

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

FEDERAL TRADE COMMISSION,)	
)	
Plaintiff,)	
)	Case No. 1:15-cv-1080
v.)	
)	
STERIS CORPORATION, <i>et al.</i> ,)	
)	
Defendants.)	
)	
)	

**DEFENDANT STERIS CORPORATION’S ANSWER TO
PLAINTIFF FEDERAL TRADE COMMISSION’S COMPLAINT**

Defendant STERIS Corporation (“STERIS”), by and through its undersigned counsel, answers Plaintiff Federal Trade Commission’s (“FTC”) Complaint and asserts its affirmative defenses as follows:

STERIS lacks knowledge of and excludes for purposes of its answer, any information contained in or related to highly confidential information or documents provided by Synergy in connection with the FTC’s investigation of the proposed transaction between STERIS and Synergy that was disclosed only to counsel. To the extent not specifically admitted in the following paragraphs, the allegations in the Complaint are denied.

I. NATURE OF THE CASE

1. STERIS admits that it is the second-largest provider of contract sterilization services in the world, and that Sterigenics is the largest provider of contract sterilization services in the world, but denies that the world is a relevant market for purposes of the Complaint. STERIS avers that Synergy's United States operations are smaller than STERIS and Sterigenics, and Synergy is not materially larger, from a capacity perspective, than many other contract sterilization firms serving North America, including Iotron, E-BEAM Services, NUTEK, Midwest, and Sterilization Services; and Synergy's United States operations are smaller than or comparable in size to several U.S. in-house sterilization operations. STERIS admits that sterilization is a critical final step in the manufacture of many healthcare products and is necessary to eliminate bacteria and other microorganisms living on or in products, and that the U.S. Food and Drug Administration requires sterilization for certain products. STERIS denies the remaining allegations set forth in paragraph 1 of the Complaint.

2. STERIS admits that it operates ten ethylene oxide ("EO") sterilization facilities and eleven gamma sterilization facilities in the United States. STERIS admits that Sterigenics operates fourteen gamma sterilization facilities in the United States, ten EO facilities, and one electron beam ("e-beam") facility, and operates gamma, e-beam, and EO facilities outside the United States. STERIS admits that Synergy operates more than three dozen contract sterilization facilities, including gamma sterilization facilities, outside the United States, and offers e-beam and EO sterilization services in the United States. STERIS avers that the FTC's selective quotation of unidentified material offered without context is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if identified, for a

complete and accurate description of their contents. STERIS denies the remaining allegations set forth in paragraph 2 of the Complaint.

3. STERIS admits that the three primary methods of sterilization currently used in the United States are gamma radiation, e-beam radiation, and EO gas. STERIS admits that customers choose sterilization methods based on a product's physical characteristics, packaging, the volume of products requiring sterilization, and the capabilities of each sterilization modality, but avers that customers consider other factors as well. STERIS admits that gamma radiation sterilizes by exposure to a radioactive isotope, Cobalt 60, and has deep penetration capabilities. STERIS admits that e-beam has different penetration characteristics than gamma radiation and that it is effective for low-density products sterilized in low volumes, but avers that e-beam's effectiveness is not limited to low-density products that are sterilized in low volumes. STERIS avers that e-beam can and does compete with gamma radiation as a sterilization modality and that e-beam is an appropriate alternative sterilization method for most products being sterilized by gamma in the U.S. today. STERIS admits that EO is a non-radiation form of sterilization that exposes products to gas to kill unwanted organisms, and that EO is effective only if gas diffuses freely through packaging and makes contact with all product surfaces requiring sterilization. STERIS avers that not all customers have the same preferences and therefore denies the allegations regarding customer preferences. STERIS denies the remaining allegations set forth in paragraph 3 of the Complaint.

4. STERIS avers that the FTC's selective quotation of unidentified material offered without context is misleading as framed, and STERIS respectfully refers the Court to the quoted documents, if identified, for a complete and accurate description of their contents. STERIS avers that e-beam is a functional and economically viable alternative sterilization method to gamma for

almost all applications. STERIS denies the remaining allegations set forth in paragraph 4 of the Complaint.

5. The allegations contained in the first sentence of paragraph 5 constitute conclusions of law to which no response is required. To the extent a response is deemed required, STERIS denies that the relevant product market is limited to contract radiation sterilization services. STERIS denies that EO is not an economical and practical substitute for contract radiation sterilization services. STERIS admits that the effectiveness of EO sterilization can be influenced by factors including packaging material, configuration of products in totes, and configuration of those totes. The final sentence of paragraph 5 contains a legal conclusion to which no response is required. To the extent a response is deemed required, STERIS denies the allegations. STERIS denies the remaining allegations set forth in paragraph 5 of the Complaint.

6. STERIS admits that many medical device manufacturers use their own in-house sterilization facilities to sterilize a portion of their products. The FTC's assertion of the relevant market constitutes a legal conclusion to which no response is required. To the extent a response is deemed required, STERIS denies the allegations. STERIS admits that some suppliers of medical devices with in-house capabilities use contract sterilizers to provide some portion of their sterilization needs and back-up sterilization services. STERIS avers that it competes for medical device manufacturers' sterilization business against their use of existing in-house sterilization facilities and the threat of increased utilization or expansion of such facilities. STERIS denies the remaining allegations set forth in paragraph 6 of the Complaint.

7. STERIS lacks knowledge or information sufficient to form a belief as to the concerns of unidentified customers about the availability and pricing of gamma sterilization, and therefore denies those allegations. STERIS admits that e-beam may become an even closer

economic substitute to gamma in the future, but avers that e-beam is already a close economic substitute to gamma. STERIS specifically denies that e-beam is an uneconomical alternative for the vast majority of products that are sterilized with gamma radiation. The final sentence of paragraph 7 constitutes a legal conclusion to which no response is required. To the extent a response is deemed required, STERIS denies the allegations. STERIS denies the remaining allegations set forth in paragraph 7 of the Complaint.

8. Paragraph 8 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed required, STERIS denies those allegations and all other remaining allegations set forth in paragraph 8 of the Complaint.

9. STERIS admits that one of the factors that customers may consider is the distance from their manufacturing or distribution sites to gamma sterilization service providers, which may affect transportation costs and turnaround times. STERIS denies the remaining allegations set forth in paragraph 9 of the Complaint.

10. The first sentence of paragraph 10 constitutes a legal conclusion to which no response is required. To the extent a response is deemed required, STERIS denies the allegation. STERIS denies the allegations set forth in paragraph 10 of the Complaint. STERIS avers that the Merger Guidelines are not controlling authority.

11. STERIS admits that Synergy competes outside the United States and is a small U.S. contract radiation player today that offers e-beam sterilization services, but denies that it is a significant competitor with STERIS and denies that STERIS competes with Synergy outside of the United States. STERIS denies that Synergy is “an actual potential entrant with its x-ray sterilization business,” and avers that the phrase “actual potential entrant” is self-contradictory and irrelevant to any valid theory of antitrust liability. Upon information and belief, STERIS

avers that Synergy also offers EO sterilization in the U.S. STERIS denies the remaining allegations set forth in paragraph 11 of the Complaint.

12. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 12 of the Complaint and therefore denies all allegations set forth in paragraph 12 of the Complaint.

13. STERIS admits that its proposed merger with Synergy was announced on October 13, 2014. STERIS lacks knowledge or information sufficient to form a belief regarding the remaining allegations set forth in paragraph 13 of the Complaint and therefore denies them.

14. STERIS admits that the FTC issued Second Requests to STERIS and Synergy in January 2015, and that the Second Requests asked for information regarding STERIS's and Synergy's "relevant services," which the Second Request defined as "each contract sterilization service offered by the company, including, but not limited to, gamma sterilization, x-ray sterilization, electron beam sterilization, and ethylene oxide sterilization." STERIS avers that the FTC's selective reference to unidentified written material or communications, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the referenced documents, if identified, for a complete and accurate description of their contents. STERIS lacks knowledge or information sufficient to form a belief regarding the remaining allegations set forth in paragraph 14 of the Complaint and therefore denies them.

15. STERIS denies that any alleged U.S. x-ray entry by Synergy would have occurred, or that it would have had a large and lasting competitive impact, and a de-concentrating effect if it had occurred, in each relevant market. STERIS avers that the FTC's selective quotation of unidentified written material or communications, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if

identified, for a complete and accurate description of their contents. STERIS lacks knowledge or information sufficient to form a belief regarding the remaining allegations set forth in paragraph 15 of the Complaint and therefore denies them.

16. STERIS denies the allegations set forth in paragraph 16 of the Complaint.

17. STERIS admits that building and operating a new or expanded gamma facility requires capital expenditures, regulatory approvals, and time. STERIS denies the remaining allegations set forth in paragraph 17 of the Complaint.

18. STERIS avers that the FTC's selective quotation of unidentified written material or communications, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if identified, for a complete and accurate description of their contents. STERIS avers that the expected cost savings are verifiable; that a significant portion of the savings is merger-specific; and that the savings are likely to be passed on to customers. STERIS denies the remaining allegations set forth in paragraph 18 of the Complaint.

II. BACKGROUND

A. Jurisdiction and Venue

19. STERIS admits that the FTC purports to bring this action under Section 13(b) of the FTC Act, 15 U.S.C. §53(b), and 28 U.S.C. §§ 1331, 1337, and 1345.

20. STERIS admits that paragraph 20 of the Complaint accurately quotes Section 13(b) of the FTC Act, 15 U.S.C. §53(b).

21. STERIS admits the allegations set forth in paragraph 21 of the Complaint.

22. STERIS admits that it is incorporated in and transacts substantial business in the Northern District of Ohio and is subject to personal jurisdiction therein. STERIS admits that this

District is a proper venue as to STERIS. STERIS lacks knowledge or information sufficient to form a belief regarding the propriety of venue as to Synergy and therefore denies the remaining allegations contained in paragraph 22.

B. Defendants

23. STERIS denies that \$127.5 million of its 2014 revenues derived from contract gamma sterilization services performed at facilities in Ohio, California, Illinois, Massachusetts, New Jersey, New York, Puerto Rico, South Carolina, Texas, and Utah. STERIS admits the remaining allegations set forth in paragraph 23 of the Complaint. STERIS avers that the revenues referred to in paragraph 23 reflect Steris's fiscal year revenue rather than calendar.

24. STERIS lacks knowledge or information sufficient to form a belief regarding Synergy's revenues and therefore denies those allegations contained in paragraph 24. STERIS admits all other remaining allegations in Paragraph 24 of the Complaint.

C. The Merger and the Commission's Response

25. STERIS denies the allegations set forth in paragraph 25 of the Complaint. STERIS avers that it announced a recommended offer under United Kingdom law and no merger agreement has been signed.

26. STERIS admits the allegations set forth in paragraph 26 of the Complaint.

27. STERIS admits the allegations set forth in paragraph 27 of the Complaint, but avers that Synergy certified substantial compliance on April 16, 2015.

28. STERIS admits the allegations set forth in paragraph 28, but avers that the FTC did not have reason to believe that Defendants executed a Merger Agreement in violation of Section 5 of the FTC Act, and avers that the merger, if consummated, would not violate Section 7 of the Clayton Act and Section 5 of the FTC Act.

29. STERIS admits the allegations set forth in paragraph 29 of the Complaint, but denies that the preliminary injunction is necessary to minimize interim harm to competition and preserve the FTC's ability to grant an adequate remedy if it concludes that the merger is unlawful. STERIS avers that the parties agreed via stipulation not to consummate the merger until four business days after this Court renders a decision on the FTC's Motion for Preliminary Injunction.

III. THE RELEVANT PRODUCT MARKETS

30. Paragraph 30 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed required, STERIS denies those allegations and all other remaining allegations set forth in paragraph 30 of the Complaint.

A. Background on Contract Radiation Sterilization Services

31. STERIS admits the allegations set forth in paragraph 31 of the Complaint, but avers that x-ray sterilization is currently used for sterilizing mail by the United States government.

Contract Gamma Sterilization Services

32. STERIS admits the allegations set forth in paragraph 32 of the Complaint.

33. STERIS denies the allegations set forth in paragraph 33 of the Complaint.

34. STERIS avers that its website speaks for itself and respectfully refers the Court to its website, once the cited portion is identified for a complete and accurate description of its contents. STERIS denies the allegations in paragraph 34 regarding the number of products that can only be sterilized by contract gamma sterilization services. STERIS avers that e-beam can be used cost-effectively to sterilize most products that are sterilized with gamma radiation. STERIS denies the remaining allegations set forth in paragraph 34 of the Complaint.

Contract X-ray Sterilization Services

35. STERIS admits that x-ray sterilization uses a high-powered electron beam machine to produce x-ray radiation. STERIS admits that, historically, x-ray sterilization has not been used in the United States. STERIS avers that there are many reasons x-ray sterilization has not been used, and the fact that no machine existed that was capable of sterilizing products as cost effectively as gamma or other sterilization methods is but one reason. STERIS further avers that no x-ray machine historically existed or currently exists that is capable of sterilizing products as cost effectively as gamma or other sterilization methods. STERIS denies the remaining allegations set forth in paragraph 35 of the Complaint.

36. STERIS admits that x-ray is theoretically capable of the depth of penetration of gamma radiation. STERIS admits x-ray raises different regulatory issues than gamma sterilization. STERIS avers that e-beam can be used to sterilize most products that are sterilized with gamma radiation. STERIS denies the remaining allegations set forth in paragraph 36 of the Complaint.

Contract E-beam Sterilization Services

37. STERIS admits the allegations set forth in paragraph 37 of the Complaint except to the extent that the allegations imply that e-beam can only be used to sterilize small volumes of low-density homogeneous products. STERIS avers that e-beam is currently used to sterilize large volumes of such products as well. STERIS avers that e-beam can be used to sterilize most products that are sterilized with gamma radiation. STERIS denies the remaining allegations set forth in paragraph 37 of the Complaint.

38. STERIS denies the allegations set forth in Paragraph 38 that e-beam is not a cost-effective option for sterilizing denser products and that e-beam is not a cost-effective or practical

substitute for sterilizing most products that are currently sterilized with gamma radiation.

STERIS avers that e-beam can be used to sterilize most products that are sterilized with gamma radiation. STERIS lacks knowledge or information sufficient to form a belief as to unspecified statements by unidentified customers and therefore denies those allegations. STERIS avers that the FTC's selective quotation of unidentified written material or communications, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if identified, for a complete and accurate description of their contents. STERIS denies the remaining allegations contained in Paragraph 38.

B. The Market for Contract Radiation Sterilization Services

39. STERIS admits that today, gamma sterilization accounts for 85% of radiation sterilization services sold in the United States, and that e-beam accounts for the remaining 15%. STERIS avers that e-beam can be used to sterilize most products that are sterilized with gamma radiation, and that e-beam's share of radiation sterilization services sold in the United States has been increasing over time. The last sentence of paragraph 39 contains a legal conclusion to which no response is required. To the extent a response is deemed required, STERIS denies the allegation. STERIS denies the remaining allegations set forth in paragraph 39 of the Complaint.

40. STERIS lacks knowledge or information sufficient to form a belief as to unspecified views of unidentified customers, and therefore denies those allegations. STERIS lacks knowledge or information sufficient to form a belief as to whether Sterigenics discounts its gamma sterilization prices when an e-beam sterilization plant is nearby, and therefore denies that allegation. STERIS denies the remaining allegations set forth in paragraph 40 of the Complaint.

41. STERIS admits that it faces gamma sterilization capacity limitations and that it decided to expand sterilization capacity at its Chester, New York, and Ontario, California

facilities with e-beam rather than gamma. STERIS admits that the project was approved based on an assumption that a significant number of gamma customers would move to e-beam.

STERIS avers that the FTC's selective quotation of unidentified written material or communications from both Synergy and STERIS, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if identified, for a complete and accurate description of their contents. STERIS denies the remaining allegations set forth in paragraph 41 of the Complaint.

42. STERIS avers that e-beam sterilization provided by contract and in-house providers is already competitive with gamma and that switching from gamma to e-beam is already occurring. STERIS admits that in the future even more gamma customers may switch to e-beam sterilization due to Cobalt 60 supply issues. STERIS denies the remaining allegations set forth in paragraph 42 of the Complaint.

43. STERIS admits that x-ray and gamma sterilization are theoretically capable of sterilizing some products of the same density and heterogeneity. STERIS lacks knowledge or information sufficient to form a belief as to the unspecified views of unidentified customers, and therefore denies those allegations. STERIS avers that the FTC's selective quotation of unidentified written material or communications from Synergy personnel, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if identified, for a complete and accurate description of their contents. STERIS lacks knowledge or information sufficient to form a belief as to Synergy's confidential business strategy when it was exploring the possibility of U.S. entry with x-ray and therefore denies those allegations. STERIS denies the remaining allegations set forth in paragraph 43 of the Complaint.

EO Sterilization is Not a Substitute for Radiation Sterilization Services

44. STERIS admits that there are technical differences between EO sterilization and gamma sterilization, but avers that many products can be cost effectively sterilized using either method of sterilization. The FTC's allegation of the relevant product market constitutes a legal conclusion to which no response is required. To the extent a response is deemed required, STERIS denies that EO sterilization is properly excluded from the relevant product market. STERIS lacks knowledge or information sufficient to form a belief as to unspecified statements by unidentified customers and therefore denies those allegations. STERIS denies the remaining allegations set forth in paragraph 44 of the Complaint.

45. STERIS denies that EO sterilization often takes significantly longer than other sterilization methods. STERIS admits the remaining allegations set forth in paragraph 45, but avers that STERIS and Sterigenics each offer sterilization services that are capable of completing the sterilization cycle, from receipt of product to shipping the unsterilized product back to the customer, in less than 24 hours.

In-House Sterilization is Not a Viable Substitute for Most Customers

46. The FTC's allegation of the relevant product market constitutes a legal conclusion to which no response is required. To the extent a response is deemed required, STERIS denies that in-house gamma sterilization services are properly excluded from the relevant product market. Upon information and belief, STERIS admits that most in-house gamma sterilization facilities are operated by medical device manufacturers. STERIS further admits that its contract sterilization customers do not rely on in-house gamma sterilization facilities to satisfy all of their sterilization requirements. STERIS lacks knowledge or information sufficient to form a belief

as to the remaining allegations set forth in paragraph 46 of the Complaint, and therefore denies them.

47. STERIS admits that building and operating a new or expanded gamma facility requires capital expenditures, regulatory approvals, and time. STERIS denies the remaining allegations set forth in the first sentence of paragraph 47 of the Complaint. STERIS admits that Sterigenics acquired Nordion, Inc. in 2014 and that Sterigenics sells gamma sterilization services. On information and belief, STERIS admits that there are questions about the future availability and supply of Cobalt 60, a situation exacerbated by the FTC's clearance of the Sterigenics-Nordion transaction in 2014. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 47 and therefore denies them.

48. STERIS admits that some customers with in-house sterilization capabilities use contract gamma sterilization services as a backup when their facilities are down and some customers with in-house sterilization capabilities also use contract sterilization services. STERIS denies the remaining allegations set forth in paragraph 48 of the Complaint.

**C. The Market for Contract Gamma and X-ray Sterilization
Services Sold to Targeted Customers**

49. STERIS admits that it noted, in a presentation to the FTC staff in connection with expressing concerns about the proposed Sterigenics-Nordion transaction, that “[t]he majority of products sterilized with gamma irradiation cannot be converted to E-Beam without significant time, effort and cost.” STERIS avers that the FTC's selective quotation of and omission of other relevant passages from this presentation, is incomplete and out of context as framed in the Complaint, and STERIS respectfully refers the Court to the quoted document, if identified, for a complete and accurate description of its contents. STERIS denies the remaining allegations set forth in paragraph 49 of the Complaint.

50. STERIS lacks knowledge or information sufficient to form a belief as to Sterigenics' customer negotiations, strategies, and pricing, and therefore denies those allegations. STERIS denies the remaining allegations set forth in paragraph 50 of the Complaint. STERIS avers that e-beam can be used to sterilize most products that are sterilized with gamma radiation.

51. STERIS admits the allegations contained in Paragraph 51 that customers could switch some portion of products currently utilizing contract gamma sterilization services to e-beam sterilization. STERIS denies the remaining allegations set forth in paragraph 51 of the Complaint.

IV. THE RELEVANT GEOGRAPHIC MARKETS

52. The FTC's allegation of the relevant geographic market constitutes a legal conclusion to which no response is required. To the extent a response is deemed required, STERIS denies that allegation. STERIS denies all other allegations in paragraph 52 of the Complaint.

53. Upon information and belief, STERIS admits that transportation costs and turnaround times are among the factors considered by customers in choosing services. STERIS also admits that a customer may use sterilization providers more than 500 miles away from that customer's plants if the sterilization provider has a facility near the customer's regular shipping route. Upon information and belief, STERIS admits that contract radiation sterilization companies locate their plants near the customers for which they expect to compete. STERIS denies all other remaining allegations set forth in paragraph 53 of the Complaint.

54. STERIS lacks knowledge or information sufficient to form a belief as to how other contract sterilization providers set pricing, and therefore denies those allegations. STERIS denies the remaining allegations set forth in paragraph 54 of the Complaint.

55. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 55 of the Complaint, and therefore denies them.

56. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 56 of the Complaint, and therefore denies them.

57. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 57 of the Complaint, and therefore denies them.

58. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 58 of the Complaint, and therefore denies them.

59. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 59 of the Complaint, and therefore denies them.

V. MARKET STRUCTURE

60. On information and belief, STERIS denies that STERIS and Sterigenics are currently the only providers of contract gamma sterilization services in the United States. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 60 of the Complaint, and therefore denies them.

A. Market Participants

Contract Gamma Sterilization Services

61. STERIS admits that it has eleven gamma sterilization facilities in the United States. STERIS denies that \$127.5 million of its 2014 revenues derived from contract gamma sterilization services performed at facilities in Ohio, California, Illinois, Massachusetts, New Jersey, New York, Puerto Rico, South Carolina, Texas, and Utah. STERIS avers that the revenues referred to in paragraph 61 reflect Steris's fiscal year revenue rather than calendar. STERIS admits the remaining allegations set forth in paragraph 61 of the Complaint.

62. STERIS lacks knowledge or information sufficient to form a belief as to Sterigenics' revenues as set forth in paragraph 62 of the Complaint, and therefore denies those allegations. STERIS denies that Sterigenics is the only U.S. contract gamma sterilization provider other than STERIS. Upon information and belief, STERIS admits all other allegations set forth in paragraph 62 of the Complaint.

Contract X-ray Sterilization Services

63. STERIS admits that Synergy does not offer contract gamma sterilization services in the United States. Upon information and belief, STERIS admits that Synergy owns and operates a facility in Däniken, Switzerland that performs both gamma and x-ray sterilization services. STERIS avers that Synergy's United States operations are smaller than STERIS and Sterigenics, and Synergy is not materially larger, from a capacity perspective, than many other contract sterilization firms serving North America, including Iotron, E-BEAM Services, NUTEK, Midwest, and Sterilization Services, and Synergy's United States operations are smaller than or comparable in size to several U.S. in-house sterilization operations. STERIS denies the remaining allegations set forth in paragraph 63 of the Complaint.

64. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 64 of the Complaint, and therefore those allegations.

65. STERIS admits that e-beam sterilization services providers, including Nutek, may attempt to provide x-ray sterilization services by modifying their e-beam machines. Upon information and belief, STERIS avers that such activity is already underway. STERIS denies the remaining allegations set forth in paragraph 65 of the Complaint.

Contract E-Beam Sterilization Services

66. Upon information and belief, STERIS admits that Synergy has e-beam facilities located in San Diego, California; Denver, Colorado; Saxonburg, Pennsylvania; and Lima, Ohio. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 66 of the Complaint, and therefore denies them.

67. Upon information and belief, STERIS admits that Sterigenics operates a contract e-beam sterilization facility in San Diego, California. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 67 of the Complaint, and therefore denies them.

68. STERIS admits the allegations set forth in paragraph 68 of the Complaint, but avers that STERIS is adding e-beam capacity at its existing gamma sterilization facilities in Chester, New York (opening in June 2016) and Ontario, California (opening in March 2016).

69. STERIS admits that e-beam contract sterilization services are offered by E-BEAM Services Inc. in Cranbury, New Jersey and Lebanon, Ohio; Nutek in Hayward, California; and Iotron in Columbia City, Indiana. STERIS avers that the FTC's selective quotation and summation of unidentified written material or communications, offered without context, is misleading as framed, and STERIS respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. STERIS lacks knowledge or information sufficient to form a belief to the remaining allegations set forth in paragraph 69 of the Complaint, and therefore denies those allegations.

B. Market Concentration

70. STERIS denies the allegations set forth in paragraph 70 of the Complaint.

71. STERIS admits that the FTC considers HHI as a measure of purported concentration and avers that the Horizontal Merger Guidelines, speak for themselves. STERIS avers that the Horizontal Merger Guidelines are not controlling authority. STERIS denies the remaining allegations set forth in paragraph 71 of the Complaint.

72. STERIS denies that the HHIs alleged in paragraph 72 reflect the HHIs for the properly defined relevant product markets, and denies all other remaining allegations set forth in paragraph 72 of the Complaint.

73. STERIS denies the allegations set forth in paragraph 73 of the Complaint.

VI. ANTICOMPETITIVE EFFECTS

74. STERIS admits that STERIS and Sterigenics are contract radiation sterilization providers. STERIS lacks knowledge or information sufficient to form a belief as to Synergy's alleged deployment of x-ray sterilization in the United States and whether Synergy was on the verge of entering the United States with what it considered to be a disruptive sterilization technology, x-ray, that would allow it to compete directly for Steris and Sterigenics' customers, and therefore denies those allegations. STERIS denies the remaining allegations set forth in paragraph 74 of the Complaint.

75. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 75 of the Complaint, and therefore denies them.

76. STERIS lacks knowledge or information sufficient to form a belief as to the first sentence in paragraph 76, and therefore denies those allegations. STERIS denies the remaining allegations set forth in paragraph 76 of the Complaint.

A. Synergy Was Entering the Relevant Markets Prior to the Merger

The Early Stages of Synergy's U.S. X-ray Plan

77. STERIS admits that Synergy acquired an x-ray facility in Däniken, Switzerland. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 77, and therefore denies them.

78. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 78 of the Complaint, and therefore denies them.

The X-ray Plan Ramp-Up

79. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 79 of the Complaint, and therefore denies them.

80. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 80 of the Complaint, and therefore denies them.

81. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 81 of the Complaint, and therefore denies them.

82. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 82 of the Complaint, and therefore denies them.

83. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 83 of the Complaint, and therefore denies them.

84. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 84 of the Complaint, and therefore denies them.

85. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 85 of the Complaint, and therefore denies them.

86. STERIS admits that the proposed merger of Synergy and STERIS was announced on October 13, 2014. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 86 of the Complaint, and therefore denies them.

Synergy's Actions Post-Merger Announcement

87. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 87 of the Complaint, and therefore denies them.

88. STERIS avers that Synergy's documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 88 of the Complaint, and therefore denies them.

89. STERIS avers that Synergy's documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 89 of the Complaint, and therefore denies them.

90. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 90 of the Complaint, and therefore denies them.

91. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 91 of the Complaint, and therefore denies them.

Synergy's Actions After the FTC Issued Second Requests

92. STERIS admits the allegations set forth in paragraph 92 of the Complaint, but avers that x-ray sterilization does not currently compete with gamma sterilization in the United States.

93. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 93 of the Complaint, and therefore denies them.

94. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 94 of the Complaint, and therefore denies them.

B. Synergy's U.S. X-ray Entry Would Result in Substantial Procompetitive Effects

Synergy's Entry Would Have a Significant De-concentrating Effect on the Relevant Markets

95. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 95 of the Complaint, and therefore denies them.

96. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 96 of the Complaint, and therefore denies them.

97. STERIS denies the allegations set forth in paragraph 97 of the Complaint.

98. STERIS denies the allegations set forth in paragraph 98 of the Complaint.

99. STERIS lacks knowledge or information sufficient to form a belief as to allegations set forth in paragraph 99 of the Complaint, and therefore denies them.

Synergy's X-ray Entry Would Have Created Substantial Price and Non-Price Benefits for Customers

100. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 100 of the Complaint, and therefore denies them.

101. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 101 of the Complaint, and therefore denies them.

102. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 102 of the Complaint, and therefore denies them.

103. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 103 of the Complaint, and therefore denies them.

104. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 104 of the Complaint, and therefore denies them.

105. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 105 of the Complaint, and therefore denies them.

106. Upon information and belief, STERIS admits that some customers have indicated they are concerned about the effect of Cobalt 60 supply on gamma sterilization prices in the future. STERIS avers that the FTC's clearance of the Sterigenics-Nordion transaction in 2014 has contributed to this uncertainty and potential volatility. STERIS denies the remaining allegations set forth in paragraph 106 of the Complaint.

107. STERIS admits that the FDA approved x-ray sterilization for Surgicel in September 2014. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 107, and therefore denies them.

108. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 108 of the Complaint, and therefore denies them.

109. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 109 of the Complaint, and therefore denies them.

110. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 110 of the Complaint, and therefore denies them.

VII. ENTRY WILL NOT PREVENT THE MERGER'S COMPETITIVE HARM

111. STERIS denies the allegations set forth in paragraph 111 of the Complaint.

A. Barriers to Entry for X-Ray Sterilization Services

Synergy Has X-Ray Entry Advantages Unmatched by Any Other Firm

112. STERIS admits that Synergy is a small player in the U.S. contract radiation sterilization services business and that the only radiation sterilization service Synergy provides in the United States is e-beam. STERIS denies the remaining allegations set forth in paragraph 112 of the Complaint.

113. STERIS admits that Synergy acquired the Däniken x-ray sterilization facility in 2012 and has operated it for more than two years. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 113 of the Complaint, and therefore denies them.

114. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 114 of the Complaint, and therefore denies them.

115. STERIS admits that STERIS and, upon information and belief, Synergy and Sterigenics have some large medical device manufacturers as customers. Upon information and belief, STERIS admits that no company in the United States has an agreement with IBA to use its x-ray equipment. STERIS lacks knowledge or information sufficient to form a belief as to IBA's purported beliefs, and therefore denies that allegation. STERIS denies the remaining allegations set forth in paragraph 115 of the Complaint.

116. STERIS admits that existing contract e-beam sterilization service providers are fully capable of converting e-beam sterilization machines into x-ray sterilization machines. STERIS lacks knowledge or information sufficient to form a belief as to other companies'

considerations, and therefore denies those allegations. STERIS denies the remaining allegations set forth in paragraph 116 of the Complaint.

B. Barriers to Entry for Gamma Sterilization Services

117. STERIS admits that building and operating a new or expanded gamma facility requires capital expenditures, regulatory approvals, and time. STERIS lacks knowledge or information sufficient to form a belief as to whether future legislative restrictions may prohibit opening new gamma facilities in the United States, and therefore denies that allegation. STERIS denies the remaining allegations set forth in paragraph 117 of the Complaint.

118. STERIS denies the allegations set forth in paragraph 118 of the Complaint. STERIS avers that the cost to construct a gamma sterilization facility is dependent on numerous factors, and lacks knowledge or information sufficient to form a belief as to the FTC's alleged cost for constructing a gamma sterilization facility, and therefore denies that allegation.

119. STERIS lacks knowledge or information sufficient to form a belief as to whether regulatory requirements are more significant than the capital investment needed to open a gamma sterilization facility, and therefore denies that allegations. STERIS admits that Cobalt 60 is a material that is regulated due to environmental and health risks. STERIS further admits that the Nuclear Regulatory Commission and the International Atomic Energy Agency regulate the design of gamma sterilization facilities and the shipping of Cobalt 60, and that the Environmental Protection Agency and state agencies also regulate environmental safety aspects of handling and storing Cobalt 60 at gamma sterilization facilities. STERIS admits that building and licensing a gamma sterilization facility takes time, and STERIS avers that the length of time depends on various factors. To the extent the Complaint implies that future gamma sterilization plant construction might not be permitted at all, STERIS lacks knowledge or information

sufficient to form a belief as to the accuracy of this speculation, and therefore denies it. STERIS denies the remaining allegations set forth in paragraph 119 of the Complaint.

120. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 120 of the Complaint, and therefore denies them.

C. Barriers to Entry for E-beam Sterilization Services

121. STERIS lacks knowledge or information sufficient to form a belief as to whether an unspecified firm seeking to open a single e-beam sterilization facility has been planning to enter for approximately four years, and still does not expect to begin operations until the fall of 2015, and therefore denies those allegations. STERIS admits that a potential entrant would need to secure customers and that most customers need to test and validate their products with a potential e-beam sterilization provider before committing to use its services. STERIS avers that the cost to construct an e-beam sterilization facility is dependent on numerous factors, and lacks knowledge or information sufficient to form a belief as to the FTC's alleged cost for constructing an e-beam sterilization facility, and therefore denies that allegation. STERIS lacks knowledge or information sufficient to form a belief as to unspecified customer requirements and the alleged effect on entrants, and therefore denies those allegations. STERIS denies the remaining allegations set forth in paragraph 121 of the Complaint.

122. STERIS lacks knowledge or information sufficient to form a belief as to whether any small fringe e-beam sterilization firm or *de novo* entrant is likely to expand to enter the e-beam sterilization market in a significant manner in an unspecified timeframe under unspecified market conditions, and therefore denies that allegation. STERIS lacks sufficient knowledge or information sufficient to form a belief as to whether small e-beam providers have been unable to grow beyond a small share of contract radiation sterilization services because e-beam processing

companies have had limited success converting gamma customers, and therefore denies that allegation. STERIS avers that the FTC's selective quotation of unidentified written material or communications, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if identified, for a complete and accurate description of their contents. STERIS denies the remaining allegations set forth in paragraph 122 of the Complaint.

123. STERIS avers that the FTC's selective quotation of unidentified written material or communications, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if identified, for a complete and accurate description of their contents. STERIS denies the remaining allegations set forth in paragraph 123 of the Complaint.

**VIII. EFFICIENCIES WILL NOT COUNTERACT
THE MERGER'S COMPETITIVE HARM**

124. STERIS denies the allegations set forth in paragraph 124 of the Complaint.

125. STERIS avers that the FTC's selective quotation of unidentified written material or communications, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if identified, for a complete and accurate description of their contents. STERIS denies the remaining allegations set forth in paragraph 125 of the Complaint.

IX. LIKELIHOOD OF SUCCESS ON THE MERITS AND NEED FOR RELIEF

126. Paragraph 126 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed required, STERIS denies those allegations and all other remaining allegations set forth in paragraph 126 of the Complaint.

127. STERIS denies the allegations set forth in paragraph 127 of the Complaint.

128. STERIS denies the allegations set forth in paragraph 128 of the Complaint.

129. STERIS denies the allegations set forth in paragraph 128 of the Complaint.

AFFIRMATIVE AND OTHER DEFENSES

STERIS asserts the following defenses, without assuming the burden of proof on such defenses that would otherwise rest with the FTC:

FIRST DEFENSE

The FTC's Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

Granting the relief sought is contrary to the public interest.

THIRD DEFENSE

The alleged relevant geographic market definitions fail as a matter of law.

FOURTH DEFENSE

The Complaint fails adequately to allege a relevant product market.

FIFTH DEFENSE

The Complaint fails to allege harm to competition.

SIXTH DEFENSE

The Complaint fails to allege harm to any consumers.

SEVENTH DEFENSE

The Complaint fails to allege harm to consumer welfare.

EIGHTH DEFENSE

The alleged harm to potential competition is not actionable

NINTH DEFENSE

The FTC cannot show that, even if it is successful in blocking the proposed merger, that Synergy will ever provide contact x-ray sterilization services in the United States.

TENTH DEFENSE

The combination of the Defendants' businesses will be procompetitive. The merger will result in substantial merger-specific efficiencies, cost synergies, and other procompetitive effects that will directly benefit consumers. These benefits greatly outweigh any and all proffered anticompetitive effects.

ELEVENTH DEFENSE

The FTC fails to allege a time frame for the alleged anticompetitive effects.

RESERVATION OF RIGHTS TO ASSERT ADDITIONAL DEFENSES

STERIS has not knowingly or intentionally waived any applicable defenses, and it reserves the right to assert and rely upon other applicable defenses that may become available or apparent throughout the course of the action. STERIS reserves the right to amend, or seek to amend, its answer or affirmative defenses.

PRAYER FOR RELIEF

WHEREFORE, STERIS requests that the Court enter judgment in its favor as follows:

- A. The Complaint be dismissed with prejudice;
- B. No injunctive relief issues to the FTC;
- C. Costs incurred in defending this action be awarded to STERIS; and
- D. Any and all other relief as the Court may deem just and proper.

Dated: June 12, 2015

Respectfully submitted,

/s/ John M. Majoras

John M. Majoras (Ohio Bar. No. 0036780)

JONES DAY

Street Address:

325 John H. McConnell Blvd., Suite 600

Columbus, OH 43215-2673

Mailing Address:

P.O. Box 165017

Columbus, OH 43216-5017

Telephone: (614) 469-3939

Facsimile: (614) 461-4198

Email: jmmajoras@jonesday.com

Geoffrey S. Irwin (admitted *pro hac vice*)

Louis K. Fisher (admitted *pro hac vice*)

Michael S. Fried (admitted *pro hac vice*)

Tara Lynn R. Zurawski (admitted *pro hac vice*)

JONES DAY

51 Louisiana Avenue, N.W.

Washington, D.C. 20001-2113

Telephone: (202) 879-3939

Facsimile: (202) 626-1700

Email: gsirwin@jonesday.com

Email: lkfisher@jonesday.com

Email: msfried@jonesday.com

Email: tzurawski@jonesday.com

Counsel for Defendant STERIS Corporation

CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2015, I caused the foregoing to be electronically filed with the Clerk of Court using the CM/ECF system, causing it to be served on all registered users to be noticed in this matter, including:

Michael Moiseyev
Tara Reinhart
Daniel K Zach
Peter Colwell
FEDERAL TRADE COMMISSION
400 7th St., SW
Washington, DC 20024
Email: mmoiseyev@ftc.gov
Email: treinhart@ftc.gov
Email: dzach@ftc.gov
Email: pcolwell@ftc.gov

Counsel for Plaintiff Federal Trade Commission

David H. Bamberger
Julie A. Gryce
DLA Piper LLP (US)
500 8th Street, N.W.
Washington, D.C. 20004
Email: david.bamberger@dlapiper.com
Email: Julie.gryce@dlapiper.com

Paolo Morante
Steven E. Levitsky
DLA Piper LLP (US)
1251 Avenue of the Americas, 27th Floor
New York, NY 10020
Email: paolo.morante@dlapiper.com
Email: steven.levitsky@dlapiper.com

Counsel for Defendant Synergy Health PLC

/s/ John M. Majoras

John M. Majoras (Ohio Bar. No. 0036780)

JONES DAY

Street Address:

325 John H. McConnell Blvd., Suite 600

Columbus, OH 43215-2673

Mailing Address:

P.O. Box 165017

Columbus, OH 43216-5017

Telephone: (614) 469-3939

Facsimile: (614) 461-4198

Email: jmmajoras@jonesday.com

Counsel for Defendant STERIS Corporation