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.	)	

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR LEAVE TO FILE A SUPPLEMENTAL COMPLAINT

Plaintiffs Natural Resources Defense Council (NRDC), Center for Science in the Public Interest (CSPI), Food Animal Concerns Trust (FACT), Public Citizen, and Union of Concerned Scientists (UCS) seek leave to file a Supplemental Complaint to challenge the U.S. Food and Drug Administration's (FDA's) denial of two citizen petitions. Granting Plaintiffs' motion will promote an efficient resolution of the entire controversy between the parties and will not prejudice the Defendants (collectively, FDA).

STATEMENT OF FACTS

Plaintiffs filed this action on May 25, 2011, and filed an amended complaint on July 7, 2011. Plaintiffs claimed that (1) FDA had violated the Administrative Procedure Act, 5 U.S.C. § 706(1), and the Federal Food, Drug, and Cosmetic Act (Food and Drug Act), 21 U.S.C. § 360b(e)(1), by failing to withdraw approvals for subtherapeutic uses of penicillin and tetracyclines in animal feed, after finding in 1977 that these drug uses were not shown to be safe for human health; and (2) FDA had delayed unreasonably in ruling on citizen petitions filed in 1999 and 2005 (the Petitions). The Petitions, filed by CSPI, FACT, Public Citizen, and UCS, requested that FDA withdraw approvals for nontherapeutic uses of antibiotics in livestock if those antibiotics are also important to human medicine. The Petitions cited numerous studies and reports by public health organizations worldwide, all concluding that using medically important antibiotics in livestock—particularly for nontherapeutic purposes such as increasing the rate of weight gain—presents serious risks to human health. Such drug use promotes the development of antibiotic-resistant bacteria that can be, and have been, transferred from animals to people.

FDA sought a sixty-day extension to respond to Plaintiffs' complaint. Plaintiffs consented, on the condition that FDA agree to an expeditious schedule for briefing the merits, given the long history of agency inaction and the urgency of the public health concerns. Plaintiffs filed a motion for summary judgment on October 6, 2011, in accordance with the Court-ordered briefing schedule. On November 7, 2011, the day before FDA's response to Plaintiffs' motion for summary judgment was due, FDA denied both Petitions, mooting the unreasonable delay claim. FDA then requested, and eventually received, an additional extension of time to file its response and cross-motion for summary judgment on Plaintiffs' remaining claim, which are now due on January 9, 2012.

In denying the Petitions, FDA did not dispute the science or analysis underlying them. On the contrary, the agency acknowledged 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)." FDA explained, nonetheless, that "for various reasons the Agency has decided not to institute formal withdrawal proceedings at this time and instead" has sought to address the problem by issuing a nonbinding draft guidance document, which recommends that livestock producers voluntarily refrain from using medically important antibiotics for production purposes. FDA made no attempt to explain whether or how its alternative approach comports with its statutory duty to withdraw approvals for animal drugs that are unsafe or not shown to be safe for the uses for which they were approved. *See* 21 U.S.C. § 360b(e)(1).

Plaintiffs now move for leave to file a Supplemental Complaint to challenge FDA's denials of the Petitions. Counsel for FDA has indicated that FDA will oppose this motion.

ARGUMENT

Rule 15(d) of the Federal Rules of Civil Procedure permits a party to move to "serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented." Fed. R. Civ. P. 15(d). Rule 15(d) reflects "a liberal policy favoring a merit-based resolution of the entire controversy between the parties." *Witkowich v. Gonzales*, 541 F. Supp. 2d 572, 590 (S.D.N.Y. 2008) (internal quotation marks omitted); *accord Wells v. Harris*, 185 F.R.D. 128, 133 (D. Conn. 1999) ("The purpose of Rule 15(d) is to promote as complete an adjudication of the dispute between the parties as possible by allowing the addition of claims which arise after the initial pleadings are filed." (internal quotation marks omitted)). Whether to grant a motion under Rule 15(d) is committed to the sound discretion of the district court. 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). "Absent undue delay, bad faith, dilatory tactics, undue prejudice to the party to be served with the proposed pleading, or futility," a motion for leave "should be freely granted." *Id.* (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

Granting Plaintiffs' motion would "promote the economic and speedy disposition of the controversy between the parties." *Bornholdt v. Brady*, 869 F.2d 57, 68 (2d Cir. 1989). Plaintiffs' new claim challenging FDA's denial of the Petitions is closely related to Plaintiffs' claim that FDA's failure to withdraw approval of subtherapeutic uses of penicillin and tetracyclines in animal feed, in accordance with its 1977 safety findings, is an agency action unlawfully withheld. *See Eison v. Kallstrom*, 75 F. Supp. 2d 113, 116 (S.D.N.Y. 1999) (explaining that the allegations in the supplemental pleading "'do not need to arise out of the same transaction or occurrence as the original; they need only bear some relationship to the subject of the original pleading'" (quoting 3 James Wm. Moore et al., *Moore's Federal Practice*, ¶ 15.30, at 15-108 (3d ed. 1998))). The facts underlying the two claims are strikingly similar: In both cases, FDA has acknowledged that nontherapeutic uses of antibiotics in livestock present serious risks to human health, but, for reasons unrelated to—and in contravention of—its statutory obligations under the Food and Drug Act, FDA has failed or refused to withdraw its prior approval for such drug uses. Instead, the agency has relied entirely on the willingness of drug sponsors and livestock producers to take voluntary measures to address the problem. FDA has offered neither a statutory justification for this decision, nor evidence that a nonbinding approach will have any effect on industry practices. The drugs implicated by FDA's 1977 safety findings are among the drugs covered by the Petitions. Given the substantial factual overlap, granting Plaintiffs' motion would

promote judicial economy and a speedy, merits-based resolution of the entire dispute between the parties.

Plaintiffs' motion for leave to supplement is made in good faith and without undue delay. FDA denied the Petitions just two months ago, on November 7, 2011. *See Aktiebolag v. Andrx Pharms., Inc.*, 695 F. Supp. 2d 21, 30 (S.D.N.Y. 2010) (finding no undue delay where plaintiffs informed the court of their intention to move to supplement their complaint three months after the need for supplementation arose).

Finally, there is no undue prejudice to FDA. In evaluating "prejudice," courts consider "whether the assertion of the new claim would . . . require the opponent to expend significant additional resources to conduct discovery and prepare for trial" or "significantly delay the resolution of the dispute." *Block v. First Blood Assocs.*, 988 F.2d 344, 350 (2d Cir. 1993) (considering motion to amend pleading under matching standards of Fed. R. Civ. P. 15(a); *see Quaratino*, 71 F.3d at 66). Granting Plaintiffs' motion at this stage of the litigation will not require FDA to expend significant additional resources. Plaintiffs' Supplemental Complaint raises issues closely related to those presented by their First Amended Complaint, filed on July 7, 2011, and this case is unlikely to involve discovery. *See Witkowich*, 541 F. Supp. 2d at 591 (finding no undue prejudice where plaintiff would be adding a new claim after defendants had filed a motion for summary judgment but before a trial date had been set). Nor will granting the motion significantly delay the resolution of the dispute. Plaintiffs respectfully propose the following schedule for briefing the merits of the new claim: (1) Plaintiffs would file a supplemental motion for summary judgment on February 13, 2012; (2) FDA would respond to Plaintiffs' motion by February 27, 2012; and (3) Plaintiffs would reply by March 5, 2012. Under

this schedule, the entire dispute will be fully briefed less than a month after briefing otherwise would have concluded.

CONCLUSION

For these reasons, Plaintiffs respectfully request that this Court grant them leave to file the Supplemental Complaint.

Dated: January 6, 2012

Respectfully submitted,

s/ Mitchell S. Bernard
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