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' REPLY IN SUPPORT OF MOTION FOR LEAVE TO FILE A SUPPLEMENTAL COMPLAINT

This Court should grant Plaintiffs leave to file the Supplemental Complaint because Plaintiffs' existing claim and their proposed new claim are factually and legally connected. Both claims involve the U.S. Food and Drug Administration's (FDA's) refusal to withdraw approval for potentially unsafe drugs, on the ground that the agency is instead pursuing a program of "voluntary reform." FDA's reliance on an unenforceable, extra-statutory approach to the regulation of drugs that are "not shown to be safe" is contrary to the mandate of the Federal

Food, Drug, and Cosmetic Act (Food and Drug Act), 21 U.S.C. § 360b(e)(1). Because Plaintiffs' claims involve overlapping facts and rely on the same substantive statutory provision, granting Plaintiffs' motion would promote an efficient resolution of the entire dispute between the parties.

FDA has already benefited from repeated delays in this litigation, and it has used those delays to take administrative actions calculated to support its litigation positions. Nonetheless, Plaintiffs now propose a slightly revised briefing schedule to accommodate FDA's concern about compiling an administrative record. This schedule is appropriate in light of the serious risks to public health posed by the drugs at issue, and it will not prejudice FDA.

ARGUMENT

I. Granting Plaintiffs' Motion Would Promote an Efficient Resolution of the Entire Dispute between the Parties

Leave to file a supplemental pleading "should be freely permitted when the supplemental facts connect it to the original pleading." *Quaratino v. Tiffany & Co.*, 71 F.3d 58, 66 (2d Cir. 1995). Here, contrary to FDA's contention, there is substantial factual and legal overlap between Plaintiffs' existing claim (the Findings Claim) and their proposed new claim (the Third Claim).

The Findings Claim is based on FDA's findings that penicillin and tetracyclines in animal feed "have not been shown to be safe" for human health. *See* Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264, 56,288 (Oct. 21, 1977), Ex. B to Decl. of Jennifer A. Sorenson, Oct. 5, 2011 (Dkt. 33-2); Penicillin-Containing Premixes, 42 Fed. Reg. 43,772, 43,772 (Aug. 30, 1977), Ex. A to Decl. of Jennifer A. Sorenson, Oct. 5, 2011 (Dkt. 33-1). These findings obligate FDA under the Food and Drug Act to withdraw approval for the drugs, unless the drug sponsors can demonstrate in a formal hearing that the drugs are safe. *See* 21 U.S.C. § 360b(e)(1). FDA issued notices of opportunity for a hearing on proposals to

withdraw approval for the drugs in 1977, but it has never acted on the proposals nor held a hearing.

Last month, in a made-for-litigation maneuver, FDA published a notice withdrawing the 1977 notices of opportunity for a hearing. *See* Withdrawal of Notices of Opportunity for a Hearing, 76 Fed. Reg. 79,697 (Dec. 22, 2011), Ex. L to Decl. of Amy A. Barcelo, Jan. 9, 2012 (Dkt. 44-12). FDA did not recant its 1977 findings that penicillin and tetracyclines in animal feed have not been shown to be safe. On the contrary, FDA admitted that it "remains concerned about" antibiotic resistance and "continues to view [it] as a significant public health issue." *Id.* at 79,698, 79,700. The agency stated that the withdrawal of the 1977 notices "should not be interpreted as a sign that FDA no longer has safety concerns about the use of medically important antibiotics in food producing animals." *Id.* at 79,700. FDA explained, however, that it would prefer to address the mounting problem of antibiotic resistance by "promoting voluntary reform and the judicious use of antimicrobials." *Id.* at 79,701.

The Third Claim is based on FDA's denial of two citizen petitions (the Petitions), which requested withdrawal of approval for several classes of medically important antibiotics used nontherapeutically in livestock, including penicillins and tetracyclines. In denying the Petitions, FDA did not dispute the science or analysis contained in them. As in the notice withdrawing the 1977 notices of opportunity for a hearing, FDA explained that "we share your concern about the use of medically important antimicrobial drugs in food-producing animals for growth promotion and feed efficiency indications (i.e., production uses)." Final Response to Citizen Petition, New Dkt. No. FDA-2005-P-0007 (Final Response) 1 (Nov. 7, 2011), Ex. J to Decl. of Amy A. Barcelo, Jan. 9, 2012 (Dkt. 44-10). FDA denied the Petitions on one of the same bases that it withdrew the 1977 notices: the agency would prefer to address the problem of antibiotic

resistance by promoting voluntary reform. *See id.* at 3-4. The petition denials and the notice withdrawing the 1977 notices even used the same language: FDA repeated sentences and entire paragraphs nearly verbatim. *Compare* Final Response 3-4 *with* Withdrawal of Notices of Opportunity for a Hearing, 76 Fed. Reg. at 79,699-700 (three paragraphs beginning with "Based on feedback . . . ."). For example, FDA explained that it "believes" its voluntary approach represents another "pathway to achieving the same goals" contemplated by both the petitioners and the 1977 notices of opportunity for a hearing. Withdrawal of Notices of Opportunity for a Hearing, 76 Fed. Reg. at 79,699; Final Response 4.

Although the Findings Claim and the Third Claim arise under different sections of the Administrative Procedure Act (APA), both claims rely on the same substantive provision of the Food and Drug Act, 21 U.S.C. § 360b(e)(1). That provision tells FDA precisely what it must do when a previously approved animal drug is no longer shown to be safe: it must withdraw approval for the drug, unless the drug sponsor can prove the drug's safety in a formal hearing. There is no statutory basis for FDA's improvised, voluntary approach. Nor has FDA produced a shred of evidence indicating that its approach will be effective in protecting public health. The same logic underlies both of Plaintiffs' claims: FDA may not shirk its statutory duty to withdraw approval for potentially unsafe drugs on the ground that it is following an unenforceable, extra-statutory procedure. Not only are these claims "connect[ed]," they are closely related. *Quaratino*, 71 F.3d at 66.

FDA relies on a two-paragraph, out-of-circuit opinion more than fifty years old for the proposition that a court may properly deny a motion to supplement where the *only* claim asserted in the original complaint is moot. *See* Mem. in Opp'n to Pls.' Mot. for Leave to File a Supplemental Compl. (Opp'n Br.) 4 (Dkt. 46) (citing *Cherry v. Morgan*, 267 F.2d 305 (5th Cir.

1959)). That case is inapposite. Plaintiffs' Findings Claim is not moot, nor does FDA contend that it is. As demonstrated above, there is significant overlap between the Findings Claim and the Third Claim. Thus, granting Plaintiffs' motion for leave to supplement the complaint would promote an efficient resolution of the entire dispute between the parties. *See Witkowich v. Gonzales*, 541 F. Supp. 2d 572, 590 (S.D.N.Y. 2008).

II. The Equities Favor the Briefing Schedule Plaintiffs Propose

An expeditious briefing schedule is justified here. As FDA and its parent agency, the Department of Health and Human Services, have repeatedly acknowledged, antibiotic resistance—and in particular the use of medically important antibiotics in healthy livestock—presents a serious threat to public health. *See* Gov't Resp. to Pls.' Statement of Facts ¶¶ 6-9, 33-38 (Dkt. 45). FDA has been aware of this threat, and has failed to act, for many years: the agency found that penicillin and tetracyclines in animal feed were not shown to be safe more than three decades ago, and it delayed twelve and six years in responding to the Petitions. In light of the risk to human health, prompt briefing on the merits of the Third Claim is appropriate.

Moreover, FDA has already benefited from repeated delays in this case, and it has used these delays to take administrative actions calculated to reduce its litigation risk. At the outset, Plaintiffs consented to FDA's request for sixty additional days to answer the complaint, on the condition that FDA agree to an expeditious schedule for briefing cross-motions for summary judgment. On November 7, 2011, the day before FDA's response to Plaintiffs' summary judgment motion was due in this Court, FDA denied the Petitions. FDA then sought an extension to file its brief so that it could take "a significant administrative action that should moot plaintiffs' only remaining claim." Letter from Amy A. Barcelo to the Honorable Theodore H. Katz, at 2 (Nov. 7, 2011). Without receiving an extension, FDA unilaterally took one: it ignored the Court-ordered briefing deadline of November 8, 2011, for one week. *See* Letter from Jennifer

A. Sorenson to the Honorable Theodore H. Katz, at 1 (Nov. 14, 2011). After this Court granted FDA's request for an extension until January 9, 2012, FDA published a notice on December 22, 2011, withdrawing the 1977 notices of opportunity for a hearing. Contrary to its representations to the Court when it requested the extension, FDA does not now argue that Plaintiffs' Findings Claim is moot. *See* Mem. in Supp. of the Government's Mot. for Summ. J. and in Opp'n to Pls.' Mot. for Summ. J. (Dkt. 41). The Court should not reward FDA's conduct with further delay.

FDA seeks additional time to respond to Plaintiffs' Third Claim in order to compile an administrative record. Opp'n Br. 1-2, 7-8. It should not take long to assemble the record for the petition denials. Because FDA denied the Petitions recently, in November 2011, the documents it relied on should be close at hand. Nonetheless, Plaintiffs now propose a slightly amended briefing schedule to accommodate FDA's concern. Plaintiffs propose that (1) Plaintiffs file a supplemental motion for summary judgment on the Third Claim twenty days after the Supplemental Complaint is filed; (2) Defendants file a response to Plaintiffs' motion, and an administrative record, twenty days later; and (3) Plaintiffs file a reply supporting their motion ten days later. This schedule would result in expeditious briefing of the merits of the entire dispute between the parties, while also allowing FDA the same amount of time to compile an administrative record—forty days—that it would have if a petition for review were filed in an appellate court. *See* Fed. R. App. P. 17. Under all the circumstances, this is fair.

CONCLUSION

For these reasons and the reasons set forth in their opening papers, Plaintiffs respectfully request that this Court grant them leave to file the Supplemental Complaint.

Dated: January 27, 2012

Respectfully submitted,

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