

Complaint

IN THE MATTER OF

**GRIFOLS, S.A.,
AND
GRIFOLS SHARED SERVICES NORTH AMERICA, INC.**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4654; File No. 181 0081
Complaint, July 31, 2018 – Decision, September 17, 2018*

This consent order addresses the \$324 million acquisition by Grifols S.A. of Biotest US Corporation. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by (1) eliminating actual, direct, and substantial competition between Grifols and Biotest US in three local markets for the collection of human source plasma; (2) increasing the ability of the merged entity unilaterally to decrease donation fees for the collection of human source plasma in each local market; (3) reducing incentives to improve service or quality in each local market for the collection of human source plasma; and (4) increasing the likelihood that Grifols would unilaterally exercise market power in the U.S. market for hepatitis B immune globulin (“HBIG”). The consent order requires Grifols to divest plasma collection centers in three local geographic markets in the United States to Kedplasma LLC, a subsidiary of Kedrion Biopharma Inc. The Order also prohibits Grifols from acquiring any ownership interest in ADMA Biologics, which had been partially owned by Biotest US, without prior notification.

Participants

For the *Commission*: Jean McNeil, Christina Perez and David von Nirschl.

For the *Respondents*: John Ingrassia and Colin Kass, Proskauer Rose LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Grifols, S.A. (“Grifols”), a corporation subject to the jurisdiction of the Commission, has entered into an acquisition with Biotest US Corporation (“Biotest US”), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Grifols, is a corporation organized, existing, and doing business under and by virtue of the laws of the Kingdom of Spain with its executive offices and principal place of business located at Avinguda de la Generalitat, 152-158, Parc de Negocis Can Sant Joan, Barcelona, Spain 08174. Its United States address for service of process and the

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Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: General Counsel, c/o Grifols Shared Services North America, Inc., 2410 Lillyvale Avenue, Los Angeles, California 90032. In 2016, Grifols had net revenues of approximately \$4.3 billion, of which 66 percent was generated from its North American operations.

2. Respondent Grifols Shared Services North America, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Virginia with its executive offices and principal place of business located at 2410 Lillyvale Avenue, Los Angeles, California 90032.

3. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and engages in business that is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. PARTIES

4. Biotest US, is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 901 Yamato Road, Suite 101, Boca Raton, Florida 33431. Through its subsidiary, Biotest Pharmaceutical Corporation, Biotest US owns a network of 22 U.S. plasma collection centers. Prior to July 20, 2018 it also owned 41 percent of the stock of ADMA Biologics, Inc. (“ADMA”). ADMA develops, manufactures and sells human blood plasma-derived products in the United States. In 2017, Biotest US generated approximately \$187 million in revenues.

5. The Biotest Divestiture Trust, is a statutory trust organized under the laws of the State of Maryland and pursuant to the terms of a declaration of trust, dated January 17, 2018, and an Amended and Restated Declaration of Trust, dated July 8, 2018, by and among Biotest AG (an Aktiengesellschaft organized under the laws of the Federal Republic of Germany), as grantor, and Eric Rosenbach, a U.S. citizen. The mailing address of The Biotest Divestiture Trust is c/o Eric Rosenbach, Trustee, 402 Norfolk Street, Cambridge, Massachusetts 02139.

III. THE PROPOSED ACQUISITION

6. Pursuant to agreements dated December 22, 2017, Grifols agreed to acquire all of the outstanding voting securities of Biotest US from The Biotest Divestiture Trust, which included the outstanding securities of ADMA owned by Biotest US (“acquisition agreement”). Grifols and Biotest US subsequently modified the acquisition agreement (“modified acquisition”) to exclude the outstanding securities of ADMA and revalued the acquisition. The acquisition agreement and the modified acquisition (collectively, “the Acquisition”) are subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

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IV. THE RELEVANT MARKETS

7. The relevant lines of commerce in which to analyze the effects of the Acquisition are:

- a. the development, license, manufacture, marketing, distribution, and sale of hepatitis B immune globulin; and
- b. the collection of human source plasma.

8. Hepatitis B immune globulin is a plasma-derived injectable medicine used to provide patients with hepatitis B antibodies to prevent hepatitis B infections.

9. Human source plasma is a critical input for a variety of medical products that are used to treat diseases and conditions in a variety of therapeutic areas, including pulmonology, hematology, immunology, infectious disease and trauma. Human source plasma is collected from donors at plasma collection centers.

10. The relevant geographic area in which to assess the competitive effects of the Acquisition on the hepatitis B immune globulin market is the United States.

11. The relevant geographic areas in which to assess the competitive effects of the Acquisition on the collection of human plasma market are Lincoln, Nebraska; Augusta, Georgia; and Youngstown, Ohio.

V. THE STRUCTURE OF THE MARKETS

12. Only three companies—Grifols, ADMA and Saol—sell hepatitis B immune globulin in the United States. ADMA has the largest share, followed by Saol and then Grifols. Biotest US owned 41 percent of the outstanding shares of ADMA. Without the modification of the acquisition agreement, the Acquisition would have resulted in Respondent Grifols owning 41 percent of the stock of its most significant competitor.

13. Respondent Grifols and Biotest US are the only two participants in the human source plasma collection market in the three geographic areas identified in Paragraph 11. The Acquisition would give Respondent Grifols a monopoly in each of the relevant markets.

VI. ENTRY CONDITIONS

14. Entry into the hepatitis B immune globulin relevant market would not be timely, likely, or sufficient in magnitude, character, and scope to have deterred or counteracted the anticompetitive effects of the acquisition agreement. Entry would not be timely because of lengthy drug development and FDA approval timelines. In addition, entry sufficient to deter or counteract the likely competitive harm of the acquisition agreement was unlikely to occur.

15. Entry into the collection of human source plasma markets is unlikely to be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

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Entry is impeded by the scarcity of qualified donors in the geographic areas identified in Paragraph 11, such that these areas are unlikely to support a new human source plasma collection center.

VII. EFFECTS OF THE ACQUISITION

16. The effects of the Acquisition, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by increasing the likelihood that Respondent Grifols would unilaterally exercise market power in the market for hepatitis B immune globulin;
- b. by eliminating actual, direct, and substantial competition between Grifols and Biotest US in the market for the collection human source plasma;
- c. by increasing the ability of the merged entity unilaterally to decrease donation fees in the market for the collection of human source plasma; and
- d. by reducing incentives to improve service or quality in the market for the collection of human source plasma.

VIII. VIOLATIONS CHARGED

17. The Acquisition described in Paragraph 6 constitute a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

18. The Acquisition described in Paragraph 6, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirty-first day of July, 2018 issues its Complaint against said Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”) initiated an investigation of the proposed acquisition by Respondent Grifols Shared Services North America, Inc., a wholly owned subsidiary of Respondent Grifols S.A. (collectively “Grifols” or “Respondents”) of all of

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the outstanding voting securities of Biotest US Corporation (“Biotest US”). The Biotest Divestiture Trust is the ultimate parent entity of Biotest US. At the time of the announcement of the proposed acquisition, Biotest Pharmaceutical Corporation, a subsidiary of Biotest US, owned a portion of the outstanding voting securities of ADMA Biologics, Inc. (“ADMA”). Prior to Respondents’ proposed acquisition of Biotest US, Biotest US transferred or will have transferred all of the aforementioned voting securities of ADMA to either The Biotest Divestiture Trust or to ADMA. Accordingly, ADMA’s voting securities will not be acquired or held by Respondents. The Commission’s Bureau of Competition prepared and furnished to Respondents the Draft Complaint reflecting the foregoing transactions, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an agreement (“Agreement Containing Consent Orders” or “Consent Agreement”), containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint, (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true, (3) waivers and other provisions as required by the Commission’s Rules, and (4) a proposed Decision and Order and this Order to Maintain Assets; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

1. Respondent Grifols, S.A., is a corporation organized, existing, and doing business under and by virtue of the laws of the Kingdom of Spain with its executive offices and principal place of business located at Avinguda de la Generalitat, 152-158, Parc de Negocis Can Sant Joan, Barcelona, Spain 08174. Its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, is as follows: General Counsel, c/o Grifols Shared Services North America, Inc., 2410 Lillyvale Avenue, Los Angeles, California 90032.
2. Respondent Grifols Shared Services North America, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Virginia with its executive offices and principal place of business located at 2410 Lillyvale Avenue, Los Angeles, California 90032.
3. Biotest US, is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal

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place of business located at 901 Yamato Road, Suite 101, Boca Raton, Florida 33431.

4. The Biotest Divestiture Trust, is a statutory trust organized under the laws of the State of Maryland and pursuant to the terms of a Declaration of Trust, dated January 17, 2018, and an Amended and Restated Declaration of Trust, dated July 8, 2018, by and among Biotest AG (an Aktiengesellschaft organized under the laws of the Federal Republic of Germany), as grantor, and Eric Rosenbach, a U.S. citizen. The mailing address of The Biotest Divestiture Trust is c/o Eric Rosenbach, Trustee, 402 Norfolk St., Cambridge, Massachusetts 02139.
5. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS HEREBY ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Respondents” means, individually and collectively: Grifols, S.A. and Grifols Shared Services North America, Inc.; their directors, officers, employees, agents, representatives, successors, and assigns; and their joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Grifols, S.A. or Grifols Shared Services North America, Inc. (including, without limitation, Biomat USA), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Respondents will include Biotest US.
- B. “Biotest US” means Biotest US Corporation; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Biotest US Corporation (including, without limitation, Biotest Pharmaceuticals Corporation), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Decision and Order” means the:
 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and

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2. Final Decision and Order following its issuance and service by the Commission in this matter.
- E. “Plasma Donor Center Divestiture Business(es)” means the Business of the Respondents related to each of the Plasma Donor Center Divestiture Facilities to the extent that such Business is owned, controlled, or managed by the Respondents and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondents.
- F. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph IV of the Decision and Order.
- G. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondents fully transfer and deliver each of the respective Plasma Donor Center Divestiture Assets to an Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of each of the related Plasma Donor Center Divestiture Businesses, to minimize any risk of loss of competitive potential for such Plasma Donor Center Divestiture Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Plasma Donor Center Divestiture Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber, or otherwise impair the Plasma Donor Center Divestiture Assets (other than in the manner prescribed in the Decision and Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the related Plasma Donor Center Divestiture Businesses.
- B. Until Respondents fully transfer and deliver each of the respective Plasma Donor Center Divestiture Assets to an Acquirer, Respondents shall maintain the operations of the related Plasma Donor Center Divestiture Businesses in the regular and ordinary course of business and in accordance with past practice (including, without limitation, regular repair and maintenance of the assets of such business and as consistent with standard operating procedures to ensure professionalism, safety, and quality of each facility and the associated donors and employees, and to maintain any licenses with the FDA for the facility) and/or as may be necessary to preserve the full economic viability, marketability, and competitiveness of such Plasma Donor Center Divestiture Businesses and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; donors; customers; Agencies; employees; and others having business relations with each of the respective Plasma Donor Center

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Divestiture Businesses. Respondents' responsibilities shall include, but are not limited to, the following:

1. providing each of the respective Plasma Donor Center Divestiture Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans, and promotional activities for such Plasma Donor Center Divestiture Business;
 2. continuing, at least at their scheduled pace, any expenditures for each of the respective Plasma Donor Center Divestiture Businesses authorized prior to the date the Consent Agreement was signed by the Respondents, including, but not limited to, all collecting, processing, and testing of human blood or blood components (*e.g.*, plasma), evaluating and screening of donors, programing and marketing related to the recruitment of new donors and retention of donors (including, without limitation, any remuneration programs and the expenses related thereto and other donor services), and other marketing, and purchasing expenditures;
 3. providing such resources as may be necessary to respond to competition against each of the Plasma Donor Center Divestiture Facilities and/or to prevent any diminution in the collection of human blood or blood components (*e.g.*, plasma) at each of the Plasma Donor Center Divestiture Facilities during and after the Acquisition process and prior to the complete transfer and delivery of the related Plasma Donor Center Divestiture Assets to an Acquirer;
 4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Plasma Donor Center Divestiture Facilities;
 5. making available for use by each of the respective Plasma Donor Center Divestiture Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Plasma Donor Center Divestiture Business; and
 6. providing such support services to each of the respective Plasma Donor Center Divestiture Businesses as were being provided to such Plasma Donor Center Divestiture Business by Respondents as of the date the Consent Agreement was signed by Respondents, including, without limitation, use of the Blood Establishment Computer System.
- C. Until Respondents fully transfer and deliver each of the respective Plasma Donor Center Divestiture Assets to an Acquirer, Respondents shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as,

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and (ii) comparable in training, and expertise to what has been associated with the Plasma Donor Center Divestiture Facility for the relevant Plasma Donor Center Divestiture Facility's last fiscal year, including, without limitation, phlebotomists, licensed medical personnel, and personnel trained in the use of the Blood Establishment Computer System.

D. Respondents shall:

1. for a period of twelve (12) months after the Closing Date, provide the Acquirer with the opportunity to enter into employment contracts with the employees that work in the locations of each of the Plasma Donor Center Divestiture Facilities; and
2. until the Closing Date, provide all of the above-described employees with reasonable financial incentives to continue in their positions consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Business related to each of the Plasma Donor Center Divestiture Facility. Such incentives shall include a continuation of all employee compensation and benefits offered by a Respondent until the Closing Date(s).

E. Pending divestiture of the Plasma Donor Center Divestiture Assets, Respondents shall:

1. not use, directly or indirectly, any Plasma Donor Center Confidential Business Information other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to the Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
2. not disclose or convey any such Plasma Donor Center Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer, (ii) other Persons specifically authorized by the Acquirer or staff of the Commission to receive such information (*e.g.*, employees of the Respondents responsible for providing transitional services to the Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed) and *except* to the extent necessary to comply with applicable Law;
3. not provide, disclose or otherwise make available, directly or indirectly, any Plasma Donor Center Confidential Business Information to the

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employees associated with the Plasma Donor Centers that are being retained by the Respondents; and

4. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Plasma Donor Center Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access or use any Plasma Donor Center Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- F. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Plasma Donor Center Divestiture Businesses through their full transfer and delivery to an Acquirer; to minimize any risk of loss of competitive potential for the Plasma Donor Center Divestiture Businesses; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Plasma Donor Center Divestiture Assets except for ordinary wear and tear.

III.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Monitor”) to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor each Respondent’s compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.

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- D. If a Monitor is appointed, each Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor each Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission;
 2. The Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or of the Commission; and
 3. The Monitor shall serve until Respondents complete each of the divestitures required by this Order and complete any transitional services required to be provided to an Acquirer under this Order or related Remedial Agreement(s), *provided, however*, that the Monitor's service shall not extend more than two (2) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.
- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Each Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability,

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except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.

- H. Respondents shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by each Acquirer with respect to the performance of a Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by each Respondent of its obligations under the Orders.
- I. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as the Monitor pursuant to the Decision and Order.
- N. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondents have fully complied with this Order to Maintain Assets, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with the Orders.

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- A. Respondents shall include in their reports, among other things that are required from time to time, a detailed description of its efforts to comply with the relevant paragraphs of the Orders, including: a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, and (ii) transitional services being provided by the Respondents to the Acquirer; and a detailed description of the timing for the completion of such obligations.
- B. Respondents shall verify each compliance report with a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee specifically authorized to perform this function, or self-verified in the manner set forth in 28 U.S.C. § 1746. Respondents shall submit an original and 2 copies of each compliance report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov. In addition, Respondents shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission on the same timing as, the reports of compliance required to be submitted by Respondents pursuant to the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of: Grifols, S.A.; Grifols Shared Services North America, Inc.; Biotest US Corporation; or The Biotest Divestiture Trust;
- B. any proposed acquisition, merger, or consolidation of: ; Grifols, S.A.; Grifols Shared Services North America, Inc.; Biotest US Corporation; or The Biotest Divestiture Trust; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters address, the

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notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and
- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the later of:

- A. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. the day after the divestiture of all of the Plasma Donor Center Divestiture Assets, as required by and described in the Decision and Order, has been completed; or
- C. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

DECISION

The Federal Trade Commission (“Commission”) initiated an investigation of the proposed acquisition by Respondent Grifols Shared Services North America, Inc., a wholly owned subsidiary of Respondent Grifols S.A. (collectively “Grifols” or “Respondents”) of all of the outstanding voting securities of Biotest US Corporation (“Biotest US”). The Biotest Divestiture Trust is the ultimate parent entity of Biotest US. At the time of the announcement of the proposed acquisition, Biotest Pharmaceutical Corporation, a subsidiary of Biotest US, owned a portion of the outstanding voting securities of ADMA Biologics, Inc. (“ADMA”). Prior to

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Respondents' proposed acquisition of Biotest US, Biotest US transferred or will have transferred all of the aforementioned voting securities of ADMA to either The Biotest Divestiture Trust or to ADMA. Accordingly, ADMA's voting securities will not be acquired or held by Respondents. The Commission's Bureau of Competition prepared and furnished to Respondents the Draft Complaint reflecting the foregoing transactions, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an agreement ("Agreement Containing Consent Orders" or "Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint, (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true, (3) waivers and other provisions as required by the Commission's Rules, and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the said Acts, and that a complaint should issue stating its charges in that respect. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Grifols, S.A., is a corporation organized, existing, and doing business under and by virtue of the laws of the Kingdom of Spain with its executive offices and principal place of business located at Avinguda de la Generalitat, 152-158, Parc de Negocis Can Sant Joan, Barcelona, Spain 08174. Its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, is as follows: General Counsel, c/o Grifols Shared Services North America, Inc., 2410 Lillyvale Avenue, Los Angeles, California 90032.
2. Respondent Grifols Shared Services North America, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Virginia with its executive offices and principal place of business located at 2410 Lillyvale Avenue, Los Angeles, California 90032.
3. Biotest US, is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 901 Yamato Road, Suite 101, Boca Raton, Florida 33431.

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4. The Biotest Divestiture Trust, is a statutory trust organized under the laws of Maryland and pursuant to the terms of a Declaration of Trust, dated January 17, 2018, and an Amended and Restated Declaration of Trust, dated July 8, 2018, by and among Biotest AG (an Aktiengesellschaft organized under the laws of the Federal Republic of Germany), as grantor, and Eric Rosenbach, a U.S. citizen. The mailing address of The Biotest Divestiture Trust is c/o Eric Rosenbach, Trustee, 402 Norfolk St., Cambridge, Massachusetts 02139. The Trust Agreement for the Biotest Divestiture Trust is contained in Non-Public Appendix I of the Order.
5. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS HEREBY ORDERED that, as used in the Order, the following definitions shall apply:

- A. “Respondents” means, individually and collectively: Grifols, S.A. and Grifols Shared Services North America, Inc.; their directors, officers, employees, agents, representatives, successors, and assigns; and their joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Grifols, S.A. or Grifols Shared Services North America, Inc. (including, without limitation, Biomat USA), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Respondents will include Biotest US.
- B. “Biotest US” means Biotest US Corporation; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Biotest US Corporation (including, without limitation, Biotest Pharmaceuticals Corporation), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Acquirer(s)” means the following:
 1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or

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2. a Person approved by the Commission to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- E. “Acquisition” means Respondents’ acquisition of Biotest US pursuant to the Acquisition Agreement.
- F. “Acquisition Agreement” means the *Stock Purchase Agreement* by and between Grifols Shared Services North America, Inc., Biotest US Corporation, Biotest AG, and, solely for the purposes of Section 7.13 of the *Stock Purchase Agreement*, as guarantor, Grifols, S.A. dated December 22, 2017, and the *Amendment* [amendment insert] dated [insert] that were submitted by the Respondents to the Commission in this matter. The Acquisition Agreement is contained in Non-Public Appendix I.
- G. “Acquisition Date” means the date on which Respondents acquire fifty percent (50%) or more of the outstanding voting securities of Biotest US.
- H. “ADMA” means ADMA Biologics, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 465 State Route 17, Ramsey, New Jersey 07446.
- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the operation of the Business of a Plasma Donor Center. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- J. “Applicant Plasma” means human plasma collected from any of the Plasma Donor Center Divestiture Facilities that has not been fully tested and cleared within the Respondents’ donor management system (*i.e.*, Blood Establishment Computer System) for subsequent use or distribution.
- K. “Blood Establishment Computer System” means the computer hardware, computer software, peripheral devices, networks, and documentation (*e.g.*, users manuals and standard operating procedures) as required by the FDA pursuant to 21 CFR 211.68, 606.100(b), and 606.160 that apply to blood establishment validation systems, and any other components of such a system as required by the FDA in order to (i) ensure the proper diagnosis of disease or other conditions in donors of human blood or blood components, or (ii) to prevent disease by preventing the release of unsuitable blood and blood components.
- L. “Business” means the activities related to the collection and processing of human blood and blood components (*e.g.*, plasma) conducted at Plasma Donor Centers.

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- M. “Closing Date” means, as to each Plasma Donor Center Divestiture Facility, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Plasma Donor Center Divestiture Facility to an Acquirer pursuant to this Order.
- N. “Collection Materials” means materials used under the standard operation procedures for blood collection, handling, and processing at each of the Plasma Donor Center Divestiture Facilities (*e.g.*, plasma collection tubes).
- O. “Current Operating Condition” means that, as of the date of delivery to the Acquirer, the machine meets or exceeds all current operational, functional, and productive capabilities required to perform plasmapheresis.
- P. “Disposable Medical Supplies” means general medical products regularly used in the conduct of the Business of a Plasma Donor Center that are intended for one-time or temporary use (*e.g.*, gloves, needles, bandages, paper products, syringes, and wipes).
- Q. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph V of this Order.
- R. “Domain Name” means the domain name(s) (uniform resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- S. “Government Entity” means any Federal, state, local, or non-U.S. government; any court, legislature, government agency, or government commission; or any judicial or regulatory authority of any government.
- T. “Fixtures and Equipment” means all furniture, fixtures, furnishings, machinery, equipment, supplies and other tangible personal property used or held for use in the operation of the Business of each of the Plasma Donor Center Divestiture Facilities respectively, or if leased, the Respondents’ leasehold interest therein.
- U. “Kedplasma” means (i) Kedplasma LLC, wholly-owned subsidiary of Kedrion S.p.a. and a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at Parker Plaza, 400 Kelby Street, Fort Lee, New Jersey 07024; or (ii) Kedrion S.p.a, a corporation organized, existing, and doing business under and by virtue of the laws of the Italian Republic with its registered office located at Località Ai Conti – 55051 Barga (Lucca) - frazione Castelvecchio Pascoli, Italy and any other subsidiary of Kedrion S.p.a.

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- V. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- W. “Monitor” means any monitor appointed pursuant to Paragraph IV of this Order or Paragraph III of the related Order to Maintain Assets.
- X. “Orders” means this Decision and Order and the related Order to Maintain Assets.
- Y. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- Z. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.
- AA. “Ownership Interest” means any voting or non-voting stock, share capital, equity, notes convertible into any voting or non-voting stock, or other interest in an entity.
- BB. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups, or affiliates thereof.
- CC. “Plasma Donor Center(s)” means a facility used for the collection of whole blood or plasma from human donors that operates in accordance with FDA rules related to the evaluation of the eligibility of potential donors and to the storing, processing, tracking, testing, and shipping of human blood or blood components for further manufacturing and use in blood or plasma-based therapies.
- DD. “Plasma Donor Center Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the operation of the Business of a Plasma Donor Center.
- EE. “Plasma Donor Center Confidential Business Information” means all information owned by, or in the possession or control of, a Respondent that is not in the public domain and that is directly related to the conduct of the Business of the Plasma Donor Center Divestiture Facilities. The term “Plasma Donor Center Confidential Business Information” *excludes*, and Respondents are not required to submit the following information to an Acquirer:
 - 1. information relating to a Respondent’s general business strategies or practices that does not discuss with particularity the Business of a particular Plasma Donor Center Divestiture Facility;
 - 2. information specifically excluded from the Plasma Donor Center Divestiture Assets conveyed to the Acquirer;

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3. information that is contained in documents, records, or books of a Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Plasma Donor Center Divestiture Facilities acquired by that Acquirer or that is exclusively related to Plasma Donor Centers retained by the Respondents; and
4. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

FF. “Plasma Donor Center Contracts” means all contracts or agreements:

1. pursuant to which a Third Party provides any specialized services necessary to the operation of the Business of the specified Plasma Donor Center Divestiture Facility to a Respondent including, but not limited to, consultation arrangements; and/or
2. pursuant to which a Third Party provides any equipment necessary to the operation of the Business of the specified Plasma Donor Center Divestiture Facility to a Respondent; and
3. pursuant to which a Third Party provides any software necessary to the operation of the Business of the specified Plasma Donor Center Divestiture Facility to a Respondent.

provided, however, that where any such contract or agreement also relates to a Plasma Donor Center(s) that is being retained by the Respondents, a Respondent shall, at the Acquirer’s option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Plasma Donor Center Divestiture Facility, but concurrently may retain similar rights for the Plasma Donor Centers retained by the Respondents.

GG. “Plasma Donor Center Divestiture Agreement(s)” means the following:

1. *Plasma Center Purchase Agreement* by and between Kedplasma LLC and Biomat USA, Inc., dated June 18, 2018;
2. *Transition Services Agreement* by and between Kedplasma LLC and Biomat USA, Inc., dated June 18, 2018; and
3. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreement(s).

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The Plasma Donor Center Divestiture Agreements are contained in Non-Public Appendix II.A. The Plasma Donor Center Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

HH. "Plasma Donor Center Divestiture Assets" means all rights, title, and interest in and to the Business of Respondents related to each of the Plasma Donor Center Divestiture Facilities, to the extent legally transferable and as such assets and rights are in existence as of the date the Respondents sign the Consent Agreement in this matter, and to be maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date, including, without limitation, the following:

1. all rights to all of the leasehold interests in the real property at which the Plasma Donor Center Divestiture Facility is located and the building and improvements thereon;
2. all rights to all of the Plasma Donor Center Contracts;
3. all Fixtures and Equipment;
4. all Plasma Donor Center Approvals;
5. at the Acquirer's option, all Applicant Plasma in inventory as of Closing Date;
6. at the Acquirer's option, either (i) all plasmapheresis machines used or held for use in the operation of the Business at each respective Plasma Donor Center Divestiture Facility (which machines shall be delivered to the Acquirer in Current Operating Condition), or (ii) a license for an interim period to use all plasmapheresis machines used or held for use in the operation of the Business at each respective Plasma Donor Center Divestiture Facility (which machines shall be provided to the Acquirer in Current Operating Condition) for a time sufficient to allow the Acquirer to transition to the Acquirer's own plasmapheresis machines;
7. at least two (2) weeks supply (in the ordinary course of business) of Collection Materials at each Plasma Donor Center Divestiture Facility;
8. at least two (2) weeks supply (in the ordinary course of business) of Disposable Medical Supplies at each Plasma Donor Center Divestiture Facility;

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9. at least two (2) weeks supply (in the ordinary course of business) of janitorial supplies, including such supplies as are required to prevent exposure to potentially infectious materials;
10. all donor records and registries related to the blood or blood component (e.g., plasma) donations made at the particular Plasma Donor Center Divestiture Facility, including any records made by personnel at that Plasma Donor Center Divestiture Facility relating to the collection of plasma from a donor;
11. all computers and computer equipment, printers, software and databases, routers, servers, switches and timeclocks and documentation related to any of the foregoing used or held for use in the operation of the Business of each Plasma Donor Center Divestiture Facility (all cabling within each center shall remain in place), which shall also include access to any computer databases or donor information connected or related to each Plasma Donor Center Divestiture Facility at the corporate level held outside the respective Plasma Donor Center Divestiture Facility;
12. at the Acquirer's option, a license for an interim period to the Blood Establishment Computer System that was in use in connection with the operation of each Plasma Donor Center Divestiture Facility prior to the Acquisition for a time sufficient to allow the Acquirer to transition to the Acquirer's own Blood Establishment Computer System for that facility;
13. all Website(s) related exclusively to the specified Plasma Donor Center Divestiture Facility;
14. the content related exclusively to the specified Plasma Donor Center Divestiture Facility that is displayed on any Website that is not dedicated exclusively to the specified Plasma Donor Center Divestiture Facility;
15. at the option of the Acquirer, all Plasma Donor Center Contracts related to the specified Plasma Donor Center Divestiture Facility; and
16. all of a Respondent's books, records, and files directly related to the foregoing;

provided, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Plasma Donor Center Divestiture Facility and a Plasma Donor Center retained by the Respondents and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Plasma Donor Center Divestiture Facility; or (ii) for which any Respondent has a legal obligation to retain the original copies, that Respondent shall be required to provide only copies or relevant excerpts of the documents and materials

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containing this information. In instances where such copies are provided to the Acquirer, the Respondents shall provide the Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondents provide the Acquirer with the above-described information without requiring a Respondent completely to divest itself of information that, in content, also relates to Plasma Donor Centers retained by the Respondents.

II. “Plasma Donor Center Divestiture Facility(ies)” means the Plasma Donor Centers located at the following addresses, individually and collectively:

1. 3160 Wrightsboro Road, Augusta, Georgia 30909;
2. 2002 N Street, Lincoln, Nebraska 68510; and
3. 444 Martin Luther King Jr. Boulevard, Youngstown, Ohio 44502.

JJ. “Plasma Donor Center Employee Information” means the following, for each employee of a Plasma Donor Center Divestiture Facility, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each employee of a Plasma Donor Center Divestiture Facility (including former employees who were employed by a Respondent within ninety (90) days of the execution date of any Remedial Agreement); and
2. with respect to each such employee, the following information:
 - a. direct contact information for the employee, including telephone number;
 - b. the date of hire and effective service date;
 - c. job title or position held;
 - d. a specific description of the employee’s responsibilities related to the relevant Plasma Donor Center Divestiture Facility; *provided, however*, in lieu of this description, a Respondent may provide the employee’s most recent performance appraisal;
 - e. the base salary or current wages;
 - f. the most recent bonus paid, aggregate annual compensation for the relevant Respondent’s last fiscal year, and current target or guaranteed bonus, if any;

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- g. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
 - h. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
- 3. at the Acquirer's option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

KK. "Relevant Geographic Markets" means the following:

- 1. City of Lincoln, Nebraska;
- 2. City of Augusta, Georgia; and
- 3. City of Youngstown, Ohio.

LL. "Remedial Agreement(s)" means the following:

- 1. any agreement between a Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement to supply specified products (or components thereof) or services, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
- 2. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of that Respondent related to a Plasma Donor Center Divestiture Facility(ies) or other Order requirement to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
- 3. any agreement between a Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement by that Respondent to supply specified products

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(or components thereof) or services, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

4. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of that Respondent related to a Plasma Donor Center Divestiture Facility(ies) or other Order requirement to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

MM. “Third Party(ies)” means any non-governmental Person other than the following: a Respondent; or an Acquirer of particular assets or rights pursuant to this Order.

NN. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Plasma Donor Center Divestiture Facilities.

II.

IT IS FURTHER ORDERED that:

- A. Not later than thirty (30) days after the Order Date, Respondents shall divest the Plasma Donor Center Divestiture Assets, absolutely and in good faith, to Kedplasma pursuant to, and in accordance with, the Plasma Donor Center Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Kedplasma or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Plasma Donor Center Divestiture Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Plasma Donor Center Divestiture Assets to Kedplasma prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Kedplasma is not an acceptable purchaser of any of the Plasma Donor Center Divestiture Assets, then Respondents shall immediately rescind the transaction with Kedplasma, in whole or in part, as directed by the Commission, and shall divest the Plasma Donor Center Divestiture Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the

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Commission, and only in a manner that receives the prior approval of the Commission;

provided further, that if Respondents have divested the Plasma Donor Center Divestiture Assets to Kedplasma prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Plasma Donor Center Divestiture Assets to Kedplasma (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Closing Date, Respondents shall provide the Acquirer with the opportunity to review all contracts or agreements that are Plasma Donor Center Contracts for the purposes of the Acquirer's determination whether to assume such contracts or agreements.
- C. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Plasma Donor Center Divestiture Assets to an Acquirer, and to permit the Acquirer to continue the Business of the Plasma Donor Center Divestiture Facility;

provided, however, Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant Third Parties.

- D. Respondents shall:
 - 1. submit to the Acquirer, at Respondents' expense, all Plasma Donor Center Confidential Business Information;
 - 2. deliver all Plasma Donor Center Confidential Business Information:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
 - 3. pending complete delivery of all such Plasma Donor Center Confidential Business Information to the Acquirer, provide that Acquirer and the Monitor (if any has been appointed) with access to all such Plasma Donor Center Confidential Business Information and employees who possess or

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are able to locate such information for the purposes of identifying the books, records, and files that contain such Plasma Donor Center Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, directly or indirectly, any such Plasma Donor Center Confidential Business Information other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to the Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
5. not disclose or convey any Plasma Donor Center Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer, (ii) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed) and *except* to the extent necessary to comply with applicable Law;
6. not provide, disclose or otherwise make available, directly or indirectly, any Plasma Donor Center Confidential Business Information to the employees associated with the Plasma Donor Centers that are being retained by the Respondents; and
7. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Plasma Donor Center Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access or use any Plasma Donor Center Confidential Business Information that they are prohibited from receiving for any reason or purpose.

E. Respondents shall:

1. not later than ten (10) days after a request from the Acquirer, provide the Acquirer with the Plasma Donor Center Employee Information;
2. for a period of twelve (12) months after the Closing Date, provide the Acquirer with the opportunity to enter into employment contracts with the

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employees that work in the locations of each of the Plasma Donor Center Divestiture;

3. until the Closing Date, provide all of the above-described employees with reasonable financial incentives to continue in their positions consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Business related to each of the Plasma Donor Center Divestiture Facility. Such incentives shall include a continuation of all employee compensation and benefits offered by a Respondent until the Closing Date(s).
- F. Until Respondents complete the divestiture of the Plasma Donor Center Divestiture Assets to the Acquirer:
1. Respondents shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Business associated with each Plasma Donor Center Divestiture Facility;
 - b. minimize any risk of loss of competitive potential for that Business;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the Plasma Donor Center Divestiture Assets;
 - d. ensure the assets related to each Plasma Donor Center Divestiture Facility are provided to the Acquirer without disruption, delay, or impairment of any regulatory approval processes related to the Business associated with each Plasma Donor Center Divestiture Facility; and
 2. Respondents shall not sell, transfer, encumber, or otherwise impair the Plasma Donor Center Divestiture Assets (other than in the manner prescribed in this Order).
- G. For a period of ten (10) years beginning on the Order Date, Respondents shall not, directly or indirectly, through subsidiaries, partnerships or otherwise, without providing prior written notification to the Commission:
1. acquire any ownership or leasehold interest in any facility that has operated as a Plasma Donor Center within (6) months prior to the date of such proposed acquisition within any of the Relevant Geographic Markets; or

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2. acquire any Ownership Interest in any entity that owns any interest in or operates a Plasma Donor Center, or owned any interest in or operated any Plasma Donor Center within six (6) months prior to such proposed acquisition in any of the Relevant Geographic Markets;

provided however, that advance written notification shall not apply to the construction of new facilities by Respondents or the acquisition of or leasing of a facility that has not operated as a Plasma Donor Center within six (6) months prior to Respondents' offer to purchase or lease.

Said notification shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as "the Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and notification is required only of Respondents and not of any other party to the transaction. Respondents shall provide the Notification to the Commission at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not consummate the transaction until twenty (20) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition; *provided, however*, that the advanced written notification provisions of this Paragraph shall not apply to any transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. 18a.

- H. The purpose of the divestiture of the Plasma Donor Center Divestiture Assets and the related obligations imposed on the Respondents by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with each Plasma Donor Center Divestiture Facility;
 2. to create a viable and effective competitor that is independent of Respondents in the Business of each Plasma Donor Center Divestiture Facility; and
 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

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III.**IT IS FURTHER ORDERED** that:

- A. In connection with, or as a result of Respondents' acquisition of the voting securities of Biotest US or pursuant to the Acquisition Agreement, Respondents shall not, directly or indirectly, acquire or hold:
1. any Ownership Interest in ADMA;
 2. any rights to nominate or obtain representation on the Board of Directors of ADMA;
 3. any rights to exercise dominion or control over ADMA; or
 4. any rights to direct, supervise, or manage the business of ADMA (including any rights to participate in the formulation, determination, or direction of any business decisions of ADMA).
- B. For a period of ten (10) years beginning on the Order Date, Respondents shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, without providing advanced written notification to the Commission:
1. acquire any Ownership Interest in ADMA;
 2. acquire any rights to nominate or obtain representation on the Board of Directors of ADMA; or
 3. acquire any assets or rights owned or controlled by ADMA exclusively used in the research, development, manufacture, distribution, marketing, or sale of hepatitis B immune globulin (*e.g.*, Nabi-HB®), including, without limitation, any FDA applications or approvals (*e.g.*, biological license) related to hepatitis B immune globulin.

Said notification shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as "the Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and notification is required only of Respondents and not of any other party to the transaction. Respondents shall provide the Notification to the Commission at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R.

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§ 803.20), Respondents shall not consummate the transaction until twenty (20) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition; *provided, however*, that the advanced written notification provisions of this Paragraph shall not apply to any transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. 18a.

The purpose of the requirements of Paragraph III is to ensure that the Respondents will not hold the voting securities of ADMA and will not seek to exert, or exert influence over the business operations of ADMA.

IV.

IT IS FURTHER ORDERED that:

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Monitor”) to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreements.
- B. The Commission shall select the Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor each Respondent’s compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If a Monitor is appointed, each Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
 - 1. The Monitor shall have the power and authority to monitor each Respondent’s compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission;

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2. The Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or of the Commission; and
 3. The Monitor shall serve until Respondents complete each of the divestitures required by this Order and complete any transitional services required to be provided to an Acquirer under this Order or related Remedial Agreement(s), *provided, however*, that the Monitor's service shall not extend more than two (2) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.
- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Respondents shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by the Acquirer with respect to the performance of a Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by a Respondent of its obligations under the Order.

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- I. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- M. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

V.

IT IS FURTHER ORDERED that:

- A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Plasma Donation Center Divestiture Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by a Respondent to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and

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divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
 - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 - 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by a Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

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4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the

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relevant provisions of this Order or the Order to Maintain Assets in this matter.

8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

VI.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. to assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the

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divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided further, however, that pursuant to this Paragraph, a Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VII.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- E. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

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VIII.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition Date, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition Date occurred, including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov.
- B. Within five (5) days of each Closing Date, Respondents shall submit to Commission staff a letter certifying the date on which that particular divestiture occurred, including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov.
- C. Within thirty (30) days after the Order Date, and every thirty (30) days thereafter until Respondents have completed the divestitures required by this Order, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which the Respondents intend to comply, are complying, and have complied with these requirements of this Order. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Orders, including:
 - 1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, and (ii) transitional services being provided by Respondents to the Acquirer; and
 - 2. a detailed description of the timing for the completion of such obligations.
- D. One (1) year after the Order Date, annually for the next nine (9) years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.
- E. Respondents shall verify each compliance report with a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee specifically authorized to perform this function, or self-verified in the manner set forth in 28 U.S.C. § 1746. Respondents shall submit an original and 2 copies of each compliance report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov. In addition, Respondents shall

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provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

IX.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of Grifols, S.A. or Grifols Shared Services North America, Inc.;
- B. any proposed acquisition, merger, or consolidation of Grifols, S.A. or Grifols Shared Services North America, Inc.; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

X.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to a Respondent made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters address, the notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and
- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on September 17, 2028.

By the Commission.

Analysis to Aid Public Comment

NON-PUBLIC APPENDIX I
ACQUISITION AGREEMENT

[Cover Page]

[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II.A
AGREEMENTS RELATED TO THE
PLASMA DONOR CENTER DIVESTITURE ASSETS

[Cover Page]

[Redacted From the Public Record Version, But Incorporated By Reference]

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

INTRODUCTION

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Grifols S.A. and its subsidiary Grifols Shared Services North America, Inc. (collectively “Grifols”). The purpose of the Consent Agreement is to remedy the anticompetitive effects resulting from Grifols’ proposed acquisition of Biotest US Corporation (“Biotest US”) from The Biotest Divestiture Trust. The proposed Decision and Order (“Order”) contained in the Consent Agreement requires Grifols to divest plasma collection centers in three local geographic markets in the United States to Kedplasma LLC (“KedPlasma”), a subsidiary of Kedrion Biopharma Inc. (“Kedrion”). Grifols is also prohibited from acquiring any ownership interest in ADMA Biologics (“ADMA”), which had been partially owned by Biotest US, without prior notification.

Analysis to Aid Public Comment

The proposed Consent Agreement has been placed on the public record for 30 days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make it final.

THE ACQUISITION

Pursuant to an agreement dated December 22, 2017, Grifols proposed to acquire all of the outstanding voting securities of Biotest US from The Biotest Divestiture Trust, which included the outstanding securities of ADMA owned by Biotest US. Grifols and Biotest US subsequently modified the acquisition agreement to exclude the outstanding securities of ADMA and revalued the acquisition. The acquisition and the modified acquisition (collectively, “the Acquisition”) are subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

The Commission’s Complaint alleges that the Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by (1) eliminating actual, direct, and substantial competition between Grifols and Biotest US in three local markets for the collection of human source plasma; (2) increasing the ability of the merged entity unilaterally to decrease donation fees for the collection of human source plasma in each local market; (3) reducing incentives to improve service or quality in each local market for the collection of human source plasma; and (4) increasing the likelihood that Grifols would unilaterally exercise market power in the U.S. market for hepatitis B immune globulin (“HBIG”). The proposed Consent Agreement would remedy the alleged violations by preserving the competition that would otherwise be eliminated as a result of the proposed Acquisition.

THE PARTIES

Headquartered in Barcelona, Spain, Grifols is a vertically integrated global healthcare company. Grifols specializes in the collection of plasma, and the development and production of several plasma-derived products. Grifols operates or manages approximately 192 plasma collection centers throughout the United States and sells a wide variety of plasma-derived blood products, including HBIG. In 2016, Grifols had net revenues of approximately \$4.3 billion.

Biotest US is a wholly owned subsidiary of The Biotest Divestiture Trust headquartered in Boca Raton, Florida. Through its subsidiary, Biotest Pharmaceutical Corporation, Biotest US owns a network of 22 U.S. plasma collection centers. Prior to the signing of the Consent Agreement, it also owned 41 percent of the stock of ADMA. ADMA develops, manufactures and sells human blood plasma-derived products in the United States, including HBIG. In 2017, Biotest US generated approximately \$187 million in revenues.

Analysis to Aid Public Comment

RELEVANT MARKETS AND STRUCTURE OF THE MARKETS**Plasma Collection Centers**

Grifols and Biotest are the only two companies with plasma collection centers in three geographic areas in the United States: (1) Lincoln, Nebraska; (2) Augusta, Georgia; and (3) Youngstown, Ohio. Donated plasma is a critical input for a variety of medical products that are used to treat diseases or conditions in multiple therapeutic areas, including pulmonology, hematology, immunology, infectious disease, and trauma. Plasma collection centers are often located near universities, military installations, and other areas with a sufficient number of potential donors. Centers typically compensate donors by paying them a per-donation fee. Donors choose their donation center based on proximity, convenience, quality of the facility, and the donor fee. Plasma centers typically compete on these dimensions to attract individuals interested in selling their blood.

The relevant geographic markets for the provision of plasma collection services are local due to the limited distance individuals are willing or able to travel to donate plasma. Donors typically will not travel more than 25 minutes, or 15 to 20 miles, to donate plasma, though each plasma collection center's draw area may differ based on the ease of travel and transportation and the density of population. In each of the geographic areas of concern, Grifols and Biotest operate plasma collection centers very close to each other, and the next-closest alternative is quite distant. In Lincoln, Nebraska, Grifols and Biotest are less than a mile apart and the closest alternative plasma collection centers are an hour away in Omaha. Likewise, in Augusta, Georgia, they are approximately six miles apart and in Youngstown, Ohio, they are approximately nine miles apart, and for each market the alternatives are located over an hour away.

Hepatitis B Immune Globulin

HBIG is a plasma-derived product used as a prophylaxis to treat healthcare professionals or patients exposed or potentially exposed to hepatitis B, and to prevent recurrence of hepatitis B in hepatitis B-positive liver transplant patients. There are no viable substitutes for HBIG. The market for HBIG is highly concentrated. There are three HBIG products sold in the United States: ADMA's Nabi HB, Saol Therapeutics' ("Saol") HepGam B, and Grifols' HyperHep. ADMA's Nabi HB is the market leader, while Saol's HepGam B and Grifols' HyperHep are the second and third leading product lines, respectively.

The relevant geographic market in which to analyze the proposed Acquisition's effects in the HBIG market is the United States. Plasma-derived products, such as HBIG, must be approved by the U.S. Food and Drug Administration ("FDA") for sale in the United States. The FDA further requires that these products be made solely from plasma collected in the United States in FDA-approved collection centers and manufactured in FDA-approved plants. Plasma-derived products not approved for sale in the United States are not viable alternatives for U.S. consumers.

Analysis to Aid Public Comment

COMPETITIVE EFFECTS OF THE ACQUISITION

Plasma Collection Centers

In the three geographic areas at issue—Lincoln, Nebraska; Augusta, Georgia; and Youngstown, Ohio—the proposed Acquisition raises competitive concerns because, post-Acquisition, Grifols would own all of the plasma collection centers in each area, which would affect its incentives to offer competitive donor fees and/or quality of service. Thus, the proposed Acquisition would likely result in diminished service, quality, and longer wait times for donors in each market. In addition, Grifols likely would be able to exercise market power by unilaterally decreasing donor fees at one or both of the plasma donor centers in each geographic area.

Hepatitis B Immune Globulin

The proposed Acquisition would significantly increase market concentration and eliminate substantial competition between the first- and third-largest suppliers of HBIG in the United States. Prior to the parties' restructuring the transaction, Grifols would have acquired an approximately 41 percent ownership stake in ADMA, one of its two rivals in the United States HBIG market. This ownership stake would have given Grifols the incentive to increase significantly the price of its HBIG product because it would recapture sufficient revenues through its stake in ADMA to offset any sales lost due to Grifols' price increases.

ENTRY

Plasma Collection Centers

Entry into the plasma collection service markets in Lincoln, Nebraska; Augusta, Georgia; and Youngstown, Ohio is not likely to occur in a timely and sufficient manner to deter or counteract the likely anticompetitive effects of the Acquisition. New entry is unlikely due to the scarcity of qualified donors necessary to justify opening a new plasma collection center in each of these geographic areas.

Hepatitis B Immune Globulin

Entry into the HBIG market would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry would require significant investment of time and money for product research and development, regulatory approval by the FDA, and establishment of a U.S. sales and service infrastructure. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market. These obstacles make entry in the HBIG more challenging and less likely to avert the anticompetitive effects of the proposed Acquisition.

Analysis to Aid Public Comment

THE CONSENT AGREEMENT

The proposed Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by: (1) requiring Grifols to divest its plasma collection centers in Lincoln, Nebraska; Augusta, Georgia; and Youngstown, Ohio to Kedplasma; (2) prohibiting Grifols from obtaining ownership or control of any ADMA stock; and (3) requiring Grifols to provide prior notice to the Commission if it seeks to repurchase any of the divested plasma collection centers or any ownership interest in ADMA.

Kedplasma is a well-qualified acquirer of Grifols' plasma collection centers. Kedplasma is a subsidiary of Kedrion, a leading manufacturer of protein products and the fifth-largest producer of plasma proteins worldwide. Kedrion currently operates plasma collection centers in the United States, Germany, and Hungary. In the United States, Kedplasma operates 15 plasma collection centers and it anticipates opening two additional centers in 2018 (none of which currently competes or will compete with the to-be-divested Grifols' plasma collection centers).

The proposed Consent Agreement contains several provisions designed to ensure the successful divestiture of the plasma collection centers to Kedplasma. Grifols is required to obtain the consents of all third parties that are necessary to permit Grifols to divest the plasma collection centers to the buyer. This provision ensures that the buyer will have the assets necessary to continue operating the business of the divested centers in a competitive manner. In addition, the Consent Agreement requires Grifols to provide Kedplasma with the opportunity to interview and hire employees affiliated with the divested centers, as well as with information about each employee. Next, the Consent Agreement requires Grifols to provide all employees with reasonable financial incentives to remain in their positions until the buyer assumes control of each divested center. This will ensure that the buyer has access to personnel who are familiar with the centers' donors and their donation schedules, and donation policies necessary to preserve the marketability, viability, and competitiveness of each center. Finally, the Consent Agreement requires Grifols to maintain the centers and prevent the destruction, deterioration, or impairment of the equipment and assets of the centers until they are divested to ensure that they remain competitive.

Before entering the Consent Agreement, and in consultation with Commission staff, Biotest US transferred ownership of all ADMA stock to its parent, The Biotest Divestiture Trust. Because Grifols is not acquiring The Biotest Divestiture Trust, it will neither acquire the ADMA stock previously held by Biotest US nor any other ownership interest in ADMA. To prevent Grifols from reacquiring the interest in ADMA, the proposed Consent Agreement explicitly prohibits Grifols from directly or indirectly acquiring any ownership interest in ADMA or obtaining any rights to nominate or obtain representation on the Board of Directors of ADMA. It also requires Grifols to provide notification prior to any future acquisition of ownership interest in ADMA or any of the other divested plasma collection center assets.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or the Order to Maintain Assets, or to modify their terms in any way.

Complaint

IN THE MATTER OF

READYTECH CORPORATION

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT

Docket No. C-4659; File No. 182 3100

Complaint, October 17, 2018 – Decision, October 17, 2018

This consent order addresses ReadyTech Corporation’s representations concerning its participation in the Privacy Shield framework agreed upon by the U.S. and the European Union. The complaint alleges that ReadyTech represented that it was actively in the process of certifying compliance with the EU-U.S. Privacy Shield framework when, in fact, ReadyTech never completed the necessary steps to finalize its application, and was not certified to participate in the EU-U.S. Privacy Shield framework. The consent order prohibits ReadyTech from making misrepresentations about its membership in any privacy or security program sponsored by the government or any other self-regulatory or standard-setting organization, including, but not limited to, the EU-U.S. Privacy Shield framework and the Swiss-U.S. Privacy Shield framework.

Participants

For the *Commission*: *Monique F. Einhorn*.

For the *Respondents*: *Jeffrey Pietsch, Weintraub Tobin*.

COMPLAINT

The Federal Trade Commission (“FTC”), having reason to believe that ReadyTech Corporation, a corporation, has violated the Federal Trade Commission Act (“FTC Act”), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent ReadyTech Corporation is a California corporation with its principal office or place of business at 2201 Broadway, Suite 725, Oakland, CA 94612.
2. Respondent provides online and instructor-led training.
3. The acts and practices of Respondent as alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act.
4. Respondent has set forth on its website, <https://www.readytech.com/policies/privacy-policy/>, privacy policies and statements about its practices, including statements related to its participation in the EU-U.S. Privacy Shield framework agreed upon by the U.S. government and the European Commission.

Privacy Shield

5. The EU-U.S. Privacy Shield framework (“Privacy Shield”) was designed by the U.S. Department of Commerce (“Commerce”) and the European Commission to provide a