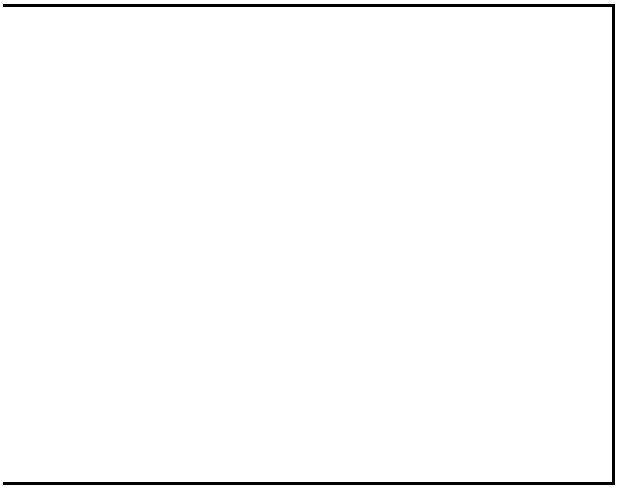

which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as a

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER

I.

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

A. "Fresenius" means Fresenius Medical Care AG & Co. KGaA, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including Fresenius Medical Care Holdings, Inc.), divisions, groups, and affiliates controlled by Fresenius Medical Care AG & Co. KGaA, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Daiichi" means Daiichi Sankyo Company, Ltd., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including Daiichi Sankyo, Inc., Luitpold Pharmaceuticals, Inc., and American

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I. "HHS" means the United States Department of Health & Human Services including all of its agencies and offices including, but not limited to, CMS.

J. "HHS-CMS Requirement" means:

1. any statute or regulation, including, but not limited to, 42 U.S.C. § 1395w-3a, and 42 C.F.R. Part 414, Subparts J and K;

2. any HHS review or study of Manufacturer's Average Sales Price and other prices, comparisons of such prices, or modifications of payment amounts for drug products, including, but not limited to 42 U.S.C. § 1395w-3a(d); and

3. any HHS or CMS guidance, ruling, statement of policy, or agreement Relating To or affecting the average sales price payment methodology as set forth in 42 U.S.C. § 1395w-3a, including, but not limited to the valuation of intra-company transfer prices for the purposes of calculating, or determining payment of, the Manufacturer's Average Sales Price for Venofer.

K. "License Agreement" means the "License, Distribution, Manufacturing and Supply Agreement by and between Luitpold Pharmaceuticals, Inc., American Regent, Inc. and Fresenius USA Manufacturing, Inc. July 8, 2008," attached as Confidential Exhibit A to this Order. For purposes of this Order, the License Agreement includes sales and distribution contracts between Respondent Daiichi and its Venofer customers that have or will be assumed and serviced by Respondent Fresenius.

L. "Manufacturer's Average Sales Price" has the same meaning as that in 42 U.S.C. § 1395w-3a(c), including any supplements, modifications, amendments, or changes, thereto, and any HHS or CMS guidance, ruling, statement of policy, or agreement relating thereto.

M. "Material Confidential Information" means competitively sensitive, proprietary, and all other information that is not in the public domain owned by or pertaining to a Person or a Person's business, and includes, but is not limited to, all customer lists, price lists, contracts, cost information, marketing methods, patents, technologies, processes, or other trade secrets.

N. "Person" means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, division, or department, including HHS and CMS, or other business or legal entity.

O. "Relating To" means pertaining in any way to, and is not limited to that which pertains exclusively to or primarily to.

P. "Venofer" means a drug product covered by NDA 21-135, in all dosage forms, formulations, line extensions and package configurations and comprising iron sucrose as an active ingredient, used for the treatment of anemia in end stage renal disease kidney dialysis

patients, and any improvements to such formulations or dosages as hereafter may be developed and marketed, and including any next generation parenteral iron product, including VIT-45 (ferric carboxymaltose) that may be developed and marketed in the United States.

II.

IT IS FURTHER ORDERED that:

A. Respondent Fresenius shall:

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comply with, or CMS's ability to enforce, such Change. *PROVIDED, FURTHER, HOWEVER*, that before Respondent Fresenius' obligations under Paragraph II.A. terminate, Respondent Fresenius (1) shall receive a statement from CMS notifying Respondent Fresenius that the Change now regulates Respondent Fresenius' calculation of the value of intra-company transfers of Venofer to Fresenius Clinics for purposes of reporting the Manufacturer's Average Sales Price for Venofer to CMS, and (2) shall have complied with the reporting requirements of Paragraph VII.

B. Respondent Fresenius shall not, directly or indirectly

V.

IT IS FURTHER ORDERED that [redacted]

opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff

B. Within thirty (30) days after Respondent Fresenius terminates its reporting of the Manufacturer's Average Sale Price of Venofer to CMS, Respondent Fresenius shall submit to the Commission a written report detailing the circumstances of such termination. Respondent Fresenius shall include in such report a written statement from CMS documenting the termination of its reporting of the Manufacturer's Average Sale Price for Venofer to CMS.

C. Within ten (10) days after the United States Food and Drug Administration has approved a generic Venofer ANDA, Respondent Fresenius shall submit to the Commission and CMS a report stating that the ANDA was approved.

D. Within ten (10) days after Respondent Fresenius sells Venofer to a purchaser at a price pursuant to Paragraph II.A.2.b., Respondent Fresenius shall submit to the Commission and CMS a report stating:

1. the price it is charging for Venofer to a purchaser pursuant to Paragraph II.A.2.b., and

2. when it began selling Venofer at that price.

The reporting requirements of this Paragraph VII.C. shall apply every time Respondent Fresenius changes the price it is selling Venofer to a purchaser pursuant to Paragraph II.A.2.b.

E. If, pursuant to Paragraph II.A.2.b., Respondent Fresenius changes how it reports the price of each intra-company transfer described in Paragraph II.A.1, for purposes of calculating the Manufacturer's Average Sales Price for Venofer, then by January 10, 2012, Respondent Fresenius shall submit to the Commission and CMS a report stating when and if Respondent will revert to the obligations in Paragraph II.A.2.a.

F. Within thirty (30) days after any Change as described in Paragraph II.A. of this Order and before Respondent Fresenius terminates its obligations under Paragraph II.A., Respondent Fresenius shall submit to the Commission a written report detailing the circumstances of such Change and an explanation of why such Change supercedes Respondent Fresenius' obligations pursuant to Paragraph II.A. of this Order. Such report shall include a statement from CMS notifying Respondent Fresenius that the Change now regulates Respondent Fresenius' calculation of the Manufacturer's Average Sales Price for Venofer to CMS.

G. Beginning twelve (12) months after the date this Order becomes final, and annually thereafter on the anniversary of the date this Order becomes final, until the Order terminates, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which the Respondent is complying and has complied with this Order. Respondent Fresenius shall submit at the same time a copy of these reports to the Monitor, if any Monitor has been appointed.

CONFIDENTIAL EXHIBIT A

[Redacted From Public Record Version But Incorporated By Reference]

CONFIDENTIAL EXHIBIT B

[Redacted From Public Record Version But Incorporated By Reference]