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ATTORNEYS FOR PLAINTIFFS

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF WYOMING**

CODY LABORATORIES, INC., a Wyoming corporation, and LANNETT CO., INC., a Delaware corporation,	)	
	)	
Plaintiffs,	)	Civil Action No. 2:10-cv-00147-ABJ
	)	
v.	)	PLAINTIFFS' MOTION FOR
	)	CLARIFICATION, AMENDMENT
THE HONORABLE KATHLEEN SEBELIUS, SECRETARY, U.S. Department of Health and Human Services, and DR. MARGARET A. HAMBURG, COMMISSIONER, U.S. Food and Drug Administration,	)	OR RECONSIDERATION OF ORDER
	)	
Defendants.	)	

**PLAINTIFFS' MOTION FOR CLARIFICATION, AMENDMENT, OR RECONSIDERATION OF ORDER**

Plaintiffs Cody Laboratories, Inc. (“Cody”) and its parent corporation Lannett Co., Inc. (“Lannett”) (collectively “Cody/Lannett”), by and through their undersigned counsel, hereby move for clarification of this Court’s Order of July 26, 2010 (“Order”) in the above-captioned case. Specifically, Cody/Lannett seeks clarification of whether, in addition to denying Cody/Lannett’s Motion for Temporary Restraining Order and Preliminary Injunction (“Motion for TRO/PI”), the Court intended by its Order to dismiss, *sua sponte*, Cody/Lannett’s case in its entirety.<sup>1</sup> If the Court did not so intend, Cody/Lannett respectfully request amendment of the Order to clarify that Cody/Lannett’s case has not been dismissed. If the Court did so intend, Cody/Lannett respectfully request that the Court issue an order clarifying the basis for such dismissal and reconsidering the Order. In support of this motion, Cody/Lannett state as follows:

1. Cody/Lannett filed the Complaint, the Motion for TRO/PI, and a memorandum in support thereof on July 21, 2010.
2. The Defendants filed their brief in opposition to the Motion for TRO/PI on July 22, 2010.
3. The Court held a hearing on the Motion for TRO/PI on July 23, 2010.
4. No other motion was noticed by either party or heard on July 23, 2010 in this case.
5. After argument on the Motion for TRO/PI, the Court issued a ruling from the bench analyzing the Motion for TRO/PI under the applicable four factor test.

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<sup>1</sup> Cody/Lannett do not, by this motion, seek reconsideration of the Court’s decision with respect to the issue of whether temporary and injunctive relief should issue in this case.

6. After providing its analysis, the Court denied the Motion for TRO/PI from the bench. During its ruling from the bench, the Court gave no indication of any intention to dismiss the case in its entirety.

7. While the hearing was in progress, the Defendants filed a “[Proposed] Order Denying Motion for Temporary Restraining Order and Preliminary Injunction” (“Proposed Order”).<sup>2</sup>

8. The Proposed Order totaled 39 pages and paralleled the Government’s Brief. The Proposed Order was more akin to a Memorandum Opinion than a traditional order and contained alternative arguments, many of which seemed to have been rejected by the Court. In addition, the Proposed Order was also far broader with respect to its findings of fact and conclusions of law than the Court’s ruling from the bench.<sup>3</sup>

9. On July 26, 2010, the Court signed the Defendants’ Proposed Order without making any modifications to the Proposed Order.

10. The Court’s Order denied Cody/Lannett’s Motion. See Order at 39.

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<sup>2</sup> The Defendants’ served the Proposed Order on counsel for Cody/Lannett while the hearing was in progress.

<sup>3</sup> Indeed, footnote 3 of the Order apparently strikes all factual allegations in the Complaint pursuant to U.S.D.C.L.R. 83.7.2. This issue was never raised at the hearing. Had it been raised, Cody/Lannett would certainly have sought an opportunity to fully address the issue as Cody/Lannett believes that a complaint, rather than a petition, is the appropriate vehicle action in this case insofar as U.S.D.C.L.R. 83.7.2(b) contemplates review of an agency action made on the record whereas Cody/Lannett’s Complaint specifically alleges a violation of the APA based upon the Defendants’ failure to develop *any* administrative record in regard to its “new drug” determination. Indeed, this lack of formal agency proceeding or record was specifically noted by Cody/Lannett’s counsel during oral argument on the Motion, and the Court noted that all it had seen from the record was “letters going back and forth.” See Transcript at 14:19-15:16. Thus, if U.S.D.C.L.R. 83.7.2 were deemed applicable to claims of the sort alleged by Cody/Lannett, such review would necessarily occur without any record and without any factual allegations, which would be an illogical interpretation of the rule.

11. In addition, though no motion to dismiss was ever filed in this case, no hearing on such a motion was ever held, and no briefing of the issues inherent in a motion to dismiss occurred as contemplated by the Rules 12(b)(2) and 12(b)(6) of the Federal Rules of Civil Procedure, the Court's Order also appears to have dismissed the case in its entirety. See Order at 39.

12. Given that: (1) the Court's Order was entitled "Order Denying Motion for Temporary Restraining Order and Preliminary Injunction"; (2) no motion to dismiss was pending in this case; (3) the analysis in the Order appears to be limited to analyzing the case for purposes of determining whether temporary and preliminary injunctive relief is appropriate; (4) the Court never gave any indication in its ruling from the bench that it intended to dismiss the case; (5) no final judgment has been entered in this case, Cody/Lannett are unclear whether the Court in fact intended by its Order to dismiss the case in its entirety, *sua sponte*.

13. If the Court did in fact intend by its Order to dismiss the case *sua sponte*, it is not clear to Cody/Lannett from the Order whether the basis (or bases, if alternative grounds exist) for such dismissal was jurisdictional, justiciability, failure to state a claim, or some other grounds. If the Court in fact intended to dismiss the case, this clarification would be necessary in order for Cody/Lannett to evaluate its options moving forward, including whether to file an amended Complaint or to appeal a final judgment.

14. Cody/Lannett do not seek to re-litigate any issue the Court has actually decided in ruling on the Motion for TRO/PI. Rather, Cody/Lannett seek a clarification as to whether the Court did in fact intend to dismiss the Complaint itself, *sua sponte*.

15. In addition, Cody/Lannett wish to clarify whether the Court intended by its Order to rule on some of the ultimate issues in the case without discovery or briefing. This is particularly significant with respect to certain of the Court's statements in the Order regarding whether Cody/Lannett's product is a "new drug" for purposes of the Food, Drug, and Cosmetic Act of 1938.<sup>4</sup> As the grandfathering provisions of the law have been rarely litigated, Cody/Lannett would certainly seek the opportunity to be heard on the substance of its contention that its drug is not a "new drug," a question about which there was only limited discussion during the July 23, 2010 hearing on the Motion for TRO/PI.

12. The Court's clarification is important not only for this case so that Cody/Lannett may proceed appropriately, but for the Food and Drug industry as well, as the Court's Order has already been publicized and, to the extent it addresses the merits of the underlying issues (rather than the temporary and preliminary injunctive relief standard), will likely be viewed as breaking new legal ground.<sup>5</sup> As such, if the Order is not clarified and amended, Cody/Lannett expect that the Order will be frequently cited as some of the only legal authority in this area of law, and it may be regularly relied upon by the FDA as providing legal support for highly controversial positions taken by the agency.

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<sup>4</sup> For example, in its order the Court apparently took the position that "it is impossible for plaintiffs to demonstrate that their drug's labeling contained the same representations concerning the conditions of its use in 1938 that it presently contains." Order at 29 (internal quotations admitted). In making such a determination, the Court would have been required to make a final determination on a weighty legal question about the proper interpretation of a rarely construed statute as well as to reach a variety of factual determinations about which no record had yet been fully developed.

<sup>5</sup> See Posting of Kurt R. Karst to FDA Law Blog, [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2010/07/district-court-denies-motion-for-temporary-restraining-order-and-preliminary-injunction-in-marketed-.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/07/district-court-denies-motion-for-temporary-restraining-order-and-preliminary-injunction-in-marketed-.html) (July 26, 2010, 21:04 EST).

13. Counsel for Cody/Lannett contacted counsel for the Defendants by telephone to inform him of this motion and to confer pursuant to U.S.D.C.L.R. 7.1(b)(1). Counsel for Defendants does not agree with the motion.

WHEREFORE, Cody/Lannett respectfully request that this Honorable Court issue an order regarding its July 26, 2010 Order, clarifying the following issues:

- (1) Whether the Court intended, by its Order, to dismiss the case *sua sponte*;
- (2) If the Court intended to dismiss the case *sua sponte*, identifying the basis or bases for dismissal; and
- (3) If the Court did not intend to dismiss the case *sua sponte*, whether the Court intended its Order to be a final and conclusive determination concerning any of the underlying substantive issues in the case.
- (4) Whether the Court will permit the parties to schedule a Rule 16 conference pursuant to the Federal Rules of Civil Procedure.

DATED July 30, 2010

Respectfully submitted,

/s/ Matthew J. Kelly

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## CERTIFICATE OF SERVICE

I hereby certify that on July 30, 2010, I served a true and correct copy of the foregoing via electronic service on the following:

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