IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF WYOMING

CODY LABORATORIES, INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil No. 2:10-cv-00147-ABJ
	)	
THE HONORABLE KATHLEEN SEBELIUS, Secretary of Health and Human Services, et al.,	)	
	)	
Defendants.	)	

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

This matter comes before the Court on defendants' motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). A hearing on the motion was held on October 8, 2010.

Plaintiffs recently began marketing an unapproved drug – a morphine sulfate solution. In their three-count complaint brought under the Administrative Procedure Act ("APA"), plaintiffs allege that the United States Food and Drug Administration ("FDA") has improperly determined that their unapproved product is a "new drug" that is not "grandfathered" under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a ("FDCA" or "Act"). Plaintiffs also assert that the FDA did not properly compile an administrative record of this "grandfathering" determination. Finally, plaintiffs allege that they were similarly situated to a competitor whose morphine sulfate product was approved, Roxane Laboratories, but were treated differently.

Plaintiffs seek relief that would preclude FDA from initiating enforcement action against them for marketing this unapproved product.

Plaintiffs initiated this action on July 21, 2010, by filing a complaint for declaratory and injunctive relief. On the same day, plaintiffs filed a motion for temporary restraining order and preliminary injunction. In their motion, plaintiffs requested an injunction that would prevent the FDA from initiating an enforcement action against plaintiffs with respect to their morphine sulfate product. The Court held an oral argument on plaintiffs' motion on July 23. The Court denied plaintiffs' motion for emergency relief in an oral ruling at the hearing, and then in a written order issued on July 26. The written Order also dismissed the complaint. On July 30, plaintiffs filed a motion for reconsideration to the extent the that Order had dismissed their complaint. The Court heard argument on this motion on August 13, and granted plaintiffs' motion to the extent that jurisdictional issues may be more fully briefed. The Court directed defendants to file a motion pursuant to Rules 12(b)(1) and 12(b)(6) on or before August 30.

BACKGROUND

I. Statutory and Regulatory Scheme

The manufacture and distribution of drugs in the United States is governed by the FDCA, which provides that "no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with FDA] . . . is effective with respect to such drug." 21 U.S.C. § 355(a). A new drug application ("NDA") must contain,

among other information, "full reports of [clinical] investigations" showing that "such drug is safe for use and . . . effective in use." *Id.* § 355(b); *see also id.* § 355(j) (permitting an abbreviated new drug application ("ANDA") for generic drugs in which they demonstrate safety and efficacy by reference to an approved NDA). FDA is charged with enforcing the FDCA and may take enforcement action, including injunction and seizure, to remove unapproved new drugs from the market. *Id.* §§ 331-32, 334, 371(a).

Comprehensive federal regulation of drugs has developed over time. Congress' first significant public health law, the Federal Food and Drugs Act of 1906, prohibited the sale of drugs that were adulterated and misbranded but did not require that drugs receive premarket approval. Pub. L. No. 59-384, 34 Stat. 768. Not until 1938, when Congress enacted the FDCA, were drug manufacturers required to obtain premarket approval by submitting reports of safety investigations and proposed drug labeling to FDA for review. Pub. L. No. 75-717, 52 Stat. 1040; *see also Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009) (observing that the 1938 Act's "most substantial innovation" was that a manufacturer was prohibited from distributing a drug until its application became effective, and FDA was permitted to "reject an application if it determined that the drug was not safe for use as labeled"). In 1962, Congress amended the FDCA to require drug manufacturers to submit additional evidence, including adequate and well-controlled clinical investigations, to FDA establishing that their drugs are not only safe but also effective

"under the conditions of use prescribed, recommended, or suggested in the proposed labeling." Pub. L. No. 87-781, § 102(d), 76 Stat. 780, 781 (codified at 21 U.S.C. § 355(d)).

In both the 1938 and 1962 laws, Congress exempted drugs that met the requirements of narrow "grandfather provisions" from certain provisions of the Act. *United States v. Rutherford*, 442 U.S. 544, 548 (1979). The 1938 grandfather clause, which is the clause at issue in this litigation,[1] exempts from the FDCA's "new drug" definition "any drug that was subject to the [] Food and Drug[s] Act of 1906, if its labeling retained the same representations concerning conditions of use made prior to 1938." *Id.* at 548 n.3. This exemption, now codified at 21 U.S.C. § 321(p), states that a "new drug" is:

> "Any drug . . . not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a 'new drug' if at any time prior to the enactment of this Act [enacted June 25, 1938] it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use . . . ."

[1] *See* Complaint ("Compl.") ¶¶ 30-32. When Congress amended the FDCA in 1962, it added a second grandfather clause that, unlike the 1938 grandfather clause, does not exempt a drug from the "new drug" definition found in 21 U.S.C. 321(p), nor from the requirement that manufacturers demonstrate the safety of their drug products. Rather, if satisfied, "the 1962 grandfather clause simply relieved manufacturers of pre-1962 drugs from having to demonstrate the effectiveness of their drugs." *United States v. Articles of Drug . . . 5,906 Boxes*, 745 F.2d 105, 108 (1st Cir. 1984) ("[S]afety . . . has been a requirement for exemption from new drug approval procedures since 1938."). The 1962 grandfather clause was not codified.

(emphases added). Thus, under the 1938 grandfather clause, a manufacturer is not required to submit an NDA to establish the safety and effectiveness of a drug if that drug was on the market prior to passage of the 1938 Act and has retained in its labeling the identical representations concerning the conditions of use as it had prior to passage of the 1938 Act. "Conditions of use include, among other things, what the drug is recommended for, how it is to be administered, and in what quantities it is to be administered." Laetrile Comm'r's Decision, 42 Fed. Reg. 39,768, 39,792 (Aug. 5, 1977) (setting forth FDA's interpretation of the scope and application of the FDCA's grandfather clauses, which was subsequently reviewed and upheld by the Tenth Circuit in *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980)); *see also* 21 C.F.R. § 314.200(e)(2) (describing the documentation, including "past and present quantitative formulas, labeling, and evidence of marketing," necessary to support a claim that a drug is exempt from the new drug safety and effectiveness requirements by virtue of the grandfather clause).[2]

In addition, the term "drug," as it is used in the FDCA's "new drug" definition, 21 U.S.C. § 321(p), refers not to the active ingredients of a drug product but to the entire finished product,

[2] Although 21 C.F.R. § 314.200 pertains to an administrative hearing process not relevant to plaintiffs' product, the amount and type of documentation necessary to demonstrate that a drug product is exempt from the new drug provisions of the Act under the 1938 (or the 1962) grandfather clause is the same regardless of the context. Indeed, when it finalized what is now § 314.200(e), FDA stated that it had "thoroughly reviewed the information to be required by the format and conclude[d] that all of it is relevant to the 'grandfather' status of a drug." 39 Fed. Reg. 9,750, 9,759 (Mar. 13, 1974).

including all inactive ingredients. *See United States v. Generix Drug Corp.*, 460 U.S. 453, 454, 460 (1983) (rejecting the contention "that the term 'drug' means only the active ingredient in a product" and holding that "drug" refers "to the entire product").

Thus, in order to be exempt from the new drug definition under the 1938 grandfather clause, a manufacturer must prove that "the identical drug," including all inactive ingredients, was on the market between 1906 and 1938, and that its "labeling with respect to . . . conditions of use has undergone no changes whatsoever" and its "composition is completely identical to its composition" prior to enactment of the FDCA in 1938. 42 Fed. Reg. at 39,788 ("The proof required would necessarily involve the production of quantitative formulas, labeling, and evidence of marketing both for the pre-1938 use and for the present use.") (emphases added); *see also Rutherford*, 616 F.2d at 457 (holding that "the several requirements" of the grandfather clause cannot be met where a drug has not exhibited "consistency in [its] formula" and "consistent labeling").[3] Any change in a drug's concentration or formulation since 1938 or any effort to modernize its labeling deprives the drug of its grandfathered status. *See Allan Drug Corp.*, 357 F.2d. at 718-19 (holding that a drug product "loses the immunity of the Grandfather

[3] The *Rutherford* court's analysis relates to the requirements of the 1962 grandfather clause, as is true of most courts that have considered claims of grandfather status under the FDCA. In light of the Tenth Circuit's admonition in *Allan Drug Corp.* that the 1938 and 1962 grandfather clauses should be construed similarly, this order refers without distinction to precedents discussing both clauses. 357 F.2d at 718 ("While the exempting language of the basic Act [the 1938 grandfather clause] and the Amendment [the 1962 grandfather clause] is verbally different, they are undoubtedly intended to mean the same thing.").

clause and becomes a new drug" subject to the FDCA's premarket approval requirements even if there is no more than a "mere change in the labeling after the effective date of the Act"); *Articles of Drug . . . 5,906 Boxes*, 745 F.2d at 114 (finding that a drug was not grandfathered where the manufacturer had engaged in "voluntary relabeling to eliminate questionable uses" and added a safety warning regarding use in children).

"[A]s an exemption to a comprehensive regulatory statute concerned with public safety, the grandfather clause is to be strictly construed, and [a drug manufacturer] bears the burden of proof as to each condition." *Articles of Drug . . . 5,906 Boxes*, 745 F.2d at 113; *see also Allan Drug Corp.*, 357 F.2d at 718 ("Since we are dealing with a Grandfather Clause exception, we must construe it strictly against one who invokes it."); *Durovic v. Richardson*, 479 F.2d 242, 250 (7th Cir. 1973) (same); *USV Pharm. Corp. v. Richardson*, 461 F.2d 223, 227-28 (4th Cir. 1972) (same); *United States v. An Article of Drug (Bentex Ulcerine)*, 469 F.2d 875, 878 (5th Cir. 1972) (same). Although the defense that a drug is grandfathered has been raised many times, it is extremely rare for a court to find that the requirements for grandfather status have been met. *See* Peter Barton Hutt et al., *Food and Drug Law*, 599 (3d ed. 2007) ("No drug has yet been judicially determined to fall within the 1938 or 1962 grandfather clause."); *but see United States v. Lanpar Co.*, 293 F. Supp. 147, 152 (N.D. Tex. 1968) (finding that drugs were marketed "prior to the enactment of the [FDCA]" and at such time "contained the same representations concerning conditions of their use as now" but ordering them destroyed because they were adulterated – a

ruling the government did not appeal). This is hardly surprising in that "[v]ery few drug products have labeling that has not changed in any respect since 1938" and "most drug products have changed their formulations in some respect in the last 45-plus years." Donald O. Beers, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*, § 1.04[E] (7th ed. 2008); *see also FDA Marketed Unapproved Drugs – Compliance Policy Guide* (hereinafter cited as "Unapproved Drugs CPG"), Sec. 440.100 (June 2006) at 11 ("[T]he Agency believes it is not likely that any currently marketed prescription drug product is grandfathered or is otherwise not a *new drug*.") (attached to plaintiffs' complaint as Exhibit A).

II. FDA's Enforcement Policy Regarding Marketed Unapproved Drugs

FDA estimates that "perhaps as many as several thousand drug products are marketed illegally without required FDA approval." Unapproved Drugs CPG at 2. This is largely attributable to the piecemeal development of federal drug regulation. *See id.* at 8-12 (describing various historical reasons that unapproved drugs remain on the market). For instance, before the 1962 amendments, FDA permitted thousands of drugs that were similar or identical to drugs with approved NDAs to be marketed without independent FDA approval. *See Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 614 (1973); *see also Hoffmann-LaRoche Inc. v. Weinberger*, 425 F. Supp. 890, 894 (D.D.C. 1975). In addition, many other drugs were introduced to the market before 1962 based upon their manufacturers' beliefs that the drugs were either grandfathered, generally recognized as safe ("GRAS") and therefore not "new drugs" under 21

U.S.C. § 201(p), or otherwise exempt from regulation under the FDCA. *See Hynson, Westcott & Dunning*, 412 U.S. at 624 ("It is estimated that by 1969 there were five identical or similar drugs for every drug with an effective NDA.").

After FDA was chastened by the court in *Hoffmann-LaRoche* for permitting new drugs to be marketed without the pre-market approval mandated by the 1962 FDCA amendments, the Agency began a sustained initiative to address the problem. 425 F. Supp. at 894 (declaring that a lack of "administrative resources to insure compliance . . . cannot be permitted to postpone to some indefinite future date the implementation" of a "clear statutory requirement"). The first version of FDA's Unapproved Drugs CPG was issued in 1976. *United States v. Sage Pharms., Inc.*, 210 F.3d 475, 478 (5th Cir. 2000). In it, FDA "acknowledge[d] the continued marketing of new drugs without approval and reaffirm[ed] that all . . . new drugs . . . require an approved NDA or ANDA for marketing." *Id.* at 479 (quotation marks omitted). FDA's efforts under the 1976 Unapproved Drugs CPG focused on drugs that FDA had approved as safe between 1938 and 1962, or drugs that were similar or identical to such drugs, but that FDA had not yet evaluated for effectiveness as mandated by the 1962 FDCA amendments. *See Hynson, Westcott & Dunning*, 412 U.S. at 614 (observing that the transitional provisions of the 1962 amendments permitted about 3,400 drugs to remain on the market until FDA could complete a retrospective review of those drugs' effectiveness). Such drugs are the focus of FDA's Drug Efficacy Study Initiative and are commonly called "DESI" drugs. FDA's effort to remove unapproved DESI drugs from

the market continues today. *See*, *e.g.*, *Trimethobenzamide Hydrochloride Suppositories; Withdrawal of Approval*, 72 Fed. Reg. 17,556 (Apr. 9, 2007) (announcing the withdrawal of FDA approval for a drug evaluated for effectiveness by FDA under the ongoing DESI program).

After an unapproved, high concentration Vitamin E injection, E-Ferol, was linked to the deaths of 40 infants in 1983, FDA broadened its focus on marketed unapproved drugs beyond DESI drugs to encompass all illegally marketed unapproved drugs. *See* Unapproved Drugs CPG at 10. Among these were drugs like E-Ferol, whose manufacturers contended that their products did not require FDA approval because they were grandfathered or otherwise exempt from the FDCA's new drug definition. *See* Philip M. Boffey, *The Tragic Case History of Intravenous Vitamin E*, N.Y. Times, May 27, 1984 ("Neither [the manufacturer nor the distributor of E-Ferol] had sought FDA approval to market the solution, a process that would have required clinical trials to demonstrate it was safe and effective" because they believed "that approval was unnecessary because the product was not a new drug, but a variation of others long on the market."); *see also United States v. Hiland*, 909 F.2d 1114, 1118 (8th Cir. 1990) (upholding criminal convictions of those who manufactured and distributed E-Ferol, rejecting claim that defendants reasonably believed "E-Ferol could be lawfully marketed without a new drug approval"). In the wake of the tragedy and in response to Congressional oversight, FDA "significantly revised and expanded" its Unapproved Drugs CPG in 1984, "to cover all marketed unapproved prescription drugs, not just DESI products." Unapproved Drugs CPG at 10; *see also*

Deficiencies in FDA's Regulation of the Marketing of Unapproved New Drugs: The Case of E-Ferol, H.R. Rep. No. 98-1168 (1984); Prescription Drugs Marketed Without Approved New Drug Applications; Revised Compliance Policy, 49 Fed. Reg. 38,190 (Sept. 27, 1984).

Although FDA had "been working on the unapproved drugs issue steadily through the years," the Agency decided to place "renewed emphasis on this issue" in 2006, and announced that removing unapproved new drugs from the market would be "a significant focus for [FDA] going forward." Statement of Steven K. Galson, Director of FDA's Center for Drug Evaluation and Research (June 8, 2006), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm153703.htm. Contemporaneously with this announcement, FDA again revised and reissued the Unapproved Drugs CPG, resulting in the version of the CPG that plaintiffs attached to their complaint.

In the Unapproved Drugs CPG, FDA emphasized that it intended to continue its effort to rid the market of "illegally marketed drugs [that] must obtain FDA approval," including those being sold in reliance on unfounded claims of grandfather status. Unapproved Drugs CPG at 2; *see also id.* at 11 ("In light of the strict standards governing exceptions to the approval process, it would be prudent for firms marketing unapproved products to carefully assess whether their products meet those standards."). Although the Unapproved Drugs CPG was "intended to provide notice that any product that is being marketed illegally is subject to FDA enforcement

action at any time," *id.* at 4, FDA also conceded that limited resources would prevent it from taking immediate action against all such drugs. *Id.* at 2. Thus, in order to "clarify for . . . the regulated industry how we intend to exercise our enforcement discretion regarding unapproved drugs," FDA explained in the Unapproved Drugs CPG that it planned to use a "risk-based approach" in its regulatory efforts and set forth specific factors that may cause the Agency to prioritize enforcement actions against certain unapproved drugs. *Id.* at 2-3; *see also Sage Pharms.*, 210 F.3d at 479 (acknowledging that FDA's CPG was a reasonable response when "[c]onfronted with limited resources and a multitude of unapproved drugs already on the market"). Among these are drugs that have potential safety risks and drugs that threaten the new drug approval process by competing directly with an FDA approved drug. Unapproved Drugs CPG at 3-5, 7 (explaining that removal of unapproved drugs from the market in the latter situation provides an incentive for manufacturers to expend the requisite effort and financial commitment to obtain an approved NDA).

When a company obtains approval to market a drug that other companies have been marketing illegally, FDA may, in its discretion, allow a limited period of continued marketing by manufacturers of unapproved versions before the initiation of any enforcement actions, in order to alleviate potential shortages and allow consumers to adjust to the imminent removal of the unapproved products from the market. *Id.* at 5-6.

III. Regulatory History of Plaintiffs' Drug Product

For the past five years, plaintiffs have manufactured and distributed a high concentration prescription morphine sulfate solution to be administered orally for the relief of acute and chronic pain. Compl. ¶¶ 22-23. Plaintiffs' product is not approved and has not been evaluated for safety or effectiveness by FDA. *Id.* at ¶ 33. On March 30, 2009, plaintiffs each received an FDA warning letter informing them that the marketing of their product "without an approved application constitutes a violation of [the FDCA]" and that "[f]ailure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction." *Id.*, Exs. B & C.[4] FDA stated that it planned to exercise enforcement discretion for a limited period of time and did not intend to initiate an enforcement action against them unless the product was still being manufactured more than 60 days after the date of the letter or distributed more than 90 days after the date of the letter. *Id.*

On the same day that FDA sent these warning letters to plaintiffs, FDA also sent warning letters to other manufacturers of high concentration morphine sulfate oral solutions and certain other unapproved narcotics. *See* Q&A for Consumers about FDA's Action Involving Unapproved Narcotics (listing the nine firms that received warning letters for unapproved narcotics), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/

[4] *See* FDA, Regulatory Procedures Manual, ch. 4, § 4-1-1 (Mar. 2009) ("Warning letters are issued to achieve voluntary compliance and to establish prior notice."), available at http://www.fda.gov/ ICECI/Compliance Manuals/RegulatoryProceduresManual/default.htm.

EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm165587.htm. In its public announcement, FDA explained that it was taking action against marketers of unapproved high concentration morphine sulfate solutions, in part, because a comparable approved product was available: morphine sulfate 20 mg/5ml solution for oral use manufactured by Roxane. *Id.*; *see also* Unapproved Drugs CPG at 3, 5-7.

After FDA issued the nine warning letters, it "heard from the pain management community that the impending market removal of unapproved morphine sulfate oral solution 20 mg/ml products," which were marketed by plaintiffs and others, "would impose extreme hardship on palliative care patients and their families" because the approved product was a lower concentration and some patients had difficulty swallowing even small doses of liquids. Compl. ¶¶ 23, 55, Exs. D & E. In light of these concerns, on April 9, 2009, FDA sent follow-up letters informing plaintiffs and others that it would "extend the period of enforcement discretion set forth in the Warning Letter to ensure that palliative care patients have access to morphine sulfate oral solution 20 mg/ml," and that FDA would exercise enforcement discretion for "180 days after any firm receives approval for a morphine sulfate oral solution 20 mg/ml product." *Id.* The letters encouraged plaintiffs to contact an employee in FDA's Office of New Drugs (whose name and phone number were given in the letters) about obtaining the approval for their product. *Id.*

On May 1, 2009, counsel for plaintiffs responded to the warning letters and asserted that plaintiffs' product was exempt from the FDCA's new drug approval requirements because it met

the requirements of the 1938 grandfather clause. Compl., Exs. F & G. The letters also acknowledged that plaintiffs had "begun work" on an NDA application but would "need some guidance concerning the data expected in the application" and that it was anticipated "that the [FDA] reviewing division would help advise [plaintiffs] throughout this process." *Id.* Ex. F at 6; Ex. G at 5. On May 6, 2009, FDA received a written request from plaintiff Lannett for a pre-Investigational New Drug (IND) application meeting. *Id.* at ¶ 58. (An NDA must be supported by evidence from adequate and well-controlled clinical trials, and before beginning such trials companies are required to submit an IND. *See* 21 U.S.C. § 355(i).) FDA informed plaintiff Lannett on May 11, 2009, that its request for a pre-IND meeting had been granted and scheduled for July 1, 2009. *Id.* at ¶¶ 58, 62.

On January 25, 2010, FDA approved an NDA from Roxane for a high concentration 20 mg/ml morphine sulfate oral solution – the same concentration as plaintiffs' product. *Id.* at ¶ 66. Roxane had submitted its NDA on August 25, 2009, and received priority review of its application consistent with FDA's policy of expediting review of a product where no approved satisfactory alternative therapy exists. *Id.* at ¶ 66, Compl. Ex. Q; *see also* FDA Center for Drug Evaluation and Research, *Review Classification Procedure*, MAPP 6020.3 (explaining that "priority review" for an NDA may be available where there is no approved alternative therapy), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPolicies Procedures/UCM082000.pdf.

Plaintiff Lannett submitted an NDA for its own 20 mg/ml morphine sulfate oral solution on February 26, 2010, a month after FDA had already approved Roxanne's product and publicly announced that approval.[5] Compl. ¶ 74. On March 1, 2010, FDA sent letters to plaintiffs and five other remaining marketers of 20 mg/ml morphine sulfate oral solution, informing them that FDA had approved Roxane's NDA and that, in accordance with the terms of the April 9, 2009, letters, FDA would exercise enforcement discretion with regard to the marketing of their products only until July 24, 2010. *Id.* at ¶ 75, Exs. M & N.

ARGUMENT

I. This Court is Without Jurisdiction Over This Case

When analyzing a Rule 12(b)(1) motion, a court may go beyond the allegations in the complaint to examine facts relevant to jurisdiction. *Holt v. United States*, 46 F.3d 1000, 1003 (10th Cir. 1995). It is not necessary to do so, however, when – as here – the factual allegations in the complaint, even when accepted as true, make clear that the court lacks jurisdiction. *See E.F.W. v. St. Stephen's Indian High School*, 264 F.3d 1297, 1302-03 (10th Cir. 2001). Although a court accepts a plaintiff's allegations of fact for purposes of a facial motion to dismiss, it is "not

[5] Pursuant to the Prescription Drug User Fee Act ("PDUFA"), FDA has committed to certain performance goals for reviewing drug approval applications. Under these goals, NDAs for drugs that offer minor improvements over existing legally marketed therapies are assigned a 10-month deadline for standard review. *See* Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85, §§ 101-109, 121 Stat. 823. Because plaintiff Lannett's NDA was filed in February 2010, and was classified as a standard review, the user fee goal date for its review is January 1, 2011.

bound by conclusory allegations, unwarranted inferences, or legal conclusions." *Hackford v. Babbitt*, 14 F.3d 1457, 1465 (10th Cir. 1994). Plaintiffs bear the burden of establishing that a court has jurisdiction. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); *McNutt v. Gen. Motors Acceptance Corp. of Indiana*, 298 U.S. 178, 182 (1936).

A. Courts Lack Jurisdiction to Enjoin FDA Enforcement Actions

Plaintiffs seek declaratory and injunctive relief to prevent FDA from taking any enforcement action to remove their unapproved high concentration morphine sulfate solution from the market. Compl. ¶ 1 & pp. 30-31. It has long been established that courts lack jurisdiction to enjoin FDA from initiating enforcement proceedings under the FDCA. *See Ewing*, 339 U.S. 594. Whether an enforcement action is simply contemplated or has already been filed, those subject to enforcement action may not file an anticipatory challenge; they must raise any defenses they have in the enforcement action itself. *Id.* at 598. "Judicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the FDCA." *Id.* at 600.

The Supreme Court reaffirmed the *Ewing* principle in *Abbott Laboratories v. Gardner*, calling the *Ewing* decision "quite clearly correct." 387 U.S. 136, 147 (1967). As the Court observed, "[t]he drug manufacturer in *Ewing* was quite obviously seeking an unheard-of form of relief which, if allowed, would have permitted interference in the early stages of an

administrative determination as to specific facts, and would have prevented the regular operation of the seizure procedures established by the [FDCA]." *Id.* at 148.

The *Ewing* rule has also been "consistently and strictly observed" by the lower courts, which have interpreted the decision to "preclude[] judicial interference with the FDA's decision to institute enforcement actions, whatever the precise context." *United States v. Alcon Labs.*, 636 F.2d 876, 881-82 (1st Cir. 1981) (emphasis added) ("The considerations from which the *Ewing* holding emerged dictate that it be applied and that the district court's order, insofar as it bars initiation of further FDA enforcement actions, be vacated."). In *Southeast Minerals, Inc. v. Harris*, 622 F.2d 758 (5th Cir. 1980), for example, the Fifth Circuit held that the jurisdictional prohibition in *Ewing* "expresses a total and complete proscription on the district court's power both to undertake a pre-enforcement review of the FDA's determination of probable cause and to enjoin federal officials from acting upon that determination by seizing products or initiating enforcement proceedings under the Act." *Id.* at 764 n.10. In addition: "The present case falls directly within the ambit of the jurisdictional prohibition established in *Ewing*. The fact that seizures of the appellees' product were yet unconsummated by federal officials at the time the appellees filed this action is of no consequence." *Id.* at 764; *see also Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 801 (2d Cir. 1980) (stating that it is "well settled" that courts "lack jurisdiction to enjoin seizure actions instituted by the FDA"); *Pharmadyne Labs, Inc. v. Kennedy*, 596 F.2d 568, 570-71 (3d Cir. 1979) (same); *Parke, Davis & Co. v. Califano*, 564 F.2d

1200, 1206 (6th Cir. 1977) (same); *Genendo Pharm. v. Thompson*, 308 F. Supp.2d 881, 883 (N.D. Ill. 2003) (same).

One of the principal reasons underlying these decisions is that permitting judicial review of agency actions in a forum other than an actual enforcement action would result in inefficient – and unprecedented – judicial review of preliminary agency decisions:

> [I]t has never been held that the hand of government must be stayed until the courts have an opportunity to determine whether the government is justified in instituting suit in the courts. Discretion of any official may be abused. Yet it is not a requirement of due process that there be judicial inquiry before discretion can be exercised. It is sufficient, where only property rights are concerned, that there is at some stage an opportunity for a hearing and a judicial determination.

Ewing, 339 U.S. at 599; *see also Alcon Labs.*, 636 F.2d at 886 (stating that "the imposition of any formal, pre-enforcement hearing requirement might seriously impair the effectiveness of the [FDCA]'s enforcement provisions").

Thus, the Supreme Court in *Ewing* has foreclosed the possibility that relief can be granted that would bar FDA enforcement actions. Because plaintiffs are attempting to preclude an *anticipated* enforcement action, the well-settled precedent applies with all the more force. FDA issues hundreds of warning letters each year.[6] Virtually all of these are resolved informally through discussions between FDA staff and those in this (highly) regulated industry. If challenges such as that brought by plaintiffs were permitted, it would undoubtedly have a severe

[6] *See* FDA Enforcement Story, Ch. 10, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm. In 2008, the most recent year that statistics are available, FDA issued 445 warning letters but filed only 8 seizures and 5 injunctions. *Id.* at 10-2.

adverse impact on FDA's role to protect the public health. FDA's ability to enforce its statutory mandate would be frustrated if, prior to even determining that initiation of an enforcement action was warranted, a lawsuit could be brought against the Agency. Because the relief sought by plaintiffs is clearly foreclosed by *Ewing* and its progeny, this action must be dismissed.

B. Plaintiffs' Challenge is Not Ripe for Adjudication

The primary purpose of the doctrine of ripeness is "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Labs.*, 387 U.S. at 148-49; *see also Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003); *Keyes v. School District No. 1*, 119 F.3d 1437, 1444 (10th Cir. 1997). The Administrative Procedure Act ("APA") authorizes judicial review only with respect to "final agency action." 5 U.S.C. § 704. Thus, the requirement of final agency action is both part of the ripeness inquiry as well as an independent basis for dismissal under the APA. In evaluating ripeness, courts examine whether the issue to be decided is "purely legal" and "whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." *Skull Valley Band of Goshute Indians v. Nielson*, 376 F.3d 1223, 1237 (10th Cir. 2004) (citation and quotation marks omitted); *see also Utah v. U.S. Dep't of Interior*, 535 F.3d 1184, 1194-95 (10th Cir. 2008) ("[W]hile we agree with [the

intervenor] that its claims largely present legal issues, this does not mean that these claims are ripe for review" because certain "abstract disagreements" would "likely narrow with further factual development.").

Plaintiffs claim that their morphine sulfate solution qualifies for the FDCA's 1938 grandfather clause, thereby exempting their product from the new drug approval requirements. Compl. ¶¶ 46, 124-25. Specifically, plaintiffs contend that their product is grandfathered because morphine sulfate was on the market before 1938 and morphine sulfate contained "the same representations concerning the conditions of its use as the drug does now." Compl. ¶ 125. If this Court were to become involved in this issue now, it would need to undertake a factual evaluation to determine whether the labeling for plaintiffs' product is the same now as it was prior to 1938, and whether the composition and formulation of the product is the same. Admittedly, plaintiffs' allegations regarding the grandfather clause are so deficient that they fail to state claim (as discussed below in section II.A.), but this does not change the fact that plaintiffs are asking this Court "to rule on a factual question 'particularly within the agency's bailiwick as opposed to a purely legal question within the primary competence of the courts.'" *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 4 (D.D.C. 1989) (quoting *Pub. Citizen Health Research v. FDA*, 740 F.2d 21, 31 (D.C. Cir. 1984)). Considerations such as the need to make a "fact-based determination as to exactly what the labeling . . . for [the] product is now and has been in the past . . . weigh strongly in favor of dismissal." *Id.*

Courts have found FDA action similar to that challenged here to be unripe. In *Biotics Research Corp. v. Heckler*, 710 F.2d 1375 (9th Cir. 1983), the FDA sent regulatory letters to Biotics stating that Biotics' drug products were in violation of the law and threatening enforcement action if Biotics did not take corrective measures. *Id.* at 1376. The court held that these letters did not constitute final agency action ripe for adjudication and that there was no jurisdiction over Biotics' complaint:

> The letters do contain conclusions by subordinate officials of the FDA that products offered by Biotics . . . are in violation of federal law and also indicate a readiness on the part of the FDA to initiate enforcement procedures if corrective measures are not taken. As the Secretary points out, however, such letters do not commit the FDA to enforcement action.

Id. at 1378; *see also id.* at 1376. Similarly, in *Estee Lauder*, Estee Lauder challenged letters from FDA stating that some of Estee Lauder's products were drugs, and sought to enjoin future FDA enforcement action. 727 F. Supp. at 1. One of the FDA letters stated: "If you are unwilling to make the changes identified in this letter, please advise us of that fact within 10 days." *Id.* at 5. The letter went on to say that if Estee Lauder were unwilling to make the changes, "the agency is prepared to take the regulatory measures discussed in our previous letters." *Id.* The court held that this agency action was not ripe for review and was not final agency action. *Id.* at 4-5. In *IMS Ltd. v. Califano*, 453 F. Supp. 157 (C.D. Cal. 1977), FDA sent a letter to IMS stating that IMS was in violation of the Food, Drug, and Cosmetic Act and threatened regulatory sanctions should IMS fail to respond to the letter. *Id.* at 158. Although the court viewed IMS' challenge as

an assertion that FDA had improperly applied a regulation to IMS' product, it held that the letter did not constitute final agency action. *Id.* at 158-60. Courts have reached similar results in cases involving the Federal Trade Commission. *See Flowers Industries v. FTC*, 849 F.2d 551, 553 (11th Cir. 1988) (finding that an FTC letter did not present a ripe case: "The FTC must seek to enforce the divestiture through civil penalties before [a plaintiff] can assert its defenses in a court of law."); *Floersheim v. Engman*, 494 F.2d 949, 954 (D.C. Cir. 1973) (dismissing a challenge to an FTC staff interpretation as "the kind of point that can be raised when an enforcement sanction is pursued"); *Direct Marketing Concepts, Inc. v. FTC,* 581 F. Supp.2d 115, 117 (D. Mass. 2008) (attempt to enjoin enforcement action failed "to present a ripe claim for judicial adjudication."); *Jerome Milton, Inc. v. FTC*, 734 F. Supp. 1416, 1420-24 (N.D. Ill. 1990) (holding that an FTC letter was not final agency action).

An enforcement action brought on behalf of FDA by the United States Department of Justice, alleging that plaintiffs' product is an unapproved new drug, would provide the appropriate forum to resolve the factual basis for plaintiffs' claim. Judicial review at this point would entangle the Court in "abstract disagreements over administrative policies," which is exactly what the ripeness doctrine is designed to prevent. *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 732-33 (1998) (citation and quotation marks omitted). Judicial appraisal will "stand on a much surer footing in the context of a specific application . . . than could be the case in the framework of the generalized challenge made here." *Toilet Goods Ass'n, Inc. v. Gardner*,

387 U.S. 158, 164 (1967). Because "further factual development would significantly advance [the Court's] ability to deal with the legal issues presented, . . . judicial resolution of the question presented here should await a concrete dispute." *Nat'l Park Hospitality Ass'n*, 538 U.S. at 812 (citation and quotation marks omitted).

C. Plaintiffs Have Not Challenged Final Agency Action

Nor have plaintiffs identified or challenged any "final agency action." Final agency action "mark[s] the consummation of the agency's decisionmaking process" and is "one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (citation and quotation marks omitted); *see also Abbott Labs.*, 387 U.S. at 148 (observing that the requirement of finality protects "agencies from judicial interference until an administrative decision has been formalized"). "Plaintiffs have the burden of identifying specific federal conduct and explaining how it is 'final agency action.'" *Colo. Farm Bureau Fed'n v. U.S. Forest Serv.*, 220 F.3d 1171, 1173 (10th Cir. 2000). Plaintiffs have not met, and cannot meet, that burden here.

Plaintiffs seek to preclude a *possible* future FDA enforcement action to remove their unapproved morphine sulfate solution from the market. Courts have consistently held, however, that the issuance of a warning letter and informal discussions with FDA staff do not constitute final agency action ripe for judicial review. *See Clinical Reference Lab., Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992) ("Regulatory letters such as the one sent [by FDA],

however, do not amount to final agency action" because "[s]uch letters do not bind the agency to the views expressed in them."), *aff'd in part and rev'd in part on other grounds,* 21 F.3d 1026 (10th Cir. 1994); *see also Dietary Supplement Coal. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992) (same); *Schering Corp. v. Heckler*, 779 F.2d 683, 686 n.18 (D.C. Cir. 1985) (holding that statements by FDA officials regarding whether a product was a "new animal drug" and the government's position in previously filed enforcement actions did not constitute final agency action); *Biotics Research Corp.,* 710 F.2d at 1378; *Estee Lauder*, 727 F. Supp. at 4-5; *IMS Ltd. v. Califano*, 453 F. Supp. at 158-60.

Indeed, the Supreme Court has held that even the FTC's *issuance* of an administrative complaint was not final agency action subject to judicial review. *FTC v. Standard Oil Co.*, 449 U.S. 232 (1980). The Court reached this result even though the complaint was "definitive" on the question regarding whether the Commission had "reason to believe" that Standard Oil was violating the Federal Trade Commission Act. *Id.* at 241. The complaint was only a determination that adjudicatory proceedings would commence. Permitting judicial review of the FTC's administrative complaint would lead to "piecemeal review which at the least is inefficient and upon completion of the agency process might prove to have been unnecessary. . . . Finally, every respondent to a Commission complaint could make the claim that [the plaintiff] had made." *Id.* at 242-43 (citations omitted); *see also Genendo Pharm.*, 308 F. Supp. 2d at 885

(holding that "FDA's filing of a forfeiture complaint does not consummate the agency's decision-making process or definitively determine the status of the products seized").

Plaintiffs could have filed a citizen petition at any time to seek FDA's views as to the claimed grandfather status of their drug, and FDA's response to such a petition would have constituted final agency action. *See* 21 C.F.R. §§ 10.25, 10.30, 10.45(d); *see also Schering Corp. v. FDA*, 51 F.3d 390, 393 (3d Cir. 1995) (holding that FDA's decision on a citizen petition "constituted final agency action from which relief could be sought in a United States District Court"); *Genendo Pharm.*, 308 F. Supp.2d at 886 (finding that the plaintiffs' claims were not ripe where they "could have sought a formal administrative ruling from the FDA by filing . . . a citizen petition"). Plaintiffs failed to take advantage of this much-used procedure under which they could have obtained a definitive statement from FDA regarding whether their morphine sulfate solution was grandfathered or otherwise exempt from the"new drug" definition. "The Supreme Court has described the 'new drug' and 'grandfather clause' issues as 'the kinds of issues peculiarly suited to initial determination by the FDA.'" *Alcon Labs.*, 636 F.2d at 889 (quoting *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653 (1973)); *see also Hynson, Westcott & Dunning*, 412 U.S. at 624 (holding that "FDA is indeed the administrative agency selected by Congress to administer the Act, and it cannot administer the Act intelligently and rationally unless it has authority to determine what drugs are 'new drugs' . . . and whether they are exempt from the [FDCA] . . . by the grandfather clause").

To date, FDA has taken no action against plaintiffs that constitutes final agency action. Because FDA's warning letters do not represent the consummation of FDA's administrative process, determine any legal rights or obligations, or affect plaintiffs' legal rights, plaintiffs' claims are not ripe for review. *See Mobil Exploration & Producing U.S., Inc. v. Dep't of Interior*, 180 F.3d 1192, 1199 (10th Cir. 1999) (dismissing for lack of jurisdiction where agency letter was not final agency action). For these reasons, the Court finds it lacks jurisdiction over plaintiffs' claims and dismisses their complaint.

D. Plaintiffs Have Failed to Exhaust Administrative Remedies

It is well established that exhaustion of administrative remedies is generally required before proceeding to federal court. *See, e.g., Bowen v. New York*, 476 U.S. 467, 484 (1986). In addition, the APA authorizes judicial review only with respect to "final agency action," 5 U.S.C. § 704, and an "agency action is final for the purposes of [the APA]" only after a plaintiff "has exhausted all administrative remedies expressly prescribed by statute or agency rule." *Darby v. Cisneros*, 509 U.S. 137, 146 (1993) (quotation marks omitted).[7]

[7] A court in the Tenth Circuit may dismiss a case for failure to exhaust administrative remedies under either 12(b)(1) or 12(b)(6), depending on whether resolution of the exhaustion issue "is intertwined with the merits of the case." *See Davis ex rel. Davis v. United States*, 343 F.3d 1282, 1296 (10th Cir. 2003) (dismissing under 12(b)(1) when the exhaustion issue was not intertwined with the merits). Here, the Court need not reach the merits of plaintiffs' claims in order to find that plaintiffs failed to exhaust their administrative remedies – because they did not file a citizen petition with FDA. Dismissal under 12(b)(1) is therefore appropriate.

Plaintiffs have made no attempt to avail themselves of, much less exhaust, the administrative remedy available to them for establishing the "new drug" status of their drug product – filing a citizen petition pursuant to 21 C.F.R. §§ 10.25 and 10.30. Under FDA's regulations, a party must first use the citizen petition process to "request that the Commissioner take or refrain from taking any form of administrative action," and that request must "be the subject of a final administrative decision based on [the citizen petition] . . . before any legal action is filed in a court." 21 C.F.R. § 10.45(b).

Courts have dismissed many cases pursuant to FDA's exhaustion requirement. For example, in *Association of American Physicians & Surgeons, Inc. v. FDA*, the court held that plaintiffs had failed to establish circumstances that might excuse filing a citizen petition, and "the Court should not attempt to resolve these arguments before the FDA has the opportunity to apply its expertise and a record is developed." 539 F. Supp.2d 4, 24 (D.D.C. 2008), *aff'd*, No. 08-5458, 2009 WL 5178484 (D.C. Cir. Nov. 27, 2009); *see also BBK Tobacco & Foods, LLP v. FDA*, 672 F. Supp. 2d 969, 977-78 (D. Ariz. 2009) (dismissing for failure to exhaust when, "[r]ather than pursue a citizen petition through the FDA, [the plaintiff] decided to wait nearly four months and file an action directly with this Court"); *Garlic v. FDA*, 783 F. Supp. 4 (D.D.C. 1992), *appeal dismissed*, 986 F.2d 546 (D.C. Cir. 1993) (table disposition); *Estee Lauder,* 727 F. Supp. at 6-7. And in *Biotics Research Corp.*, the Ninth Circuit found that "[s]everal decisions of the Supreme Court demonstrate that the traditional exhaustion requirement applies to one

seeking judicial review of FDA [new drug] status determinations" and, therefore, dismissed the plaintiffs' complaint for "failing to take advantage of this available administrative remedy" for determining the "new drug" status of their product. 710 F.2d at 1378 (citing *Hynson*, 412 U.S. at 627; *CIBA Corp. v. Weinberger*, 412 U.S. 640, 644 (1973); *Bentex Pharm.*, 412 U.S. at 653-54).

Plaintiffs' failure to use the available administrative procedure has prevented FDA from developing the factual issues in this matter and applying the agency's own interpretation of its statute and regulations to those facts, including whether plaintiffs' product: (1) "was subject to the Food and Drugs Act of 1906," Compl. ¶ 31; (2) "had labeling that contains the same representations concerning the conditions of its use" before 1938 as it does now, *id.* at ¶ 32; and (3) is "a 'new drug' within the meaning of the FDCA," *id.* at ¶ 33.

Requiring plaintiffs to submit a citizen petition to FDA before seeking judicial review would allow FDA to carefully consider and apply its expertise to plaintiffs' concerns, and the administrative process might crystalize the contested issues. *See Parisi v. Davidson*, 405 U.S. 34, 37 (1972) ("The basic purpose of the exhaustion doctrine is to allow an administrative agency to perform functions within its special competence – to make a factual record, to apply its expertise, and to correct its own errors so as to moot judicial controversies."). Because plaintiffs have failed to avail themselves of the administrative process, dismissal of this action is appropriate. *See Ass'n of Am. Physicians*, 539 F. Supp. 2d at 22 (dismissing APA and

constitutional claims when the plaintiffs neglected to file a citizen petition as mandated by FDA's regulations).

II. Plaintiffs Fail To State A Claim Upon Which Relief Can Be Granted

"To survive a motion to dismiss" under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Papasan v. Allain*, 478 U.S. 265, 286 (1986). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 129 S.Ct. at 1949; *see also Robbins v. Oklahoma*, 519 F.3d 1242, 1247 (10th Cir. 2008) ("The allegations must be enough that, if assumed to be true, the plaintiff plausibly (not just speculatively) has a claim for relief."). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 129 S.Ct. at 1949. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 1950; *see also Cory v. Allstate Ins*., 583 F.3d 1240, 1244 (10th Cir. 2009) ("Conclusory allegations without supporting factual averments are insufficient to state a claim on which relief can be based.") (citation and quotation marks omitted).

Plaintiffs claim that FDA's alleged determination that their product is a "new drug" is erroneous because their product is "grandfathered" under the FDCA. Compl. ¶¶ 124-25.

Plaintiffs also allege that FDA failed to "develop an adequate record" for this determination. *Id.* ¶ 118. Finally, plaintiffs assert that they were similarly situated to Roxane but were treated differently. *Id.* at ¶¶ 130-35. Plaintiffs' action must be dismissed because their allegations do not state a plausible claim for relief.

A. Plaintiffs' Allegations Are Insufficient to Establish a Plausible Claim That Their Drug is Grandfathered

Plaintiffs allege that their drug is not a new drug because it falls within the bounds of the exemption created by the 1938 grandfather clause.[8] Compl. ¶¶ 29-33, 124-25. If this claim were to be reviewed, it would be subject to review under the APA, and it could only be disturbed if it were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is highly deferential to the agency. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971); *Copar Pumice Co. v. Tidwell*, 603 F.3d 780, 793 (10th Cir. 2010). A reviewing court must consider whether the agency's decision was based upon a consideration of the relevant factors and whether there has been a clear error of judgment. *Overton Park*, 401 U.S. at 416. But, "[t]he scope of review under this standard is

[8] Plaintiffs do not argue that their drug is exempt by virtue of the 1962 grandfather clause. Were they to advance such an argument, it would suffer from the same infirmities as their 1938 grandfather clause claim. In addition, even if plaintiffs met the requirements of the 1962 grandfather clause, such a showing would only exempt their drug from the effectiveness requirements of the Act. Thus, plaintiffs' drug would still be an unapproved new drug because plaintiffs cannot show that their drug is "generally recognized as safe" for its intended uses by qualified experts. 21 U.S.C. § 321(p).

narrow, and [a court] may not substitute [its] judgment for that of the agency." *Ross v. FHA*, 162 F.3d 1046, 1050 (10th Cir. 1998).

This claim will not be reviewed, however, because not only is the Court without jurisdiction, plaintiffs' allegations are insufficient to state a plausible claim for relief. As explained above, to qualify for the limited grandfather clause exemption, the drug product must have the same labeling and the same composition of active and inactive ingredients as it contained prior to 1938. *See* 21 U.S.C. § 321(p); *see also* 42 Fed. Reg. at 39,788; *Rutherford*, 616 F.2d at 457; *Allan Drug Corp.*, 357 F.2d at 719; 21 C.F.R. § 314.200(e)(2).

Plaintiffs do not allege sufficient facts to qualify facially under this grandfather provision. Although plaintiffs make the vague assertion that "Morphine Sulfate was subject to the Food and Drugs Act of 1906 and its labeling contained the same representations concerning the conditions of its use as the drug does now," Compl. ¶ 125, they do not make these assertions about their drug product. Indeed, plaintiffs admit that they have only been marketing their drug for the past five years, *id.* ¶ 22, and do not allege that their product contains the same labeling as it did prior to 1938. Nor do plaintiffs allege that their drug has the same formulation, dosage form, or route of administration as it did prior to 1938. Although plaintiffs make allegations about morphine sulfate in general, they carefully avoid making allegations about their product that would qualify it for grandfathering. *Id.* at ¶¶ 16-20, 31-32. Indeed, plaintiffs have failed to produce *any* pre-1938 labeling for their drug. Thus, it is impossible for plaintiffs to demonstrate that their drug

product's "labeling contained the same representations concerning the conditions of its use" in 1938 that it presently contains. 21 U.S.C. § 321(p); *see also Allan Drug Corp.*, 357 F.2d at 719.

For these reasons, plaintiffs' allegations and arguments regarding "grandfathering" are insufficient to state a claim. Their allegations make clear that they could not carry their burden of showing that their drug meets the requirements of the 1938 grandfather clause, which must be construed "strictly against one who invokes it." *Allan Drug Corp.*, 357 F.2d at 718; *see also USV Pharm. Corp.*, 461 F.2d at 227-28 (observing, in rejecting a grandfather clause claim, "that statutory exemptions, particularly as applied to statutes concerned with public health and safety, are to be strictly and narrowly construed"). "Absent exemption by either the grandfather clause of 1938 or the grandfather clause of 1962, such classification [as a "new drug"] requires the filing of a new drug application and subsequent FDA approval before the drug may be administered." *Rutherford v. United States*, 806 F.2d 1455, 1457 (10th Cir. 1986) (citations omitted).

B. The FDA was Not Required to Compile an Administrative Record for a Non-Final Agency Action

Plaintiffs also allege that the FDA did not develop an adequate record for its decision that plaintiffs' product is a "new drug." Compl. ¶ 111-18. As explained above, FDA has made no final decision that is subject to judicial review. All that has occurred thus far is that an FDA official has sent warning letters to plaintiffs and FDA staff has discussed these letters with plaintiffs. Plaintiffs cite to nothing that would require the FDA to compile an administrative

record for a non-final decision. For this reason, plaintiffs have failed to state a claim for which relief can be granted on their "administrative record" allegation.

C. FDA Was Not Arbitrary and Capricious in Treating Plaintiffs Differently From Roxane

Plaintiffs allege that they were similarly situated to Roxane but that Roxane was given preferential treatment throughout the NDA process. Compl. ¶ 131-34. As discussed above, the FDA actions challenged by plaintiffs are subject to review by the Court under the APA, they may be disturbed only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Although plaintiffs contend that they were situated similarly to Roxane but treated differently, their own allegations reveal this not to be true. Plaintiffs acknowledge that FDA informed them that the purpose of the warning letters was to get an application from plaintiffs and not to remove their drug from the market. *See* Decl. of Arthur P. Bedrosian, Pl. TRO Mem. Ex. M ¶ 13. Plaintiffs also admit that they were told they would receive priority review if no other application had been approved at the time of their application, which is consistent with FDA policy. *Id.* ¶ 15; see Review Classification Procedure at 2. Finally, Plaintiffs concede that Roxane's NDA was submitted and approved before theirs was submitted. Pl. TRO Mem. Ex. M ¶¶ 17, 20; Compl. ¶¶ 65-66, 74. Thus, because plaintiffs were given the same opportunity as Roxane, but Roxane's NDA was submitted first, by plaintiffs' own admission they were not "similarly situated." For this reason, their allegation of disparate treatment fails to state a claim.

FDA's decision to give priority review to Roxane – an opportunity that plaintiffs concede was available to them – was consistent with FDA's well-established policies. *See Review Classification Procedure* at 2 (A"priority" designation directs FDA's "overall attention and resources to the evaluation" to the NDA so designated and sets a 6-month deadline for FDA to complete its review); *cf.* FDAAA, § 101(c) (setting a 10-month deadline for "standard" NDA review). FDA gives an NDA priority designation when a drug has "the potential for providing a significant improvement in the treatment, prevention, or diagnosis of a disease when compared to" other drugs or treatments for the same disease. *Review Classification Procedure* at 2. The lack of an approved drug for the treatment of a condition weighs in favor of granting a priority review designation. *Id.* At the time Roxane submitted its NDA (six months before plaintiff Lannett submitted its NDA), there was no approved 20 mg/ml morphine sulfate oral solution. Thus, in accordance with FDA's established procedures, Roxane's NDA received priority designation. *Id.* Plaintiffs had the same notice and opportunity to seek approval for their drug as all other manufacturers of unapproved morphine sulfate oral solutions but simply failed to take advantage of the opportunity. Rather than file an NDA as FDA suggested, and as Roxane did, plaintiffs chose to insist that their drug was exempt from the FDCA's premarket approval requirements under the 1938 grandfather clause. Compl. ¶ 60. Under these circumstances, FDA cannot be faulted for designating plaintiffs' NDA for standard review.

For the foregoing reasons, it is hereby

ORDERED that defendants' motion to dismiss is GRANTED because the court is without jurisdiction and because plaintiffs have failed to state a claim upon which relief can be granted, and it is further

ORDERED that plaintiffs' complaint and this action are DISMISSED.

Dated this _____ day of _____, 2010.

_____
ALAN B JOHNSON
UNITED STATES DISTRICT JUDGE