IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LANNETT COMPANY, INC., 13200 Townsend Road, Philadelphia, PA 19154 and LANNETT HOLDINGS, INC., 103 Foulk Road, Suite 202 Wilmington, DE 19803, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993 and UNITED STATES OF AMERICA, c/o Office of the United States Attorney for the District of Columbia, 555 4th Street, N.W. Washington, D.C. 20530, Defendants.	)	Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

In this case, Plaintiffs Lannett Company, Inc. and Lannett Holdings, Inc. ("Lannett") seek judicial review of an action by the U.S. Food and Drug Administration ("FDA") rescinding the marketing approval for one of Lannett's generic drugs based on the agency's argument that the approval was "mistakenly granted." Because an FDA drug approval is a constitutionally-protected property right, FDA's governing statute requires notice and an opportunity for a hearing before the agency may rescind a previously-granted approval. FDA nonetheless rescinded Lannett's drug approval without giving Lannett the hearing that the statute and the Constitution require. Lannett seeks the Court's intervention to set aside the rescission action, declare that the rescission action is unlawful, and enjoin FDA from rescinding the approval in the future without following hearing procedures required by law.

JURISDICTION AND VENUE

1. This action arises under the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Due Process Clause of the Fifth Amendment to the U.S. Constitution. FDA has rescinded the drug approval at issue under claimed inherent reconsideration authority allegedly established by the FFDCA (and has not withdrawn the drug approval under the authority established by 21 U.S.C. § 355(e)). This Court has jurisdiction over this action under 28 U.S.C. § 1331, to provide remedies set forth in 5 U.S.C. § 706 and 28 U.S.C. § 2201 and under the Due Process Clause of the Fifth Amendment to the U.S. Constitution.

2. Venue is proper in this District under 28 U.S.C. § 1391(e).

PARTIES

3. Plaintiff Lannett Company, Inc. is a manufacturer of generic drugs, with a principal place of business at 13200 Townsend Road, Philadelphia Pennsylvania. Plaintiff Lannett Holdings, Inc. is a company with a principal place of business at 103 Foulk Road, Suite 202, Wilmington, Delaware, that maintains, owns and manages the intangible assets of its parent company Lannett Company, Inc. Lannett Holdings, Inc. owns the drug approval at issue in this case, and the drug is to be manufactured by Lannett Company, Inc.

4. Defendant FDA has regulatory authority over, and has rescinded the marketing approval for, the drug at issue in this case. Defendant United States of America is named as a defendant pursuant to 5 U.S.C. §§ 702-703, because this is an action for judicial review of actions of an agency of the United States that have affected Plaintiffs adversely.

STATUTORY AND REGULATORY BACKGROUND

The Approval Process for Generic Drugs

5. The FFDCA establishes the regulatory regime governing FDA's premarket approval of drugs. In general, the FFDCA prohibits shipment of a drug in interstate commerce without prior approval from FDA. *See* 21 U.S.C. § 355(a).

6. In order to obtain FDA approval to market and sell a brand-name (or "innovator") drug, the sponsoring company must submit a New Drug Application ("NDA"). An NDA must outline and explain the drug's ingredients, the results of clinical tests, the results of animal studies, how the drug behaves in the body, and how

the drug is manufactured, processed, and packaged. Before approving an NDA, FDA must evaluate numerous statutorily-defined criteria, including whether the drug is safe and effective for its intended use. *See* 21 U.S.C. §§ 355(b), (d).

7. In order to obtain FDA approval to market and sell a generic drug, the sponsoring company typically must submit an Abbreviated New Drug Application ("ANDA"). An ANDA applicant may obtain FDA approval without conducting the full battery of clinical and non-clinical studies required for an NDA. *See generally* 21 U.S.C. § 355(j). An ANDA applicant may rely upon a prior FDA finding of safety and efficacy for the approved brand-name drug that is referred to in the ANDA (known as the reference listed drug), provided that the proposed generic drug is the "same" with regard to active ingredients, dosage form, route of administration, strength, and labeling. *Id*. § 355(j)(2)(A)(i), (ii), (iii), and (v).

8. In addition, before approving an ANDA, FDA must determine that the proposed generic drug is "bioequivalent" to its counterpart brand-name drug. *See* 21 U.S.C. § 355(j)(4)(F). In general, a generic drug is "bioequivalent" if, in single-dose or multiple dose clinical studies, the "rate and extent of absorption" of the generic drug and its brand-name counterpart are not significantly different. *See* 21 U.S.C. § 355(j)(8)(B).

9. In order to approve an ANDA, FDA also must find that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug are adequate to preserve its identity, strength, quality, and purity. *See* 21 U.S.C. § 355(j)(4)(A). Among other things, FDA assesses such manufacturing, processing, and packing conditions by inspecting the facility or facilities where the drug will be

manufactured. If the finished drug manufacturer will use an active pharmaceutical ingredient manufactured by a different company, FDA will review the compliance status of each named facility and inspect the facilities of both the finished drug manufacturer and the active pharmaceutical ingredient manufacturer as needed.

The Statutory Process for Withdrawing Approval for Generic Drugs

10. When FDA approves an ANDA, it grants the ANDA sponsor permission to market its drug lawfully in interstate commerce. Such a government-issued permit or license is a property interest protected by the Due Process Clause of the Fifth Amendment to the U.S. Constitution. FDA's own regulations therefore recognize that an approved ANDA is a property right that can be bought or sold. 21 C.F.R. § 314.72.

11. Because an approved ANDA is a property right, there is no lawful mechanism by which FDA can withdraw an ANDA approval without providing the ANDA holder notice and an opportunity for a hearing.

12. 21 U.S.C. § 355(e) is the only provision of the FFDCA that authorizes FDA to withdraw an ANDA approval. Section 355(e) requires "due notice and opportunity for hearing to the applicant" before an ANDA approval can be withdrawn. Section 355(e) requires FDA to provide notice and an opportunity for a hearing even in those instances in which FDA believes there is an imminent hazard to the public health. FDA does not allege that there is any such hazard in this case.

13. 21 U.S.C. § 355(e) requires FDA to withdraw approval of an ANDA for certain enumerated reasons, including circumstances under which there is evidence that an approved drug is unsafe or ineffective.

14. 21 U.S.C. § 355(e) also permits FDA, in its discretion, to withdraw approval of an ANDA for other specified reasons. These include situations in which the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of a drug are inadequate to assure and preserve its identity, strength, quality, and purity, and were not made adequate within a reasonable time after receipt of written notice specifying the matter complained of.

FDA's Enforcement Mechanisms for Approved Drugs

15. If FDA wishes to prevent distribution of a violative drug, it does not need to withdraw the drug's approval. FDA has numerous enforcement mechanisms that allow it to prevent distribution of a violative drug without withdrawing the drug's approval.

16. Working with the Department of Justice, FDA has authority to seize violative drugs or enjoin their distribution. 21 U.S.C. §§ 334, 332. FDA can demand recalls of violative drugs. 21 C.F.R. § 7.45. FDA also can prevent importation of violative foreign-manufactured finished drugs or their ingredients, through an "import alert" process in which every import entry of a violative drug is detained at the border. Threat of criminal prosecution also prevents distribution of violative drugs. *See* 21 U.S.C. § 333(a).

17. FDA typically utilizes these other enforcement mechanisms, instead of withdrawal of approval, to prevent distribution of a violative drug. FDA can utilize these other enforcement mechanisms if the agency needs to prevent distribution of a violative

drug during the pendency of proceedings to withdraw an ANDA approval under 21 U.S.C. § 355(e).

THE PARTIES' DISPUTE

18. Temozolomide is an oral chemotherapy drug used in the treatment of certain cancers. On February 15, 2011, Lannett filed an ANDA (number 202750) with FDA seeking approval for Temozolomide Capsules in 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, and 250 mg strengths. Lannett's ANDA identified a different company in China — Chongqing Lummy Pharmaceutical Co. Ltd. ("Lummy") — as the proposed manufacturer of the active pharmaceutical ingredient for the finished drug product.

19. In connection with Lannett's ANDA, FDA inspected Lummy's facility in China from March 14 to 16, 2016.

20. FDA approved Lannett's ANDA one week later, on March 23, 2016.

21. On March 29, 2016, Lannett issued a press release informing the public (including the investor community) that FDA had approved the drug.

22. On April 1, 2016, FDA sent Lannett a "General Advice" letter indicating that Lummy would not be releasing any new Temozolomide active pharmaceutical ingredient into the U.S. market until FDA deemed the Lummy facility acceptable. FDA's April 1 letter requested a conference call with Lannett to discuss two matters: (1) a commitment by Lannett not to distribute any Temozolomide product, or to recall Temozolomide product already distributed by Lannett; and (2) a "necessary withdrawal" of Lannett's ANDA.

23. The requested conference call took place on April 5, 2016. During the call, Lannett confirmed that the Temozolomide product had not been launched and that there was none on the market. Lannett also confirmed that it would not distribute any Temozolomide product with active pharmaceutical ingredient manufactured by Lummy. FDA requested Lannett to withdraw the ANDA and also indicated that it would be an option for FDA to rescind the ANDA. Lannett did not agree to withdrawal or rescission of the ANDA. After the conference call, Lannett requested FDA to state its position regarding ANDA withdrawal or rescission in writing.

The April 14, 2016 ANDA General Advice Letter

24. On April 14, 2016, Lannett received an "ANDA General Advice" letter from FDA. The letter stated that "due to review and endorsement process errors," FDA had preliminarily determined that it had made a mistake in approving Lannett's ANDA. According to FDA, the March 14-16, 2016, inspection of Lummy had identified potential violations of FDA's current Good Manufacturing Practice regulations, and FDA should have withheld approval of the ANDA.

25. The April 14, 2016, "ANDA General Advice" letter gave Lannett three options: (1) request FDA to withdraw approval of the ANDA "under 21 C.F.R. § 314.150(d)"; (2) agree to immediate rescission of the ANDA approval; or (3) provide information to FDA within 30 days demonstrating that the compliance status at Lummy was acceptable as of the date of approval (March 23, 2016). With respect to the third option, FDA indicated that it could rescind the approval "[i]f FDA affirms its preliminary

conclusion that the facility was not in compliance after reviewing any submissions made within 30 days."

26. With respect to the third option, FDA did not provide Lannett with written notice of the specific compliance concerns at Lummy. FDA also stated that it would not accept any information about remedial measures undertaken by Lummy after the date of the ANDA approval, claiming that such information "is not relevant." By basing its inquiry on a retrospective review of Lummy's compliance status as of the date of approval, FDA failed to give Lannett any opportunity to have Lummy make its manufacturing conditions "adequate within a reasonable time after receipt of written notice" within the meaning of 21 U.S.C. § 355(e).

27. On April 21, 2016, Lannett's counsel responded to the April 14, 2016, "ANDA General Advice" letter. Lannett's counsel argued that FDA had no inherent authority to rescind the ANDA approval and that the agency must follow the hearing procedures of 21 U.S.C. § 355(e) if it wished to revoke the ANDA approval. Lannett's counsel reiterated that no finished product containing the Lummy ingredient would be manufactured or distributed and proposed resolving the dispute through an ANDA supplement that would change the active pharmaceutical ingredient supplier.

The May 17, 2016 Rescission Letter

28. On May 17, 2016, FDA issued an "ANDA Approval Rescission" letter to Lannett. The letter stated that while some FDA officials had information at the time of the ANDA approval indicating that Lummy's compliance status was unacceptable, the "information was not adequately conveyed to the FDA officials making the final

decisions about the ANDA approval." The letter also stated that the approval was a mistake. It stated that the agency had authority to rescind the ANDA, because the procedures of 21 U.S.C. § 355(e) do not apply, such that there is "no applicable statute displac[ing] FDA's inherent authority to correct its mistake." The agency concluded that "FDA is correcting its error and rescinding the approval letter issued for ANDA 202750 on March 23, 2016."

29. FDA's statements in the May 17, 2016, letter establish that rescission of the ANDA was not necessary to prevent distribution of Temozolomide with active pharmaceutical ingredient manufactured by Lummy. The agency acknowledged that Lannett had voluntarily agreed that such a product would not be manufactured or distributed, stated that doing so would violate the law (thereby subjecting Lannett to enforcement remedies), and stated that FDA has implemented an import alert that will prevent future importation of the Lummy active pharmaceutical ingredient for use in manufacture of Lannett's Temozolomide Capsules.

30. The May 17, 2016, letter from FDA rescinding the ANDA approval is an "order" within the meaning of 5 U.S.C. § 551(6) because it is a final disposition in a matter other than rulemaking.

31. The May 17, 2016, rescission order is final and definitive, not tentative or interlocutory. The rescission order also determined that it is unlawful to distribute Lannett's drug. The rescission order is a final agency action within the meaning of 5 U.S.C. § 704, because it marked the consummation of the agency's decision-making

process regarding revocation of Lannett's ANDA and determined rights or obligations, or triggered legal consequences, concerning Lannett's drug.

32. Lannett currently has more than 60 approved ANDAs and other ANDAs that have been submitted but not yet approved by FDA. Lannett will continue to apply for new ANDA approvals on a continuing basis into the indefinite future. On information and belief, the rescission of approval for Lannett's ANDA (based upon an alleged mistake in overlooking information known to some at FDA at the time of approval but not known to the approving official at the time of approval) is not the only such rescission (based upon such a mistake) that FDA has recently ordered. There is a reasonable expectation that Lannett could be subjected to a rescission order again in the future, with respect to ANDA approvals for drugs other than Temozolomide.

COUNT I
Arbitrary and Capricious Agency Action

33. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 32 above.

34. FDA's rescission order is arbitrary and capricious, because it is premised upon internally contradictory rationales.

35. FDA's May 17, 2016, rescission order is premised upon the conclusion that the agency has inherent authority to rescind the ANDA approval, because the procedures of 21 U.S.C. § 355(e) allegedly are not capable of rectifying the mistake that FDA allegedly made in approving Lannett's Temozolomide Capsules. In direct contradiction, FDA's April 14, 2016, "ANDA General Advice" letter indicates that the procedures of 21

U.S.C. § 355(e) are capable of rectifying the mistake that FDA allegedly made in approving Lannett's Temozolomide Capsules. The April 14, 2016, "ANDA General Advice" letter concedes that the procedures of 21 U.S.C. § 355(e) are applicable, by giving Lannett an option of requesting the agency to withdraw approval of the ANDA "under 21 C.F.R. § 314.150(d)." A party that requests withdrawal of an ANDA approval under 21 C.F.R. § 314.150(d) does so under the authority of 21 U.S.C. § 355(e). Withdrawal of an ANDA approval under 21 C.F.R. § 314.150(d) involves "waiv[ing] the opportunity for a hearing otherwise provided for" under FDA's regulations implementing 21 U.S.C. § 355(e). Withdrawal of an ANDA approval under 21 C.F.R. § 314.150(d) also involves publication of a Federal Register notice explaining the reasons for withdrawal, because withdrawals of ANDA approvals under § 355(e) must be published in the Federal Register. 21 C.F.R. § 314.152.

36. In addition, the May 17, 2016, rescission order is premised upon the conclusion that FDA's withdrawal authority under section 355(e), on the one hand, and its inherent rescission authority on the other, are mutually exclusive authorities. Put another way, the premise of the rescission order is that if section 355(e) does not apply, FDA has authority to rescind an ANDA approval (and that if section 355(e) does apply, FDA has no authority to rescind an ANDA approval). In direct contradiction, the April 14, 2016, "ANDA General Advice" letter indicates that section 355(e) withdrawal authority and inherent rescission authority are simultaneously available, such that both authorities could address the very same alleged mistake in Lannett's ANDA approval. The April 14, 2016, "ANDA General Advice" letter indicates that the authorities are

simultaneously available by stating that Lannett may either agree to an immediate rescission or request withdrawal under section 355(e) procedures.

37. In addition, the May 17, 2016, rescission order is premised upon the conclusion that the withdrawal procedures of section 355(e) — instead of inherent rescission authority — would apply if FDA decides to revoke the ANDA approval based (at least in part) on information not previously received by the agency. In direct contradiction, the April 14, 2016, "ANDA General Advice" letter claims that the agency would have authority to rescind the ANDA approval based (at least in part) on information not previously received by the agency (submitted by Lannett in response to that General Advice letter).

38. The May 17, 2016, rescission order is an arbitrary and capricious final agency action within the meaning of 5 U.S.C. § 706(2)(A).

39. There is no adequate judicial remedy that is an alternative to the remedies requested in this Complaint.

40. Under 5 U.S.C. § 706(2)(A), this Court should hold unlawful and set aside the rescission order.

41. Under 5 U.S.C. § 706(2)(A) and 28 U.S.C § 2201, this Court should declare the rescission order unlawful.

42. Under 5 U.S.C. § 706(2)(A), this Court should enjoin FDA from revoking the approval for Lannett's Temozolomide Capsules in the future without an internally consistent rationale.

COUNT II
Agency Action in Excess of Statutory
Jurisdiction, Authority, or Limitations, or Short of Statutory Right

43. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 32 above.

44. The FFDCA refers to "withdrawal" of an ANDA approval but does not refer to "rescission" of an ANDA approval.

45. In the May 17, 2016, rescission order, FDA acknowledged that it was not relying upon the withdrawal authority set forth in 21 U.S.C. § 355(e) in rescinding Lannett's ANDA approval.

46. FDA had no statutory authority to revoke Lannett's ANDA approval without following the procedures set forth in 21 U.S.C. § 355(e).

47. 21 U.S.C. § 355(e) establishes an ANDA withdrawal process that is capable of rectifying the mistake that FDA allegedly made in approving Lannett's Temozolomide Capsules. That process displaced any inherent reconsideration authority that FDA may otherwise have had. FDA had no inherent reconsideration authority empowering the agency to rescind Lannett's ANDA approval.

48. FDA revoked the ANDA approval for Lannett's Temozolomide Capsules without following the procedures required by 21 U.S.C. § 355(e). FDA did not provide Lannett with the statutorily-required opportunity to cure the manufacturing issues of concern to the agency before revoking the approval. FDA also revoked Lannett's ANDA approval without following the hearing procedures established by section 355(e) and related FDA regulations. *See* 21 C.F.R. § 314.200; *id*. part 12.

49. The May 17, 2016 rescission order is a final agency action that revoked Lannett's ANDA approval for Temozolomide Capsules without statutory authority. The rescission order is a final agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right within the meaning of 5 U.S.C. § 706(2)(C).

50. There is no adequate judicial remedy that is an alternative to the remedies requested in this Complaint.

51. Under 5 U.S.C. § 706(2)(C), this Court should hold unlawful and set aside the rescission order.

52. Under 5 U.S.C. § 706(2)(C) and 28 U.S.C § 2201, this Court should declare the rescission order unlawful.

53. Under 5 U.S.C. § 706(2)(C), this Court should enjoin FDA from revoking the approval for Lannett's Temozolomide Capsules in the future without following the procedures established by 21 U.S.C. § 355(e).

COUNT III
Agency Action without Observance of Procedure Required by Law

54. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 32 above.

55. The FFDCA refers to "withdrawal" of an ANDA approval but does not refer to "rescission" of an ANDA approval.

56. In the May 17, 2016, rescission order, FDA acknowledged that it was not relying upon the withdrawal authority set forth in 21 U.S.C. § 355(e) in rescinding Lannett's ANDA approval.

57. 21 U.S.C. § 355(e) establishes procedures that FDA was required to follow in revoking Lannett's ANDA approval.

58. 21 U.S.C. § 355(e) establishes an ANDA withdrawal process that is capable of rectifying the mistake that FDA allegedly made in approving Lannett's Temozolomide Capsules. That process displaced any inherent reconsideration authority that FDA may otherwise have had. FDA had no inherent reconsideration authority empowering the agency to rescind Lannett's ANDA approval.

59. FDA revoked the ANDA approval for Lannett's Temozolomide Capsules without following the procedures required by 21 U.S.C. § 355(e). FDA did not provide Lannett with the statutorily-required opportunity to cure the manufacturing issues of concern to the agency before revoking the approval. FDA also revoked Lannett's ANDA approval without following the hearing procedures established by section 355(e) and related FDA regulations. *See* 21 C.F.R. § 314.200; *id*. part 12.

60. The May 17, 2016 rescission order is a final agency action that revoked Lannett's ANDA approval for Temozolomide Capsules without following required statutory procedures. The rescission order is a final agency action without observance of procedure required by law within the meaning of 5 U.S.C. § 706(2)(D).

61. There is no adequate judicial remedy that is an alternative to the remedies requested in this Complaint.

62. Under 5 U.S.C. § 706(2)(D), this Court should hold unlawful and set aside the rescission order.

63. Under 5 U.S.C. § 706(2)(D) and 28 U.S.C § 2201, this Court should declare the rescission order unlawful.

64. Under 5 U.S.C. § 706(2)(D), this Court should enjoin FDA from revoking the approval for Lannett's Temozolomide Capsules in the future without following the procedures established by 21 U.S.C. § 355(e).

COUNT IV
Direct Right of Action Under the Fifth Amendment

65. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 32 above.

66. Lannett's ANDA approval for Temozolomide Capsules is a property right protected by the Due Process Clause of the Fifth Amendment to the U.S. Constitution.

67. FDA's rescission action deprived Lannett of a property right in the ANDA approval for Temozolomide Capsules.

68. By failing to give Lannett a hearing in connection with the rescission action, FDA violated Lannett's Fifth Amendment due process right to a hearing in connection with deprivation of the property right.

69. Under the Fifth Amendment, this Court should hold unlawful and set aside the rescission action.

70. Under the Fifth Amendment and 28 U.S.C § 2201, this Court should declare the rescission action unlawful.

71. Under the Fifth Amendment, this Court should enjoin FDA from revoking the approval for Lannett's Temozolomide Capsules in the future without a hearing.

COUNT V
Agency Action Contrary to Constitutional Right or Power

72. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 32 above.

73. Lannett's ANDA approval for Temozolomide Capsules is a property right protected by the Due Process Clause of the Fifth Amendment to the U.S. Constitution.

74. The May 17, 2016, rescission order deprived Lannett of a property right in the ANDA approval for Temozolomide Capsules.

75. By failing to give Lannett a hearing in connection with the rescission order, FDA violated Lannett's Fifth Amendment due process right to a hearing in connection with deprivation of the property right. The rescission order is a final agency action contrary to constitutional right or power within the meaning of 5 U.S.C. § 706(2)(B).

76. There is no adequate judicial remedy that is an alternative to the remedies requested in this Complaint.

77. Under 5 U.S.C. § 706(2)(B), this Court should hold unlawful and set aside the rescission order.

78. Under 5 U.S.C. § 706(2)(B) and 28 U.S.C § 2201, this Court should declare the rescission order unlawful.

79. Under 5 U.S.C. § 706(2)(B), this Court should enjoin FDA from revoking the approval for Lannett's Temozolomide Capsules in the future without a hearing.

PRAYER FOR RELIEF

Plaintiff respectfully requests the Court to grant the following relief:

I. Set aside FDA's rescission of Lannett's ANDA approval;

II. Declare FDA's rescission of Lannett's ANDA approval unlawful;

III. Enjoin FDA from revoking the ANDA approval for Plaintiff's Temozolomide Capsules in the future without a hearing, and without following the procedures established by 21 U.S.C. § 355(e); and

IV. Award such other relief as this Court deems just and proper.

Respectfully submitted,

/s/ Daniel G. Jarcho

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