notice" clause immediately after the phrase "[i]f the Secretary finds," § 360b(d)(1) clearly requires notice and an opportunity for a hearing prior to the issuance of findings by the Secretary. The fact that Congress used such language in § 360b(d)(1) and used different language in § 360b(e)(1) supports the Court's conclusion that notice and an opportunity for a hearing are not required before the Secretary makes findings under the latter provision. See Novella v. Westchester Cnty., 661 F.3d 128, 142 (2d Cir. 2011) (explaining that the presence of a term in one provision and not in another was

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[11] Admittedly, the Secretary will make a second set of findings after a hearing, but the initial findings trigger the mandatory withdrawal process and, if not rebutted, provide a basis for mandatory withdrawal.

deliberate and meaningful).

Moreover, § 360b(e)(1) includes a specific note about the notice and hearing requirement when the Secretary finds that a new animal drug poses an imminent risk to humans or animals, which indicates that findings are made before a hearing. Specifically, the statute states that

> [i]f the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection . . . .

21 U.S.C. § 360b(e)(1). This provision anticipates the Secretary making findings in advance of a hearing; otherwise, the clause requiring the Secretary to provide notice and an opportunity for an expedited hearing would be redundant and nonsensical. The Court cannot adopt such an interpretation. See Conn. ex rel. Blumenthal v. Dep't of Interior, 228 F.3d 82, 88 (2d Cir. 2000) (". . . [courts] are required to 'disfavor interpretations of statutes that render language superfluous.'") (quoting Conn. Nat'l Bank v. Germain, 503 U.S. 249, 253, 112 S. Ct. 1146, 1149 (1992)). Although the Secretary's authority to make a finding of imminent

hazard "shall not be delegated," the fact that this finding is made before notice or an opportunity for a hearing are provided supports that findings pursuant to § 360b(e)(1) are made prior to a hearing. This interpretation is further buttressed by the statutory purposes underlying the FDA, the agency tasked with implementing § 360b(e)(1) and the FDCA. Specifically, the FDA "shall . . . promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner; [and] with respect to such products, protect the public health by ensuring that . . . human and veterinary drugs are safe and effective[.]" 21 U.S.C. § 393(b)(1)-(2). According to its statutory mandate, the FDA is responsible for continuously monitoring regulated drugs and reviewing new studies of their effectiveness and safety. Given this regulatory structure, it seems clear that Congress intended the FDA to monitor approved animal drugs and issue findings when new evidence indicates that a drug is no longer shown to be safe, triggering the withdrawal process.

Accordingly, based on the text and grammar of § 360b(e)(1), as well as the structure of § 360b as a whole and the overriding purpose of the FDA, the Court finds that the plain meaning of § 360b(e)(1) 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. If 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.

This interpretation is consistent with how courts have interpreted 21 U.S.C. § 355(e), the human drug parallel to § 360b(e). See Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 134, 120 S. Ct. 1291, 1301 (2000) ("If the FDA discovers after approval that a drug is unsafe or ineffective, it 'shall, after due notice and opportunity for hearing to the applicant, withdraw approval' of the drug.") (quoting 21 U.S.C. § 355(e)(1)-(3)); Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1281 (D.C. Cir. 2004) ("[S]ection 355(e) simply sets out specific, not necessarily exclusive, circumstances under which the FDA must withdraw any [human drug] approval (whether final or otherwise) after notice and hearing."); Dobbs v. Wyeth Pharms., 797 F. Supp.2d 1264, 1270-71 (W.D. Okla. 2011) ("The FDA is statutorily responsible for continually monitoring the safety of approved drugs and is authorized to take actions including, inter alia, withdrawal of approval if scientific data indicates the drug is unsafe. 21 U.S.C. § 355(e). Approval must be withdrawn if the FDA finds that . . . [a] drug is unsafe for use[.]") (internal quotation marks omitted). Although § 355(e) concerns withdrawal of FDA approval of human drugs, it contains nearly identical language to that in §

360b(e), and, in both the House and Senate Reports on the 1968 Amendments to the FDCA, § 360b(e) was described as "correspond[ing]" to § 355(e). See H.R. Rep. No. 90-875, at 5 (1967); S. Rep. No. 90-1308, at 5 (1968).

Were the Court to conclude that § 360b(e)(1) is ambiguous as to when the Secretary makes findings, the Court would defer to the agency's reasonable interpretation of the statute. See Chevron, 467 U.S. at 842-43, 104 S. Ct. 2781-82. Although in this litigation the FDA has maintained that findings pursuant to § 360b(e)(1) can only be made after a hearing, the agency's implementing regulation, 21 U.S.C. § 514.115, interprets § 360b(e)(1) to require the agency to make findings prior to a hearing. The regulation reads: "The Commissioner shall notify in writing the person holding [a NADA/ANADA] and afford an opportunity for a hearing on a proposal to withdraw approval of such [NADA/ANADA] if he finds . . . that such drug is not shown to be safe . . . ." 21 C.F.R. § 514.115(b)(3)(ii).[12] The plain language of the regulation requires the Commissioner to provide notice and an opportunity for a hearing to a drug sponsor after making a

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[12] Although § 360b(e)(1) refers to the "Secretary," defined as the Secretary of HHS in § 321(d), the Secretary has delegated to the Commissioner of the FDA all of the authority vested in him pursuant to the FDCA. (See § 1410.10 of Volume III of the FDA Staff Manual Guides, Delegations of Authority to the Commissioner Food and Drugs, attached as Ex. A to Barcelo Decl., ¶ 1(A)(1).)

finding that a drug has not been shown to be safe. It logically follows that findings are made by the Commissioner before a hearing.[13] Accordingly, if the Court were to defer to the agency's interpretation of the statute it would reach the same conclusion: findings pursuant to § 360b(e)(1) are made before a hearing and trigger the withdrawal process.

Defendants, nevertheless, argue that the regulation does not mean what it says. They claim that the regulation does not refer to the same findings as those in § 360b(e)(1); rather, Defendants assert that the regulation creates a different set of findings that are based on a lower standard than the statutory findings. To support this proposition, Defendants point to several notices of

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[13] Moreover, this interpretation is consistent with how the FDA has implemented § 360b(e)(1) and the accompanying regulations in practice. The FDA consistently represents § 360b(e)(1) as requiring notice and an opportunity for a hearing on a proposed withdrawal whenever there is a finding that a new animal drug has not been shown to be safe. Findings are consistently made pursuant to § 360b(e)(1) prior to a hearing and provide the grounds for issuing a notice and opportunity for a hearing. See Enrofloxacin for Poultry; Opportunity for Hearing ("Enrofloxacin Notice"), 65 Fed. Reg. 64,954, 64,954 (Oct. 31, 2000) ("CVM is proposing to withdraw the approval of the [NADA] for use of enrofloxacin in poultry on the grounds that new evidence shows that the product has not been shown to be safe as provided for in the [FDCA]."); Dimetridazole; Opportunity for Hearing ("Dimetridazole Notice"), 51 Fed. Reg. 45,244, 45,244 (Dec. 17, 1986) ("The [FDA], [CVM], is proposing to withdraw approval of [NADAs] for dimetridazole . . . for use in turkeys. This action is based on the [CVM's] determination that the drug is not shown to be safe for use . . . .").

proposed withdrawals that rest on a finding that there is a "reasonable basis from which serious questions about the ultimate safety of [the drug] may be inferred." See Enrofloxacin for Poultry; Opportunity for Hearing ("Enrofloxacin Notice"), 65 Fed. Reg. 64,954, 64,955 (Oct. 31, 2000). Defendants maintain that this "serious question" standard is less stringent than the "not shown to be safe" standard in § 360b(e)(1).

The Court is not persuaded by Defendants' argument. First, although the FDA references the "serious question" standard in several withdrawal notices, the regulatory standard for issuance of any such notice is a finding that the drug is "not shown to be safe." See 21 C.F.R. § 514.115(b)(3)(ii). In fact, the regulation implementing § 360b(e)(1) and authorizing the Commissioner to issue notices describes the requisite findings in exactly the same language as the statute. Compare 21 U.S.C. § 360b(e)(1)(B) ("new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary 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") with 21 C.F.R. § 514.115(b)(3)(ii) ("[n]ew evidence

not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to safe for use under the conditions of use upon the basis of which the application was approved"). Based on this language, the regulation unambiguously references and incorporates the findings referred to in § 360b(e)(1). In addition, the Commissioner considers the two findings to be interchangeable. See (Enrofloxacin Decision at 45 ("[T]he relevant statutory question is whether the animal drug 'has been shown to be safe,' 21 U.S.C. § 360b(e)(1), which, as explained earlier, has been interpreted to require that CVM show that there are serious questions about the safety of [the drug]."").)

Because the Court reads 21 C.F.R. § 514.115(b)(3) as unambiguously referencing the findings in 21 U.S.C. § 360b(e)(1), the Court cannot defer to Defendants' interpretation that the regulation creates a different set of findings based on a different standard. See Christensen v. Harris Cnty., 529 U.S. 576, 588, 120 S. Ct. 1655, 1663 (2000) ("[A]n agency's interpretation of its own regulation is entitled to deference. But [such] deference is warranted only when the language of the regulation is ambiguous.")

(internal citations omitted); Gonzalez v. Oregon, 546 U.S. 243, 257, 126 S. Ct. 904, 915-16 (2006) (refusing to apply deference to an agency's interpretation of its own regulation where the regulation merely "parroted" the statute because "[a]n agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language.").[14]

c. Application: Authority of the Director of the BVM

Defendants assert that even if a finding triggers the FDA's obligations pursuant to § 360b(e)(1), there have been no such findings in this case. Defendants maintain that the Director of the BVM, who issued the 1977 NOOHs, is not authorized to make findings pursuant to § 360b(e)(1). The statute does not explicitly authorize the Director to make findings, and Defendants therefore argue that the Court should defer to the agency's position that the Director of the BVM is not authorized to make the requisite findings. See Chevron, 467 U.S. at 842-43, 104 S. Ct. at 2781-82.

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[14] In any event, the 1977 NOOHs at issue in this case were based on findings that the drug uses in question were "not shown to be safe" and not on the "serious question" standard. And, the Court is not called on here to determine whether the standard for withdrawal of approval has been met. The only issue presently before the Court is whether the withdrawal process must move forward.

As discussed supra, if a court determines that a statute is ambiguous and that "Congress has not directly addressed the precise question at issue," the court must defer to an agency's "reasonable" interpretation of the statute it administers. Id. at 842-44, 104 S. Ct. at 2781-82. "[An] administrative implementation of a particular statutory provision qualifies for Chevron deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." United States v. Mead Corp., 533 U.S. 218, 226-27, 121 S. Ct. 2164, 2171 (2001). An agency has been delegated such authority if it has the "power to engage in adjudication or notice-and-comment rulemaking" or if there is "some other indication of a comparable congressional intent." Id., at 227, 121 S. Ct. at 2171. Factors to consider when determining whether the Chevron framework applies to an agency interpretation include "the interstitial nature of the legal question, the related expertise of the [a]gency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the [a]gency has given the question over a long period of time . . . ." Barnhart v. Walton, 535 U.S. 212, 222, 122 S. Ct. 1265, 1272 (2002). The

Second Circuit has been hesitant to apply Chevron deference to nonlegislative rules issued by agencies and has "made clear that 'interpretations contained in policy statements, agency manuals and enforcement guidelines, all of which lack the force of law – do not warrant Chevron style deference.'" De La Mota v. U.S. Dep't of Educ., 412 F.3d 71, 79 (2d Cir. 2005) (quoting Christensen v. Harris Cnty., 529 U.S. 576, 587, 120 S. Ct. 1655, 1662 (2000)); see also Estate of Landers v. Leavitt, 545 F.3d 98, 106 (2d Cir. 2008).

Here, § 360b(e)(1) is ambiguous as to whether the Director of the BVM may make the requisite findings. The text of the statute refers to findings made by the "Secretary," which the FDCA defines as the Secretary of HHS. See 21 U.S.C. § 321(d). The Secretary, in turn, delegated to the Commissioner of the FDA all of the authority vested in him pursuant to the FDCA. (See § 1410.10 of Volume III of the FDA Staff Manual Guides, Delegations of Authority to the Commissioner Food and Drugs, attached as Ex. A to Barcelo Decl., ¶ 1(A)(1).) The Commissioner, in turn, delegated authority to the Director of the BVM to issue notices of opportunity for a hearing on proposals to withdraw approval of new animal drug applications, and the authority to issue orders withdrawing approval when the opportunity for a hearing has been waived. (See § 1410.503 of Volume II of the FDA Staff Manual Guides, Issuance of Notice, Proposals, and Orders Relating to New Animal Drugs and

Medicated Feed Mill License Applications ("Staff Manual"), attached as Ex. A to Barcelo Decl., ¶ 1(A)(1)-(2).) The question before the Court is whether the authority delegated to the Director includes the authority to make findings that trigger the FDA's non-discretionary duties pursuant to § 360b(e)(1).

Defendants urge the Court to defer to their interpretation that the Director does not have authority to make such findings. Defendants argue that because the Commissioner did not delegate authority to the Director to issue orders of withdrawal *after* a hearing, the Director cannot make the findings necessary to trigger the FDA's non-discretionary duties under § 360b(e)(1). However, this argument hinges on Defendants' incorrect interpretation of § 360b(e)(1), whereby a finding can be made only after a hearing. As the Court reads § 360b(e)(1) and the accompanying regulations to contemplate findings made prior to a hearing, Defendants' reliance on the Staff Manual is of no avail. In fact, the delegations within the Staff Manual support Plaintiffs' position that the FDA is legally required to re-institute withdrawal proceedings for penicillin and tetracyclines in animal feed.

By authorizing the Director to issue notices of an opportunity for a hearing, the Commissioner necessarily authorized the Director to make the findings on which such notices of withdrawal are based. Any notice issued must "specify the grounds upon which" the

proposal to withdraw is based. 21 C.F.R. § 514.200(a). Under both the statute and the regulation, a proposal to withdraw may be based on a finding that an animal drug has not been shown to be safe. See 21 U.S.C. 360b(e)(1)(B); 21 C.F.R. § 514.115(b)(3)(ii). In practice, the Director generally states his conclusion that the drug has not been shown to be safe and cites § 360b(e)(1). See Dimetridazole; Opportunity for Hearing, 51 Fed. Reg. 45,244, 45,244 (Dec. 17, 1986) ("This [notice of intent to withdraw approval] is being [issued] in accordance with section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. § 360b(e)(1)(b)). That section requires FDA to withdraw approval of an NADA if the agency finds . . . that such drug is not shown to be safe . . . [T]he Center [for Veterinary Medicine] has determined that dimetridazole is not shown to be safe for use within the meaning of section of 512(e)(1)(B)[.]") (emphasis added); Enrofloxacin Notice, 65 Fed. Reg. at 64,954 ("CVM is proposing to withdraw the approval of the new animal drug application for use of enrofloxacin in poultry on the grounds that new evidence shows that the product has not been shown to be safe as provided for in the Federal Food, Drug, and Cosmetic Act . . . .") (emphasis added). It is clear from the FDA's own practice that the Director of the BVM is authorized to make the requisite findings that trigger withdrawal proceedings pursuant to § 360b(e)(1). Accordingly, by

explicitly delegating to the Director the authority to issue withdrawal notices, the Commissioner delegated to the Director the authority to make the findings that are a statutory prerequisite to any such notice.

This conclusion is further supported by the fact that in the event that the Director issues a notice and the drug applicant does not request a hearing, the Director is authorized to summarily issue an order withdrawing approval. (See Staff Manual ¶ 1(A)(2).) In such cases, the findings made by the Director – and upon which the initial notice was based – provide a sufficient basis to withdraw approval of a NADA under § 360b(e)(1). See Shulcon Industries, Inc.; Withdrawal of Approval of a New Animal Drug Application ("Shulcon Withdrawal"), 59 Fed. Reg. 1950, 1950 (Jan. 13, 1994) ("The notice of opportunity for a hearing stated that CVM was proposing to issue an order under [§ 360b(e)] withdrawing approval of the NADA . . . . Shulcon Industries, Inc. failed to file [a] request for a hearing. . . . [U]nder authority delegated to the Commissioner of Food and Drugs . . . and redelegated to the Center for Veterinary Medicine . . . notice is given that approval of NADA 111-068 . . . is hereby withdrawn.").

Although the FDA has been delegated the authority to pass rules and regulations carrying the force of law, the agency has not promulgated any regulation, opinion letter, or internal agency

guidance specifying the limits of the Director's delegated authority to which the Court could defer. Moreover, in practice, the Director routinely exercises the authority that the FDA now claims the Director lacks. The Court cannot defer to an interpretation that the FDA appears to have adopted solely for litigation purposes. See Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 212, 109 S. Ct. 468, 473-74 (1988) ("[The Supreme Court] h[as] never applied the principle of [Chevron deference] to agency litigating positions that are wholly unsupported by regulations, rulings, or administrative practice."). Finally, any doubt that the Director was authorized to issue the findings in the 1977 NOOHs is conclusively dispelled by the Commissioner's acknowledgment and endorsement of the Director's findings. See Penicillin and Tetracycline in Animal Feeds, 48 Fed. Reg. 4,554, 4,556 (Feb. 1, 1983).

2. Findings Regarding the Subtherapeutic Use of Penicillin and Tetracyclines

Having found that the Director of the BVM is authorized to make findings under § 360b(e)(1), the question becomes whether the Director made such findings for the subtherapeutic use of penicillin and tetracyclines. In the 1977 Penicillin Notice, the Director stated that he is

> unaware of evidence that satisfies the requirements for the safety of penicillin-containing premixes as required by [§ 360b of the FDCA] and § 558.15 of the agency's regulations. Accordingly, he concludes, on the basis of new information before him with respect to these drug products, evaluated together with the evidence available to him when they were originally approved, that the drug products are not shown to be safe . . . . The evidence, in fact, indicates that such penicillin use may be unsafe . . . .

Penicillin Notice, 42 Fed. Reg. at 43,792 (emphasis added). Similarly, in the 1977 Tetracycline Notice, the Director stated that he is

> unaware of evidence that satisfies the requirements for demonstrating the safety of extensive use of subtherapeutic tetracycline-containing premixes established by section [360b] of the [FDCA] . . . . Accordingly, he concludes, on the basis of new information before him with respect to these drug products, evaluated together with the evidence available to him when they were originally approved, that the drug products are safe only for the limited conditions of use set forth [in the Notice].

Tetracycline Notice, 42 Fed. Reg. at 56,288. Accordingly, in both the Penicillin and the Tetracycline Notices, the Director explicitly concluded that the drugs had not been shown to be safe and cited § 360b. Such a conclusion is the statutory trigger for the FDA to institute withdrawal proceedings, which it in fact did. Based on the language of the 1977 Notices, the Director made the findings necessary to trigger mandatory withdrawal proceedings for

the subtherapeutic uses of penicillin and tetracyclines in animal feed.[15]

Even if the Court were to adopt Defendants' interpretation that the Director is not authorized to make the requisite findings under § 360b(e)(1), the Court would still conclude that the FDA is legally required to hold withdrawal proceedings because the Commissioner has made the requisite findings by noting and ratifying the Director's findings. In 1983, the Commissioner published a statement of policy in the Federal Register denying several requests from drug sponsors to rescind the 1977 NOOHs, in which the Commissioner "concurr[ed]" with the Director's findings that the drugs had not been shown to be safe. See Penicillin and Tetracycline in Animal Feeds, 48 Fed. Reg. at 4,556 (explaining the Director of BVM's decision not to rescind the 1977 NOOHs because they "represent the Director's formal position that use of the drugs is not shown to be safe" and stating that "[t]he Commissioner has reviewed the Director's decision and concurs with it."). Based on this concurrence, the Commissioner has adopted and, therefore, issued findings, and the § 360b(e)(1) mandatory withdrawal

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[15] Furthermore, during oral argument, counsel for the FDA acknowledged that the Director lawfully issued the NOOHS in 1977 and that they were not ultra vires, indicating that the Director has the authority to make findings sufficient to institute withdrawal proceedings. (See Transcript of Hearing dated Feb. 23, 2012 ("Transcript"), at 12.)

proceedings have been triggered.

III. Mootness

A. Legal Standard

"It has long been settled that a federal court has no authority 'to give opinions upon moot questions or abstract propositions, or to declare principles or rules of law which cannot affect the matter in issue in the case before it.'" Church of Scientology of Cal. v. United States, 506 U.S. 9, 12, 113 S. Ct. 447, 449 (1992) (quoting Mills v. Green, 159 U.S. 651, 653, 16 S. Ct. 132, 133 (1895)). "The mootness doctrine provides that 'an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed.'" Conn. Office of Protection & Advocacy for Persons with Disabilities v. Hartford Bd. of Educ., 464 F.3d 229, 237 (2d Cir. 2006) (quoting British Int'l Ins. Co. v. Seguros La Republica, S.A., 354 F.3d 120, 122 (2d Cir. 2003)). "The existence of a real case or controversy is an irreducible minimum to the jurisdiction of the federal courts." United States v. City of New York, 972 F.2d 464, 469-70 (2d Cir. 1992) (quoting Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, 454 U.S. 464, 471, 102 S. Ct. 752, 757-58 (1982)). Accordingly, "if an event occurs while a case is pending . . . that makes it impossible for the court to grant any effectual relief whatever to a prevailing party, the [case] must be

dismissed." Church of Scientology of Cal., 506 U.S. at 12, 113 S. Ct. at 449 (internal quotation marks and citation omitted).

B. Application

Here, Defendants maintain that Plaintiffs' claim is now moot because, during the pendency of this case, the FDA rescinded the 1977 NOOHs for the subtherapeutic use of penicillin and tetracyclines in animal feed. See NOOH Withdrawals, 76 Fed. Reg. 79,697, 79,697 (Dec. 22, 2011).

Plaintiffs' claim arises under § 706(1) of the APA, which authorizes the Court to grant Plaintiffs relief if they establish that the FDA failed to take a legally required discrete action. Plaintiffs contend, and the Court agrees, that upon a finding by the FDA that a new animal drug has not been shown to be safe, the FDA is required to withdraw approval of that drug after providing notice and an opportunity for a hearing. Therefore, the trigger for FDA to initiate mandatory withdrawal proceedings is not the issuance of a NOOH but a finding that a drug has not been shown to be safe. The issuance of a NOOH is simply the first step in the mandatory withdrawal process. Accordingly, Plaintiffs are still entitled to relief and their claim is not moot if they can establish that the rescission of the NOOHs did not rescind the FDA's findings that the subtherapeutic use of penicillin and tetracyclines in animal feed has not been shown to be safe.

The record makes clear that the FDA did not rescind its findings when it rescinded the 1977 NOOHs. In the official notice rescinding the 1977 NOOHs, the FDA provided three justifications for the rescission:

> (1) FDA is engaging in other ongoing regulatory strategies developed since the publication of the 1977 NOOHs with respect to addressing microbial food safety issues; (2) FDA would update the NOOHs to reflect current data, information, and policies if, in the future, it decides to move forward with withdrawal of the approved uses of the new animal drugs described in the NOOHs; and (3) FDA would need to prioritize any withdrawal proceedings. . . .

NOOH Withdrawals, 76 Fed. Reg. 79,697, 79,698 (Dec. 22, 2011). None of these reasons addresses the initial findings that prompted the NOOHs or suggests that the FDA is rescinding those findings. Rather, in the notice rescinding the 1977 NOOHs, the FDA emphasized its continuing concerns about the subtherapeutic use of penicillin and tetracyclines. "Although FDA is withdrawing the 1977 NOOHs, FDA remains concerned about the issue of antimicrobial resistance. Today's action 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 79,698. This public announcement of the FDA's continuing safety concerns and its attempts at other strategies support the view that the FDA has not rescinded its original findings that use of the

drugs has not been shown to be safe.[16]

In addition, the 2010 Draft Guidance, which represents the FDA's current strategy to address microbial food safety issues, emphasizes the FDA's continuing concerns about the safety of the subtherapeutic use of penicillin and tetracyclines in animal feed. (See Guidance No. 209, attached as Ex. B to Barcelo Decl. at 4.) In preparing the Guidance, the FDA reviewed key scientific studies and reports and concluded that "the overall weight of evidence available to date supports the conclusion that using medically important antimicrobial drugs for production purposes is not in the interest of protecting and promoting the public health." (See id. at 13.)[17] The FDA has not issued a single statement since the

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[16] Any claim that the 1977 NOOHs are out-of-date does not relieve the FDA of its obligation to proceed with the withdrawal process. First, the agency cannot, through its own prolonged inaction, create obstacles to its statutorily mandated obligation. Second, while there have been additional scientific studies since the 1977 NOOHs were issued, they all appear to support the FDA's original finding that the use of these drugs has not been shown to be safe. Finally, nothing precludes the FDA from updating the NOOHs, so long as it does so in a reasonably prompt manner.

[17] The 2010 Draft Guidance recommends that medically important antibiotics, including penicillin and tetracyclines, be used "judiciously." (See Guidance No. 209, attached as Ex. B to Barcelo Decl. at 16.) "In light of the risk that antimicrobial resistance poses to public health, FDA believes the use of medically important antimicrobial drugs in food producing animals for production purposes (e.g., to promote growth or improve food efficiency) represents an injudicious use of these important drugs." (See id. at 16.) Strict adherence to the 2010 Draft Guidance would not permit the subtherapeutic use of penicillin

issuance of the 1977 NOOHs that undermines the original findings that the drugs have not been shown to be safe. The FDA's recent decision to rescind the 1977 NOOHs, while reiterating its continuing concerns about the safety risks posed by the subtherapeutic uses of penicillin and tetracyclines, does not absolve the agency of its statutory duty to initiate and complete withdrawal proceedings. See Am. Pub. Health Ass'n v. Veneman, 349 F. Supp. 1311, 1315-16 (D.D.C. 1972) (requiring the FDA to initiate withdrawal proceedings after finding that the agency's "many announcements . . . in the Federal Register regarding FDA conclusions about the efficacy of various drugs" constituted findings under 21 U.S.C. § 355(e), the human drug corollary to § 360b(e)).

Lastly, the fact that the FDA "is engaging in other ongoing regulatory strategies," NOOH Withdrawals, 76 Fed. Reg. at 79,698, does not relieve it of its statutory obligation to complete

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and tetracyclines. However, the 2010 Draft Guidance merely provides recommendations; there are no penalties for failing to adhere to the 2010 Draft Guidance. Nonetheless, the Draft Guidance makes clear that in the approval process for new NADAs/ANADAs, "products that ultimately move forward toward approval are those products that include use conditions that are consistent with the guidance and are intended to minimize the extent to which the product use would contribute to [antibiotic-] resistance development." (Id. at 15.) Under the FDA's current model, therefore, the NADAs/ANADAs at issue in this case would not be approved.

withdrawal proceedings. Upon a finding that the use of a drug under certain conditions has not been shown to be safe, §360b(e)(1) prescribes a clear course of conduct: issue notice and an opportunity for a hearing, and, if the drug sponsor does not demonstrate that the drug use is safe at the hearing, withdraw approval of such use.[18] The statute does not empower the agency to choose a different course of action in lieu of withdrawal proceedings, such as that embodied in the 2010 Draft Guidance. See Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin., 374 F.3d 1251, 1261 (D.C. Cir. 2004) ("[A]n agency ordered by Congress to promulgate binding regulatory requirements may not issue a non-binding policy statement that encourages but does not compel action.") (citing Pub. Citizen v. Nuclear Regulatory Comm'n, 901 F.2d 147, 157 (D.C. Cir. 1990)); Natural Res. Def. Council, Inc. v. Envtl. Prot. Agency, 595 F. Supp. 1255, 1261 (S.D.N.Y. 1984) ("The agency charged with implementing the statute is not free to evade the unambiguous directions of the law merely for administrative convenience.") (internal quotation marks and citations omitted).

Accordingly, because the rescission of the 1977 NOOHs did not rescind the original findings that the subtherapeutic use of

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[18] Of course, if the drug sponsors demonstrate that the use of the drug is safe, then the Commissioner cannot withdraw approval.

penicillin and tetracyclines in food-producing animals has not been shown to be safe, Plaintiffs' claim is not moot.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Summary Judgment on their first claim for relief is granted and Defendants' Motion for Summary Judgment is denied. Defendants are hereby ordered to initiate withdrawal proceedings for the relevant NADAs/ANADAs. Specifically, the Commissioner of the FDA or the Director of the CVM must re-issue a notice of the proposed withdrawals (which may be updated) and provide an opportunity for a hearing to the relevant drug sponsors; if drug sponsors timely request hearings and raise a genuine and substantial issue of fact, the FDA must hold a public evidentiary hearing. If, at the hearing, the drug sponsors fail to show that the use of the drugs is safe, the Commissioner must issue a withdrawal order.

The Court notes the limits of this decision. Although the Court is ordering the FDA to complete mandatory withdrawal proceedings for the relevant penicillin and tetracycline NADAs/ANADAs, the Court is not ordering a particular outcome as to the final issuance of a withdrawal order. If the drug sponsors demonstrate that the subtherapeutic use of penicillin and/or tetracyclines is safe, then the Commissioner cannot withdraw

approval.[19]

So Ordered.

THEODORE H. KATZ
UNITED STATES MAGISTRATE JUDGE

Dated: March 22, 2012
New York, New York

[19] At oral argument, both parties agreed that additional briefing is necessary on the issue of a time-line for holding a hearing and issuing a final decision in the matter. (See Transcript at 10.)