

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

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WYETH PHARMACEUTICALS,  
P.O. Box 8299  
Philadelphia, PA 19101,

Plaintiff,

v.

U.S. FOOD AND DRUG  
ADMINISTRATION,  
5600 Fishers Lane  
Rockville, MD 20857,

and

U.S. DEPARTMENT OF HEALTH AND  
HUMAN SERVICES,  
200 Independence Avenue, S.W.  
Washington, D.C. 20201,

and

KATHLEEN SEBELIUS,  
*in Her Official Capacity as Secretary of  
Health and Human Services,*  
U.S. Department of Health and Human  
Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201,

and

MARGARET HAMBURG, M.D., *in Her  
Official Capacity as Commissioner of Food  
and Drugs, U.S. Food and Drug  
Administration,*  
10903 New Hampshire Avenue,  
Silver Spring, MD 20993

Defendants.

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Civil Action No.

**COMPLAINT  
FOR DECLARATORY, INJUNCTIVE AND OTHER RELIEF**

Plaintiff Wyeth Pharmaceuticals ("Wyeth"), in its complaint against the U.S. Food and Drug Administration ("FDA" or the "Agency"), the U.S. Department of Health and Human Services, Kathleen Sebelius, in her official capacity as Secretary of the U.S. Department of Health and Human Services, and Margaret Hamburg, M.D., in her official capacity as Commissioner of FDA, alleges as follows:

### **NATURE OF THE ACTION**

1. This is an action to hold unlawful and set aside FDA's final decision approving Abbreviated New Drug Applications ("ANDAs") submitted by Orchid Healthcare ("Orchid") seeking to market a generic version of Wyeth's branded drug product Zosyn (piperacillin sodium and tazobactam sodium) as arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law. The Agency's decision—which permits the marketing of a generic drug product that cannot be safely used in the same manner as the branded product—violates the Administrative Procedure Act (APA), 5 U.S.C. §§ 701-706, and seriously endangers patient health.

2. Zosyn® ("Zosyn") is an intravenous antibiotic drug indicated for the treatment of moderate to severe bacterial infections. Like many other antibiotic drugs, Zosyn is frequently used in combination with other drug products, especially in acute and intensive care medical settings. For example, Zosyn is often co-administered with other antibiotics to treat severe and complex infections such as nosocomial pneumonia, sepsis, and infections associated with febrile neutropenia. Zosyn is also frequently co-administered with Lactated Ringer's Solution ("LRS"), a diluent and fluid resuscitation agent, in patients suffering from septic shock.

3. The generic version of Zosyn approved by FDA is based on a superseded formulation of piperacillin sodium and tazobactam sodium that Wyeth no longer markets. The

current formulation of Zosyn marketed by Wyeth includes two functional inactive ingredients, edetate disodium dihydrate ("EDTA") and citric acid monohydrate ("citric acid"), that are critical to its compatibility with other frequently used drug products including LRS. The superseded formulation contained neither EDTA nor citric acid.

4. Because the generic formulation of Zosyn approved by FDA uses the older, discontinued formulation of piperacillin sodium and tazobactam sodium, which does not contain EDTA or citric acid, its drug compatibility profile is different from Wyeth's branded version of Zosyn. In particular, the generic formulation of Zosyn approved by FDA is incompatible with LRS and cannot be safely co-administered with it.

5. The labeling for the approved generic formulation reflects this difference with Wyeth's Zosyn and indicates that the generic is incompatible with LRS.

6. For these reasons, the generic version of Zosyn approved by FDA is materially different from Wyeth's branded version in terms of composition; drug-to-drug interactivity profile; conditions of administration; and approved labeling.

7. Because healthcare professionals and patients expect approved generic drug products to be equivalent to, and freely interchangeable with, the branded counterpart, any material differences between the generic and branded product create a substantial risk of confusion, misuse, medication error, and patient harm.

8. In view of these important safety and efficacy issues, FDA's decision to approve Orchid's generic version of Zosyn is arbitrary, capricious, an abuse of discretion, and not in accordance with the law. Even though FDA has promulgated stringent requirements for identity in formulation of generic injectable drugs with their branded counterparts, material differences exist between Zosyn and Orchid's generic drug product that raise serious patient safety and

health issues, in contravention of the Federal Food, Drug and Cosmetic Act ("FDCA"), the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and FDA's implementing regulations.

9. Moreover, despite FDA's recognition that significant labeling discrepancies between the innovator and generic versions of a drug are inconsistent with the goals of safety and efficacy and Congress's mandate that generic drug and branded drug labels be substantially identical, there are material differences in labeling between Wyeth's reformulated Zosyn and the approved generic formulation that reflect differences between their drug-to-drug interactivity profiles, in contravention of the FDCA, the Hatch-Waxman Act, and FDA's implementing regulations.

10. The differences between Wyeth's reformulated Zosyn and the approved generic formulation pose a serious risk of confusion and medication error if both versions are simultaneously available in the marketplace. FDA's approval of the generic application based on the old, superseded formulation of Zosyn poses unacceptable risks to patient safety and health and is contrary to law.

11. Accordingly, Plaintiff Wyeth seeks a declaratory judgment against FDA declaring the Agency's action to be arbitrary, capricious, an abuse of discretion, and not in accordance with its statutory mandate to protect the public health and to ensure that approved drug products are safe and effective.

12. Plaintiff Wyeth also seeks a temporary restraining order and/or a preliminary or permanent injunction ordering FDA to withdraw or suspend its approval of Orchid's ANDAs, and any other ANDA that seeks to market a generic formulation of Zosyn based on the older, superseded formulation, that exhibits a different drug compatibility profile as compared to reformulated Zosyn, and includes different labeling as compared to reformulated Zosyn. If not

enjoined, FDA's decision to approve such ANDAs will result in serious harm to patients and serious and irreparable injury to the commercial reputation and interests of Wyeth.

### **JURISDICTION AND VENUE**

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1361 (mandamus).

14. The relief requested is authorized pursuant to 28 U.S.C. § 1651 (all writs act); 28 U.S.C. § 2201 (declaratory relief); and 28 U.S.C. § 2202 (further relief).

15. Wyeth has a right to bring this action pursuant to the APA, because FDA has engaged in final agency action presenting an actual controversy for which Wyeth is entitled to relief.

16. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) because this is a civil action in which one of the defendants is an officer of the United States that resides in this judicial district or an agency of the United States that resides in this judicial district.

### **PARTIES**

17. Plaintiff Wyeth Pharmaceuticals is a Delaware corporation with its principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. It is wholly-owned by Wyeth, a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940. Except in this paragraph, all references to "Wyeth" herein shall mean Wyeth Pharmaceuticals.

18. Defendant FDA, which has its principal office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993, is a federal agency headquartered in Maryland. FDA regulates prescription drugs under authority delegated by Congress and the Secretary of Health and Human Services.

19. Defendant U.S. Department of Health and Human Services, which has its principal office at 200 Independence Avenue, S.W., Washington, D.C. 20201, is a federal agency headquartered in the District of Columbia that has authority over FDA.

20. Defendant Kathleen Sebelius is sued in her official capacity as Secretary of the U.S. Department of Health and Human Services. As Secretary, Ms. Sebelius has the ultimate responsibility for the activities of the Department of Health and Human Services, including those actions complained of herein. Ms. Sebelius maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201.

21. Defendant Margaret Hamburg, M.D., is sued in her official capacity as Commissioner of the FDA. As Commissioner, Dr. Hamburg has the ultimate responsibility for the activities of the FDA, including those actions complained of herein. Dr. Hamburg maintains an office at 10903 New Hampshire Avenue, Silver Spring, MD 20993.

### **GENERAL ALLEGATIONS**

#### **I. Statutory And Regulatory Background Requiring Generic Drugs To Be Substantially "The Same" As Their Branded Counterparts**

22. A core FDA function is the promotion and protection of the public health. 21 U.S.C. §§ 301 *et seq.* FDA's "Mission Statement," *available at* <<http://www.fda.gov/aboutFDA/WhatWeDo/default.htm>>, makes clear that FDA is to exercise this function by, *inter alia*, "assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, [etc.,]...."

23. The FDCA requires that all drug manufacturers (or "sponsors") demonstrate the safety and effectiveness of their products for each intended use of their products. Innovator drug manufacturers, such as Wyeth, demonstrate safety and effectiveness by conducting

comprehensive pre-clinical and clinical studies of their products, producing extensive data which are submitted in New Drug Applications ("NDAs"). 21 U.S.C. § 355(b)(1).

24. The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, data from clinical trials establishing the efficacy of the drug for its intended uses, and labeling information for the proper use of the drug. *Id.*

25. The Hatch-Waxman Act amended the FDCA and established an abbreviated process by which generic drug companies could gain approval from the FDA to bring generic pharmaceuticals to market. 21 U.S.C. § 355(j).

26. The Hatch-Waxman Act was intended to stimulate price competition in the drug industry, while maintaining the safety and efficacy of approved drugs in the United States. H.R. Rep. No. 98-857(I), at 14-15 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647.

27. To that end, the Hatch-Waxman Act provides a mechanism by which a generic drug company can rely on the costly pre-clinical and clinical data generated by an innovator drug manufacturer, rather than having to conduct new studies, through the filing of an Abbreviated New Drug Application or "ANDA." *In re Barr Labs., Inc.*, 930 F.2d 72, 73 (D.C. Cir. 1991) (ANDA process "permits generic drug applications to piggy-back on clinical findings that FDA has already embraced" in the NDA).

28. Congress intended that this option be available, however, only if the generic drug sponsor could demonstrate in its ANDA that its drug is substantially "the same" as the listed drug in all relevant respects. 21 U.S.C. § 355(j)(2); *see also* H.R. Rep. No. 98-857(I), at 21 ("[T]he focus of the [amendments] is to provide the Food and Drug Administration (FDA) with sufficient information to assure that the generic drug is the same as the listed drug.").

29. Given that the approval of the generic drug relies on the finding of safety and efficacy made with respect to the innovator drug, Congress and FDA recognized that material differences between the products undermine the conclusion that the generic drug is as safe and effective as the innovator drug. *See, e.g.,* 57 Fed. Reg. 17950, 17961 (April 28,1992).

30. Under this statutory framework, generic drug manufacturers demonstrate safety and efficacy by providing the FDA with, *inter alia*, information sufficient to show that the active ingredient of the generic drug is "the same" as an approved pioneer drug, otherwise known as the "Reference Listed Drug," and that the proposed generic drug will include substantially the same labeling as the approved pioneer drug. 21 U.S.C. § 355(j)(2)(A); *see also* 57 Fed. Reg. at 17951 ("The statute permits ANDA's for: (1) A drug product that is the 'same' as a drug product listed in the approved drug product list published by FDA (the 'listed drug') with respect to active ingredient(s), route of administration, dosage form, strength, and conditions of use recommended in the labeling....").

**A. The Same Inactive Ingredient Requirement For Parenteral Drugs**

31. A generic drug product must contain the same active ingredient(s) as the approved pioneer drug, *i.e.*, the Reference Listed Drug. 21 U.S.C. § 355(j)(2)(A)(ii)(I).

32. For parenteral drugs (a category including all drugs administered by intravenous injection, such as Zosyn), the Agency requires that the generic drug have not only the same active ingredient(s) as the pioneer drug, but also the same inactive ingredient(s) in the same concentration(s). 21 C.F.R. § 314.94(a)(9)(iii); *see also* 54 Fed. Reg. 28872, 28883 (July 10, 1989) (FDA intended "to place more stringent limitations on the variations permitted in the inactive ingredients in the formulation of parenteral" drugs because parenteral drugs are more sensitive to formulation changes).

33. FDA recognizes limited exceptions to the general rule that the inactive ingredients present in the generic drug and the branded counterpart be identical. FDA regulations permit differences in inactive ingredients only if the affected ingredient or ingredients are used as a preservative, buffer, or antioxidant in the drug and, then, only if any such differences do not affect the safety or effectiveness of the drug. 21 C.F.R. § 314.94(a)(9)(iii); *id.* § 314.127(a)(8)(ii)(B).

34. An ANDA applicant may request that FDA waive requirements set forth in the FDA regulations for the approval of generic drugs, including certain of the requirements that generics contain the same inactive ingredients as the Reference Listed Drug. *Id.* § 314.99. However, the granting of any such waiver by FDA must be in accordance with the law and must not be arbitrary, capricious, or an abuse of discretion. *See* 5 U.S.C. § 706(2)(A). In particular, a waiver must not create serious risks to patient health and safety in contravention of FDA's statutory mandate and mission.

**B. The Same Labeling Requirement**

35. Generic drugs must also have "the same" labeling as their branded counterparts. 21 U.S.C. § 355(j)(2)(A)(v); *see also* 21 C.F.R. § 314.94(a)(8)(iv); *id.* § 314.127(a)(7).

36. The statute recognizes limited exceptions to this rule for changes arising from suitability petitions (which are not at issue here) and "for changes required ... because the new drug and the listed drug are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(2)(A)(v).

37. FDA has interpreted the labeling exception allowed by Congress to include "differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission

of an indication or other aspect of labeling protected by patent or [other] exclusivity," that arise from the difference in the identity of the manufacturer. 21 C.F.R. § 314.94(a)(8)(iv).

38. FDA has emphasized that the same-labeling requirement is critical to the Hatch-Waxman regulatory scheme. In promulgating the same-labeling regulation, FDA observed that "[e]xcept for labeling differences due to exclusivity or a patent and differences under section 505(j)(2)(v) of the act, the ANDA product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval." 57 Fed. Reg. at 17961. FDA also explained that "[c]onsistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart." *Id.*

39. The Agency has stated that the purpose behind the same-labeling requirement is to prevent the marketing of "generic drugs with diminished safety and effectiveness as their brand-named counterparts." 54 Fed. Reg. at 28884. If the proposed generic labeling involves "the marketing of generic drugs with diminished safety or effectiveness and concomitantly heightened label warnings," FDA has indicated that such labeling would not satisfy the labeling requirements of the Hatch-Waxman Act. *Id.*

**C . The Presumption Against Approving ANDAs For Generic Drug Products That Are Materially Different From The Branded Counterpart**

40. For parenteral drugs, if there are differences between the inactive ingredients used in a proposed generic drug product and the branded counterpart (other than preservatives, buffers, and antioxidants), FDA *must* consider the differences to be unsafe and refuse to approve the ANDA, absent a waiver. 21 C.F.R. § 314.127(a)(8)(ii)(B).

41. For proposed parenteral drugs that differ from the branded counterpart with respect to preservatives, buffers, or antioxidants, FDA *must* refuse to approve the ANDA unless

the applicant establishes that the differences do not affect the safety or efficacy of the generic drug, absent a waiver. *Id.*; *see also* 54 Fed. Reg. at 28884 ("the agency will presume any inactive ingredient in an applicant's proposed drug product different from that in the reference listed drug to be unsafe unless the applicant can rebut the presumption by demonstrating that the different inactive ingredient will not affect the safety of its proposed drug product.").

42. In addition, if there are differences in labeling that render the generic drug product less safe or effective as compared to the branded counterpart, FDA *must* refuse to approve the ANDA. 21 C.F.R. § 314.127(a)(7).

## **II. Factual Background**

### **A. Zosyn Is A Widely Used Intravenous Antibiotic Drug That Is Often Co-Administered With LRS**

43. Zosyn is an antibacterial drug product comprising two active ingredients: piperacillin sodium and tazobactam sodium. Zosyn is prepared and administered by reconstituting and further diluting powdered or frozen versions of the drug product in any number of approved diluents and injecting the reconstituted drug product intravenously into the patient. LRS is one of the diluents approved for use with reformulated Zosyn.

44. Zosyn is one of the most widely used intravenously administered antibiotic drugs in the United States. Annually, Wyeth estimates that nearly two million patients are administered Zosyn, either alone or in combination with other drugs.

45. Based on third-party data, Wyeth believes that 2,147,341 courses of Zosyn were administered to patients in 2006 with each course of administration lasting just over 6 days. On average, a patient received 3.6 doses of Zosyn for each day of treatment. Therefore, there were 47,155,608 total doses of Zosyn administered in 2006. 51% of the time, Zosyn was administered alone and 49% of the time, Zosyn was administered in combination with another drug product.

46. In many acute and intensive care settings, Zosyn is simultaneously co-administered through a single intravenous line with other intravenous drug products. For example, Zosyn is compatible for simultaneous co-administration with LRS. This compatibility is significant for patient care, because LRS is commonly co-administered with Zosyn in critically ill or injured patients experiencing septic shock and trauma, including in an emergency room setting. In such situations, LRS may be used to raise the patient's blood pressure by expanding the patient's fluid volume at the same time Zosyn is administered to treat bacterial infection.

47. The compatibility of Zosyn with LRS has significant clinical advantages. For seriously ill patients in need of immediate and multiple drug therapy, simultaneous administration reduces the need for additional vascular drug access sites (thereby reducing the risk of further infection) and reduces the amount of fluid administered to the patient (thereby reducing the risk of congestive heart failure).

48. In patients suffering from shock, simultaneous administration of Zosyn with LRS also prevents the need for sequential administration of the two drug products, which risks loss of blood pressure during the time in which only Zosyn is administered. Because patients suffering from shock cannot tolerate even temporary drops in blood pressure, and because even seconds may count for the survival of such patients, the ability to continuously and simultaneously resuscitate the patient with LRS while treating the underlying bacterial infection provides significant treatment advantages that improve clinical outcomes.

49. Especially in a critical care or emergency room situation in which a patient is suffering septic shock or trauma, the decision whether and how to co-administer Zosyn and LRS must be made nearly instantaneously and under considerable pressure.

50. In a typical year, physicians and nurses take advantage of the therapeutic benefits of simultaneous co-administration with LRS permitted by the reformulated version of Zosyn in tens of thousands of patients. Based on third party data, in 2006, Zosyn was administered together with LRS in an estimated 104,832 patients. Upon information and belief, nearly half (43%) of patients who received both Zosyn and LRS received the two drug products simultaneously.

**B. Material Differences Exist Between The Reformulated Version Of Zosyn And The Original, Superseded Formulation Of Zosyn**

51. Zosyn was originally approved by the FDA in 1993. At the time, the approved labeling for Zosyn warned healthcare professionals that Zosyn was not compatible with LRS because LRS deactivated the piperacillin sodium component of Zosyn when combined *in vitro*.

52. Unlike the formulation that was approved by the FDA in 1993, the formulation of Zosyn currently marketed by Wyeth *is* compatible with LRS. Its approved labeling reflects this fact and differs from the labeling for the original formulation in this respect.

53. The differences between the compatibility profile of the reformulated formulation of Zosyn and the formulation originally approved by FDA in 1993 result from the addition of the inactive ingredients EDTA and citric acid.

54. These inactive ingredients were originally added in order to address the failure of the original formulation to consistently meet compendial requirements regarding subvisible contaminants known as "particulates," but they also created substantial improvements in Zosyn's compatibility profile.

55. In 2000, Wyeth learned that certain batches of its then existing Zosyn formulation contained high levels of particulates. Although these batches met compendial standards for particulates in effect at the time of the NDA approval in 1993, they did not meet more stringent

standards that were established following the approval of the NDA. When these results were reported to the FDA by Wyeth, the Agency expressed concern about these findings.

56. After extensive research, Wyeth determined that high particulate levels could be prevented with a reformulated version of Zosyn that included the inactive ingredients EDTA and citric acid. EDTA acts as a metal-ion chelating agent and citric acid acts as a buffer. Both inactive ingredients prevent certain chemical reactions from occurring that result in particulate formation. Unlike the superseded formulation, the reformulated version of Zosyn meets compendial standards for particulates under all conditions of use approved in its labeling.

57. Additional studies involving the reformulated version of Zosyn demonstrated that, unlike the originally approved formulation, the reformulated version of Zosyn with EDTA and citric acid is compatible with LRS. (The reformulated version of Zosyn was also found to be newly compatible with two other intravenous antibiotic drug products, amikacin and gentamicin.)

58. The compatibility of the reformulated version of Zosyn with LRS is a direct result of the addition of EDTA and citric acid to the drug formulation. EDTA and citric acid prevent certain chemical reactions from occurring that result in deactivation of the active ingredient, piperacillin sodium, when Zosyn is mixed with LRS.

59. In 2005, FDA approved a supplemental NDA for a Zosyn formulation that includes EDTA and citric acid as inactive ingredients. The approved labeling for the reformulated version of Zosyn reflects the new compatibility profile of the drug. Among other changes, it no longer contains the warning against simultaneous use with LRS. In fact, the approved labeling for the reformulated version of Zosyn specifically instructs that Zosyn may be mixed with LRS.

60. Following the approval of the reformulated version of Zosyn, Wyeth immediately began phasing out the original formulation by introducing and marketing the reformulated version of Zosyn with the new FDA-approved labeling. Wyeth undertook an extensive medical education program to inform the medical community about the labeling differences between the reformulated version and the older formulation, and the advantages of the reformulated version over the older, superseded formulation, with particular focus on the enhanced compatibility of the new formulation with LRS and other compounds.

61. Upon information and belief, at present, only the new formulation is in use in the United States.

**C. FDA Has Approved A Generic Version Of Zosyn Based On The Older, Discontinued Formulation Of Zosyn That Is Not Compatible With Lactated Ringer's Solution**

62. Prior to the challenged Agency action, citizen petitions were filed by a number of generic drug manufacturers, including Orchid, requesting a determination from FDA that the original formulation of Zosyn was not discontinued for reasons of safety and efficacy.

63. On information and belief, Orchid also submitted ANDAs to FDA seeking approval to market a generic version of Zosyn.

64. Wyeth also filed a citizen petition requesting, among other things, that FDA disapprove any generic application for Zosyn that could not be used in the same manner as the Zosyn now used by medical professionals, including through simultaneous co-administration with LRS. In the alternative, Wyeth requested that FDA require any generic manufacturer whose drug could not safely be co-administered with LRS to implement a Risk Management Action Plan ("RiskMAP") to ensure that healthcare professionals were aware of and understood the differences, so that patients would not be harmed through the erroneous use of generic Zosyn in circumstances where only the new formulation would be safe and effective.

65. On September 15, 2009, FDA granted the generic manufacturers' citizen petitions and denied Wyeth's in pertinent part. FDA also approved Orchid's ANDAs on September 15, 2009. Shortly thereafter, Orchid's generic product was listed as a "therapeutic equivalent" to Wyeth's reformulated version of Zosyn in FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (also known as the "Orange Book").

66. On information and belief, the generic formulation of Zosyn approved by FDA is based on the original version of Zosyn, and does not contain EDTA or citric acid.

67. On information and belief, the generic formulation of Zosyn approved by FDA does not exhibit the same drug-to-drug compatibility profile as Wyeth's reformulated version of Zosyn that is currently on the market because the approved generic drug product is not compatible with LRS.

68. On information and belief, the labeling of the generic formulation of Zosyn approved by FDA is not the same as the approved labeling for Wyeth's reformulated version of Zosyn because the generic labeling indicates that the generic drug product is not compatible with LRS.

69. As a result, a generic version of Zosyn based upon the old, superseded formulation, which was not and is not compatible with LRS, and which has different labeling than the branded product, will shortly enter the marketplace absent action by this Court.

70. On information and belief, other generic drug manufacturers, including at least Sandoz Inc. ("Sandoz") and Abraxis Pharmaceutical Products ("Abraxis"), have also filed ANDAs with FDA seeking to market a generic version of Zosyn that is based on the original version of Zosyn.

71. On information and belief, FDA has not yet approved the ANDAs submitted by Sandoz, Abraxis, and any other generic drug manufacturer (except Orchid) seeking approval to market a generic version of Zosyn.

**D. The Generic Version Of Zosyn Based On The Older, Discontinued Formulation Presents Significant Safety And Efficacy Risks And Public Health Concerns**

72. Healthcare professionals rely on FDA to approve generic drugs that share the same safety and efficacy profiles as their branded counterparts. This reliance is entirely justified, given the language and goals embodied by the Hatch-Waxman statutory scheme and the requirement that a generic drug be substantially "the same" as the branded counterpart. *See* H.R. Rep. No. 98-857(I), at 21 ("[T]he focus of the [amendments] is to provide the Food and Drug Administration with sufficient information to assure that the generic drug is the same as the listed drug.").

73. In addressing frequently asked questions about generic drugs, FDA's own website instructs that a generic drug is a copy that is *the same* as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use. *See* FDA, "Generic Drugs: Questions and Answers," available at <<http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134147.htm>>.

74. More recently, FDA has recognized that generic drug products are "expected to be substitutable for its branded counterpart with the full expectation that the substitute product will produce the same clinical effect and safety profile...." August 10, 2009 Letter from J. Woodcock, Director, Center for Drug Evaluation and Research, to W. E. Fitzsimmons et al., Docket No. 2007-P-0111, at 15.

75. Because healthcare professionals assume that generic and branded drugs are completely interchangeable, they generally do not scrutinize the generic drug and the branded

drug for labeling differences. That is especially so in acute and critical care settings such as emergency rooms, where Zosyn is often co-administered simultaneously with LRS. When the generic drug has a different compatibility profile compared to the branded drug, these expectations of "sameness" can raise serious safety and public health issues.

76. Wyeth filed timely comments and a citizen petition demonstrating the risks and hazards to patients associated with approval of generic versions of Zosyn that are not substantially "the same" as Zosyn. Additional comments and submissions were also made to FDA by other parties, including many medical experts. Given the widespread use of Wyeth's Zosyn products, including its simultaneous co-administration with LRS in tens of thousands of patients annually, these risks and hazards are real and non-speculative.

77. Following the approval of the reformulated version of Zosyn, healthcare providers have taken advantage of its expanded compatibility profile by combining Zosyn with LRS, for example, to resuscitate hypotensive patients with volume depletion and septic shock. In a letter that Wyeth provided to the Agency in support of its citizen petition, Dr. Coleman Rotstein of McMaster University in Ontario, Canada indicated that the new formulation "is definitely an advance and permits adequate [fluid] resuscitation to occur at the same time as adequate antimicrobial therapy."

78. The ability to combine the reformulated version of Zosyn with LRS provides physicians with additional treatment options not available with the original formulation. According to Dr. Rotstein, "any chance of incompatibility or inactivation when the drugs are combined together . . . must be prevented at all costs." That is because incompatibility, of the type that characterizes the old formulation and the now-approved generic drug, results in deactivation of the Zosyn being administered to the patient. In many cases, the patient's life or

continued health depends upon immediately receiving the active, broad-spectrum antibiotic treatment afforded by Zosyn.

79. Other doctors informed FDA of their agreement with these concerns. Dr. Manjari Joshi of the University of Maryland R. Adams Cowley Shock Trauma Center submitted comments to the FDA stating that it was "common practice to hang resuscitative fluids such as LRS with Zosyn in the same IV Port." Dr. Joshi commented that a formulation of Zosyn that did not exhibit the same compatibility profile as Zosyn would be a "step backwards" in the care of acutely ill patients.

**E. The Concurrent Marketing Of A Generic Version Of Zosyn With A Branded Version That Exhibits A Different, Expanded Drug Compatibility Profile Presents The Risk Of Medication Errors Due To The Expectation Of Drug Interchangeability**

80. The simultaneous presence in the market of a generic and branded version of Zosyn that have different compatibility profiles and different rules for safe and effective administration presents serious risks of medication errors that could cause grievous harm to patients.

81. If a generic version of Zosyn based upon the old formulation were simultaneously co-administered with LRS, with which it is incompatible, it would result in the formation of biologically inactive complexes and potential loss of drug efficacy. According to FDA's regulations, "any failure of expected pharmacological action" is defined as an "adverse event." 21 C.F.R. § 314.80(a). In essence, patients would be at risk of not receiving therapeutically effective doses of badly needed antibiotics, which could have serious adverse health implications, especially in critical care situations such as those in which Zosyn and LRS are most commonly co-administered.

82. In her submission, Dr. Joshi commented that a formulation of Zosyn that did not exhibit the same compatibility profile as Wyeth's formulation of Zosyn raised serious and real risks of medication errors because "physicians and nurses generally expect generic drugs to be equivalent to, and freely interchangeable with, their branded counterparts."

83. Dr. J. Lyle Bootman is the former co-chair of the Committee on Identifying and Preventing Medication Errors of the Institute of Medicine ("IOM"), an organization chartered under the National Academy of Sciences. He is world-renowned as a leading expert on the causes and prevention of medication errors. Dr. Bootman submitted comments to the FDA confirming that, if a generic version of Zosyn were erroneously reconstituted with LRS, the result could be deactivation of the antibiotic active ingredients found in Zosyn.

84. Dr. Bootman was concerned that the "only protection against pharmacists and practitioners confusing the two versions . . . would be different package inserts. The package insert for Zosyn would reflect one set of conditions for use, while the package insert for the generic versions would set forth different conditions of use." In his view, "this reliance on buried detail in the lengthy product prescribing information is exactly the sort of labeling problem that leads to medication errors."

85. Further, Dr. Bootman stated that "[t]he generic version is likely to be used when it is not appropriate to do so, potentially resulting in harm to patients" and concluded that the "concurrent availability of non-interchangeable forms of the same drug poses a risk to the public health due to the drugs' different interactivity profiles."

86. Dr. Bootman informed FDA that, according to a recent IOM report, a hospital patient is subject to at least one medication error per day, many of which stem from confusion created by product naming, packaging, and labeling. Dr. Bootman noted that labeling and

packaging issues were cited as the cause of 33% of errors, including 30% of fatalities, reported to the U.S. Pharmacopoeia Institute for Safe Medication Practices.

87. Dr. Steven Ebert, Clinical Professor of Pharmacy at the University of Wisconsin, in comments submitted to FDA that echoed those of Dr. Rotstein, Dr. Joshi, and Dr. Bootman, wrote: "If a generic version of the old formulation of Zosyn were to be approved, it would be marketed concurrently with reformulated Zosyn. Notably, this would occur only after hospital pharmacies have had ... experience with different, improved conditions of use of reformulated Zosyn. This concurrent marketing of a branded drug and a superseded generic formulation of the same drug will create a serious risk for confusion."

88. Dr. Ebert also observed that "[c]onfusion in a hospital pharmacy can easily lead to medication errors, which in this case would result in very ill patients receiving inactivated antibiotic...."

89. As noted in Wyeth's citizen petition to FDA, the risks associated with the concurrent marketing of an older drug formulation and a new drug formulation having different compatibility profiles are present even if individual healthcare practitioners are aware of the labeling differences. Decisions about whether a healthcare facility will use a brand-name drug or a generic substitute are often made by hospital administrators rather than healthcare practitioners. The separation of decision-makers from practitioners has the potential to cause confusion among practitioners as to whether they are using Wyeth's reformulated version of Zosyn or the generic substitute based on the original formulation. Also, it is common for a physician or other practitioner to practice in two or more healthcare facilities. One facility might use Zosyn, while another might use the generic drug, creating even further potential risk of confusion and harm.

90. Because of the differences in drug compatibility between the older formulation of Zosyn, for which generic approval was sought and obtained, and Wyeth's current, branded version, the generic drug is not an appropriate substitute under all conditions of use. Serious risk of medication error arises if health care workers either are unaware of those differences or are confused about the circumstances in which substitution may or may not be appropriate.

91. The FDA's approval of a generic based upon the older formulation of Zosyn makes these conditions a virtual certainty and will lead to medication errors and grave patient harm.

92. As the evidence before the FDA concerning medication errors demonstrates, differences in the language of the two products' package inserts are not sufficient to mitigate or eliminate these risks and protect patients from harm.

93. The citizen petition filed by Wyeth addressed these safety and efficacy concerns in detail. In its citizen petition, Wyeth asked that FDA require generic drug manufacturers to establish that their generic drug products exhibit the same drug compatibility profile as the reformulated version of Zosyn. Based on evidence provided to the Agency, Wyeth noted that differences in drug interactivity between a generic drug and its branded counterpart could pose serious risks if healthcare workers either are unaware of those differences or, even if aware, are confused about which drug (generic or branded) is being administered.

94. Wyeth asked in the alternative that, if the Agency were to approve a generic substitute for Zosyn that did not have the same compatibility as Zosyn, such approval should be conditioned upon the implementation of a risk management plan or strategy designed to apprise the medical community of the differences between the generic and branded forms of the drug and to minimize the risk of confusion and the consequent adverse health consequences. *See also*

21 U.S.C. § 355-1 (providing FDA with the authority to require drug makers to implement "risk evaluation and mitigation strategies" ("REMS") to ensure that the benefits of the drug outweigh the risks of the drug).

95. The comments and submissions made to FDA by the generic drug makers addressed only the safety and efficacy of the older, superseded formulation of Zosyn. These comments and submissions did not adequately address Wyeth's concerns about safety and efficacy raised by the concurrent marketing of generic and branded drug products that could not be safely interchanged or substituted for one another.

**F. FDA's Denial Of Wyeth's Citizen Petition And Approval Of Orchid's ANDA Was Arbitrary, Capricious, And Contrary To Law**

96. On or about September 15, 2009, in a consolidated response, FDA granted the citizen petitions filed by the generic drug manufacturers and denied in part and granted in part Wyeth's citizen petition and simultaneously approved the ANDAs submitted by Orchid.

97. FDA's approval of Orchid's ANDAs was arbitrary, capricious, an abuse of discretion, and contrary to law. Further, FDA's approval of any other ANDA seeking approval to market a generic formulation of Zosyn based on the older, superseded formulation will also be arbitrary, capricious, an abuse of discretion, and contrary to law for substantially the same reasons if drug-to-drug compatibility differences also exist in these products.

98. According to FDA's decision, the generic formulation of Zosyn approved by FDA uses the older, superseded formulation of Zosyn that Wyeth no longer markets and does not contain the inactive ingredients EDTA and citric acid. September 15, 2009 Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, to Beth Brannan et al. ("FDA Decision"), at 5.

99. As a result, the approved generic formulation exhibits a different drug compatibility profile as compared to Wyeth's Zosyn product. In particular, FDA has admitted that, unlike the branded product, the generic is not compatible with LRS. *Id.* at 6.

100. FDA's decision further acknowledges that the incompatibility of the approved generic formulation with LRS results in deactivation of the piperacillin sodium active ingredient found in Zosyn. *Id.* at 16 (stating that mixing will result in an "inactive lactate-piperacillin adduct"). According to FDA, Orchid's own studies demonstrate that the presence of EDTA and citric acid in Wyeth's reformulated version of Zosyn inhibits this drug deactivation. *Id.* FDA also acknowledged that EDTA and citric acid play a role in preventing particulate formation in Zosyn. *Id.* at 9.

101. Notwithstanding its recognition that EDTA and citric acid prevent LRS from deactivating the piperacillin sodium component of Zosyn, and prevent particulate formation, the Agency determined that these two inactive ingredients were not required in the generic formulation.

102. According to FDA, citric acid fell under the exception for differences in buffers and this difference did "not affect the safety or effectiveness of the proposed product." *Id.* at 11 (citing 21 C.F.R. §§ 314.94(a)(9)(iii) and 314.127(a)(8)(ii)(B)).

103. Although FDA recognized that EDTA did not fall under any exception because it was not a buffer, preservative, or antioxidant, the Agency waived the requirement for identity in this inactive ingredient. According to FDA, "the original Zosyn formulation was safe and effective for the labeled conditions of use and was not withdrawn from the market for reasons of safety or efficacy." *Id.* at 9. Thus, in the Agency's view, "[b]ecause the original Zosyn formulation clearly meets the statutory safety standard with respect to inactive ingredients, the

Agency may rely on § 314.99(b) to grant a waiver of the regulation requirement that the ANDA formulation contain the same inactive ingredients in the same concentration with the limited exceptions for preservatives, buffers, and antioxidants." *Id.* at 12.

104. FDA's decision to approve a generic formulation that lacks two inactive ingredients that are essential to the safe co-administration of Zosyn with LRS was wrong as a matter of fact and law. That decision was based on an impermissibly narrow view of generic drug safety, which focused only on the intrinsic safety of the product under the labeled conditions for use and ignored the risks of confusion and medication error that could result in the product being used in a manner contrary to the labeled warnings. Given the evident purpose of the Hatch-Waxman Act and the related body of law governing generic approvals, statutory and regulatory requirements that products be the "same" can only be waived where the evidence demonstrates not only that the differences do not undermine the intrinsic safety of the generic product viewed in isolation, but also that they will not compromise patient health and safety under the likely conditions of actual use by clinicians. The evidence is directly to the contrary with respect to the approved generic formulation.

105. Although that was the essence of Wyeth's submission in its citizen petition, FDA failed even to address that question, much less adequately explain its reasoning, in its response to Wyeth's citizen petition. The FDA response utterly ignored the substantial evidence that approval of the generic formulation will create grave risks of harm to patients.

106. Further, FDA granted the generic drug manufacturers' request for a determination that the older, superseded formulation of Zosyn was not discontinued for reasons of safety or efficacy. FDA Decision, at 8. While this determination addresses the safety and efficacy of the older formulation *per se*, it, too, makes the same fundamental error of failing to address the risk

of medication error and confusion raised by the concurrent marketing of a generic formulation of Zosyn that exhibits a different drug compatibility profile as compared to Zosyn.

107. The Agency decision further indicated that the labeling for the approved generic formulation is different than the labeling for Wyeth's reformulated Zosyn due to differences in drug compatibility profile. Thus, unlike the labeling for Wyeth's product, the labeling for the generic drug product includes information regarding incompatibility with LRS. *Id.* at 13.

108. Although this labeling discrepancy relates to material differences in drug compatibility profiles, the Agency characterized this change as reflecting a difference in mere "formulation." *Id.* at 16. In the Agency's view, "Orchid's generic [product] is permitted to have different labeling than reformulated Zosyn to account for differences in formulation because the product is produced or distributed by a different manufacturer." *Id.*

109. This decision, too, reflects a fundamental error of law, in that it reads the manufacturer exception to authorize differences in labeling that pertain to the compatibility and safe administration of the product, which would eviscerate the statutory same-labeling requirement. Under FDA's reasoning, *any* labeling difference between a generic drug product and the branded drug product that results from an underlying difference in formulation would be acceptable under the statute.

110. Although it never addresses the actual patient safety issue raised by the Wyeth petition, the FDA decision is based upon an assumption that warnings provided in the generic labeling will be adequate "to assure the safe use of the drug." *Id.* at 11; *see also id.* at 16 ("Orchid's generic ... labeling informs health care providers about the incompatibility of Orchid's product with LRS, such that the product will be safe and effective under the labeled conditions of

use."; *id.* at 17 ("the labeling includes appropriate information to inform health care providers about compatibility with other products....").

111. The decision ignores and does not address in any way the substantial evidence before the agency that, at least in these circumstances, that assumption is incorrect. It is also completely circular, essentially finding that it is safe to permit labeling differences because the labeling will be different.

112. Finally, relying again on the assumption that the generic formulation "has appropriate labeling that adequately informs health care providers about the compatibility of the product to ensure safety and effectiveness of the product," and again wholly ignoring the substantial of product confusion and medication error, the Agency also determined that risk management efforts were not necessary for the approved generic formulation. *Id.* at 17.

113. The agency gave no explanation whatsoever for its decision not to require Orchid to implement a risk management plan to properly educate healthcare professionals about the serious risks of medication error attendant to use of its product.

### **CLAIMS FOR RELIEF**

#### **Count I – Violation of Same Inactive Ingredient Requirement**

**(Violation of 21 C.F.R. § 314.94(a)(9)(iii),  
21 C.F.R. § 314.127(a)(8)(ii)(A), and 5 U.S.C. § 706(2)(A))**

114. Wyeth incorporates by reference all allegations contained in paragraphs 1 through 113 of this Complaint as if set forth fully herein.

115. The generic formulation of Zosyn approved by FDA does not contain the inactive ingredient EDTA. EDTA does not fall under the exception for inactive ingredients that qualify as a "preservative, buffer, or antioxidant." 21 C.F.R. § 314.94(a)(9)(iii). Consequently, it is an

inactive ingredient that is *required* to be present in any generic formulation of Zosyn pursuant to FDA's regulations. *Id.*

116. Even if EDTA were considered a "preservative, buffer, or antioxidant," which it is not, the ANDA submitted by Orchid has not established that the absence of this component has no effect on safety and efficacy. *Id.* To the contrary, the absence of EDTA in the generic formulation results in drug compatibility differences between the generic version of Zosyn and Wyeth's reformulated version of Zosyn. Consequently, EDTA is an inactive ingredient that is *required* to be present in the generic formulation pursuant to FDA's regulations.

117. Although citric acid is a buffer, Orchid has not established that the absence of this component has no effect on safety and efficacy. *Id.* To the contrary, the absence of citric acid in the generic formulation results in drug compatibility differences between the generic version of Zosyn and Wyeth's reformulated version of Zosyn. Consequently, citric acid is an inactive ingredient that is *required* to be present in the generic formulation pursuant to FDA's regulations.

118. The waiver provisions of the Agency rules cannot lawfully be invoked due to the safety and efficacy issues raised by the change in inactive ingredients.

119. FDA's approval of Orchid's ANDAs constitutes final agency action that is reviewable by the district court. 5 U.S.C. § 704.

120. As set forth above, FDA's waiver of the same inactive ingredient requirement, and its consequent approval of a generic version of Zosyn that does not contain EDTA and citric acid, was arbitrary, capricious, and not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A), and in violation of the FDCA and FDA's implementing regulations.

121. FDA's action presents a serious, immediate, and irreparable risk of grave patient harm. In addition, Wyeth will suffer irreversible loss of goodwill if less favorable clinical

outcomes and patient injury result from the concurrent marketing of a generic version of Zosyn that hurts patients. Wyeth also will suffer economic harm from loss of sales revenue resulting from the approval of the generic version of Zosyn; this harm is also irreparable because monetary damages cannot be recouped from FDA for an erroneous decision of this sort.

122. There is no mechanism by which Wyeth can be made whole for the injury that would result from FDA's approval of Orchid's ANDAs if the approvals are not suspended. Wyeth is without an adequate remedy at law because of the unique nature of the harm.

123. The balance of equities and the public interest in protecting patient health favors enjoining the FDA.

### **Count II – Violation of Same Labeling Requirement**

**(Violations of 21 U.S.C. § 355(j)(2)(A)(v), 21 C.F.R. § 314.94(a)(8)(iv),  
5 U.S.C. § 706(2)(A), and 5 U.S.C. § 706(2)(C))**

124. Wyeth incorporates by reference all allegations contained in paragraphs 1 through 123 of the Complaint as if set forth fully herein.

125. The generic formulation of Zosyn approved by FDA does not have the same labeling as the labeling for Wyeth's reformulated Zosyn.

126. Because, unlike the reformulated version of Zosyn marketed by Wyeth, the approved generic formulation is not compatible with LRS, the labeling for the approved generic formulation contains warnings that are not contained in the labeling for the reformulated version of Zosyn.

127. The significant and material differences in labeling between the generic formulation of Zosyn approved by FDA and Wyeth's reformulated Zosyn violate the statutory requirement that the labels be "the same." 21 U.S.C. § 355(j)(2)(A)(v).

128. The significant and material differences in labeling between the approved generic formulation of Zosyn and Wyeth's reformulated Zosyn do not fall under any of the exceptions permitted by the same-labeling statute, or FDA's interpretation of that statute. *Id.*; 21 C.F.R. § 314.94(a)(8)(iv).

129. FDA's approval of Orchid's ANDAs constitutes final agency action that is reviewable by the district court. 5 U.S.C. § 704.

130. As set forth above, FDA's approval of a generic version of Zosyn that does not have the same labeling as Wyeth's reformulated Zosyn was arbitrary, capricious, and contrary to law within the meaning of 5 U.S.C. § 706(2)(A), in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C), and in violation of the FDCA and FDA's implementing regulations.

131. FDA's action presents a serious and irreparable risk of grave patient harm. In addition, Wyeth will suffer irreversible loss of goodwill if less favorable clinical outcomes and patient injury result from the concurrent marketing of a generic version of Zosyn that hurts patients. Wyeth also will suffer economic harm from loss of sales revenue resulting from the approval of the generic version of Zosyn; this harm is also irreparable because monetary damages cannot be recouped from the Agency.

132. There is no mechanism by which Wyeth can be made whole for the injury that would result from FDA's approval of Orchid's ANDAs if the approvals are not suspended. Wyeth is without an adequate remedy at law because of the unique nature of the harm.

133. The balance of equities and the public interest in protecting patient health favors enjoining the FDA.

**Count III – Arbitrary and Capricious Failure to Require a Risk Mitigation Plan or Strategy**

**(Violations of 5 U.S.C. § 706(2)(A) and 5 U.S.C. § 706(2)(C))**

134. Wyeth incorporates by reference all allegations contained in paragraphs 1 through 133 of the Complaint as if set forth fully herein.

135. Even if approval of the ANDA itself were not arbitrary, capricious, and contrary to law as alleged in Counts I and II, FDA was required to condition its approval on the implementation by Orchid of a suitable risk management plan to mitigate or eliminate the grave risks to patient harm caused by the marketing of a generic product that is materially different from the branded product and which cannot safely be administered in the same way.

136. At a minimum, FDA was required to address the substantial evidence of risk to patient harm in the administrative record and to provide an adequate explanation for its decision not to require implementation of a risk management plan.

137. FDA's failure to require a risk management plan, or to adequately justify its decision not to do so was arbitrary, capricious, and contrary to law within the meaning of 5 U.S.C. § 706(2)(A).

138. FDA's action presents a serious and irreparable risk of grave patient harm. In addition, Wyeth will suffer irreversible loss of goodwill if less favorable clinical outcomes and patient injury result from the concurrent marketing of a generic version of Zosyn that hurts patients. Wyeth also will suffer economic harm from loss of sales revenue resulting from the approval of the generic version of Zosyn; this harm is also irreparable because monetary damages cannot be recouped from the Agency.

139. There is no mechanism by which Wyeth can be made whole for the injury that would result from FDA's approval of Orchid's ANDAs without a risk management plan if the

approval are not suspended pending implementation of such a plan or strategy. Wyeth is without an adequate remedy at law because of the unique nature of the harm.

140. The balance of equities and the public interest in protecting patient health favors enjoining the FDA.

WHEREFORE, Wyeth prays that this Court enter:

A. A declaratory judgment pursuant to 28 U.S.C. § 2201(a) in favor of Wyeth and against Defendants, by:

(i) declaring that FDA's approval of Orchid's ANDAs was arbitrary, capricious, an abuse of discretion, and contrary to law; and

(ii) declaring that FDA's denial of Wyeth's citizen petition was arbitrary, capricious, an abuse of discretion, and contrary to law.

B. An Order granting Wyeth a temporary restraining order and/or a preliminary or permanent injunction that:

(i) directs FDA to withdraw or suspend its approval of Orchid's ANDAs, and

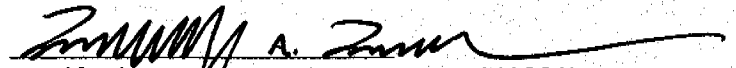
(ii) directs FDA to withdraw or suspend its approval of any ANDA seeking approval to market a generic version of Zosyn that does not contain EDTA and citric acid and is not compatible with LRS in simultaneous co-administration,

(iii) or, failing that, directs FDA to withdraw or suspend its approval of any ANDA seeking approval to market a generic version of Zosyn that does not contain EDTA

and citric acid and is not compatible with LRS unless and until the generic drug maker has adopted an effective risk management plan to minimize the risk of confusion and any adverse health consequences that may result.

C. Such other relief as this Court may deem just and proper.

Respectfully submitted,



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