



PUBLIC VERSION

June 12, 2017

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BY E-MAIL

Donald S. Clark
Secretary
Federal Trade Commission
Room 172
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Daniel P. Ducore
Assistant Director
Compliance Division
Bureau of Competition
U.S. Federal Trade Commission
Constitution Center
400 7th Street, SW
Suite CC-8416
Washington, D.C. 20024

Re: In the Matter of *Grifols, S.A.*, Docket No. C-4322; Notice of Amendment to Contract Manufacturing Agreement ("CMA") dated April 18, 2011, between Kedrion S.p.A. and Grifols Inc.

Dear Secretary Clark and Mr. Ducore:

Pursuant to Section 2.4 l(f) of the Federal Trade Commission ("Commission") Rules of Practice and Procedure, 16 C.F.R § 2.4l(f), Grifols, S.A. ("Grifols") hereby requests approval by the Federal trade Commission of an amendment to the Contract Manufacturing Agreement ("CMA") provided as part of this submission (the "Amended CMA") along with the public version of this request. We believe that the changes to the CMA are consistent with the remedial purposes of the Order because the changes are necessary to ensure Kedrion's ability to continue to compete in the U.S.

[REDACTED]

The Amended CMA is fully consistent with the Order, does not vary or contradict the terms of the Order, and is necessary for Kedrion to remain a viable going concern as contemplated by the Order. [REDACTED]

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[REDACTED] the parties have negotiated an Amended CMA on similar terms that extends the duration of the CMA by three years.

[REDACTED]

Therefore, the Amended CMA extends the duration of the existing CMA to enable Kedrion to continue to compete in the U.S. The amendment to the CMA also allows Kedrion to provide Grifols with source Plasma for both fractionation and purification into finished products that Kedrion will be able to re-sell. Absent the amendment, Kedrion will not have finished product available for sale. Under the Amended CMA, Kedrion will not require any new or separate FDA approvals to sell Koate or any other products that will be supplied by Grifols. All of the subject products are manufactured pursuant to Grifols' FDA licenses under the Kedrion name, so there will be no time lag or gap in Kedrion's ability to sell the products fractionated and purified by Grifols. Kedrion is simultaneously working to develop its own purification capabilities, which will be separately subject to FDA approval.

[REDACTED]

[REDACTED]

[REDACTED]

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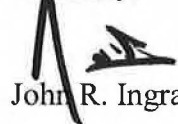
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[REDACTED]

Without these amended terms, Kedrion would no longer be able to sell not only Koate in the U.S., but also Gammaked and Albuked (Kedrion's immunoglobulin and albumin U.S. products) in the U.S. Therefore, Grifols has agreed to the modifications to enable Kedrion to remain a U.S. competitor and to avert a potentially significant health problem for Koate patients.

Pursuant to Section 4.9(c) of the Commission's Rules, 16 C.F.R. §4.9(c), Respondent Grifols requests confidential treatment of the Amended CMA. The Amended CMA contains confidential information concerning the agreement between Grifols and Kedrion, the volume of products to be transferred between Grifols and Kedrion, and fractionation fees and purification fees associated with those products. This information is similar to that contained in Confidential Exhibit A to the Order, Confidential Exhibit C to the Order, Confidential Exhibit E-1 to the Order, and Confidential Exhibit F-1 to the Order, each of which the Commission has accorded confidential treatment in this matter. Disclosure of confidential agreements between Grifols and Kedrion, the specific quantities of products to be transferred between Grifols and Kedrion, and fractionation fees and purification fees associated with those products could cause competitive harm to Kedrion and to Respondent Grifols.

Sincerely,



John R. Ingrassia

¹ There is one minor additional change in the Amended CMA related to the change of control provision.



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Confidential Attachment

cc: Eric D. Rohlek
Joel Grosberg