

PUBLIC VERSION

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

COMMISSIONERS: Edith Ramirez
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of)
)
)
 SCHERING-PLOUGH CORPORATION,) **Docket No. C-4268**
 a corporation.)
)
 and)
)
 MERCK & CO., INC.,)
 a corporation.)

**APPLICATION FOR APPROVAL OF THE SALE OF THE BARCELONETA
MANUFACTURING FACILITY TO MERIAL BARCELONETA LLC**

FRIED, FRANK, HARRIS, SHRIVER & JACOBSON, LLP
801 17th Street, N.W.
Washington, DC 20006

Counsel for Merck & Co., Inc.

PUBLIC VERSION

TABLE OF CONTENTS

	PAGE
I. INTRODUCTION	1
II. RELEVANT BACKGROUND	2
A. The Order	2
B. Merck’s Supply Relationship with Merial	3
C. The Barceloneta Manufacturing Facility	4
III. THE PROPOSED TRANSACTION SATISFIES THE PURPOSE AND OBJECTIVES OF THE ORDER AND RAISES NO COMPETITIVE ISSUES	5
A. The Transaction Raises No Competition Concerns	5
B. The Transaction Will Grant Certainty and Control to Merial Over its Own Supply Requirements for the Heartgard® Products	5
C. The Agreement Provides Merial With All Necessary Assets and Ancillary Support to Be A Viable, Independent Competitor with Respect to the Heartgard® Products	6
1. Physical Assets.....	6
2. Contracts	7
3. Permits and Other Government Approvals.....	7
4. Employees and Personnel Files	7
5. Know-How.....	8
6. All Inventory and Maintenance Stores	8
7. Transition Services Agreement (“TSA”).....	8
IV. REQUEST FOR EXPEDITIOUS APPROVAL.....	9
V. REQUEST FOR CONFIDENTIAL TREATMENT	9

PUBLIC VERSION

ANNEX INDEX

Asset Purchase Agreement.....A

PUBLIC VERSION

I. INTRODUCTION

Pursuant to Section 2.41(f) of the Federal Trade Commission (the “**FTC**” or the “**Commission**”) Rules of Practice and Procedure¹ and Paragraph III of the Decision and Order issued by the Commission in this matter on October 29, 2009 (the “**Order**”),² Merck & Co., Inc. (“**Merck**”) hereby petitions the Commission to approve the sale of the assets and properties held and used by Merck in connection with the manufacture of Heartgard® and Heartgard Plus® (together, the “**Heartgard® Products**”), including the real estate property and improvements located at State Road #2, Kilometer 56.7, Barceloneta, Puerto Rico (the “**Barceloneta Manufacturing Facility**”) to Merial Barceloneta LLC (“**Merial**”) (a subsidiary of Merial Inc.) (the “**Transaction**”) pursuant to the Asset Purchase Agreement between MSD International GmbH (Puerto Rico Branch) LLC (a wholly-owned indirect subsidiary of Merck) and Merck Sharp & Dohme De Puerto Rico, Inc. (a wholly-owned indirect subsidiary of Merck), and Merial (the “**Agreement**”), attached as Annex A.

The proposed sale to Merial of the Barceloneta Manufacturing Facility used by Merck to supply the Heartgard® Products to Merial will accomplish the purpose and objectives of the Order. The Order incorporated a Supply Agreement,³ which required Merck to temporarily supply the Heartgard® Products to Merial to ensure that Merial would remain a “viable and effective competitor that is independent of the Respondents in the research, development,

¹ 16 C.F.R. § 2.41(f).

² Capitalized terms used, but not otherwise defined, herein have the meaning set forth in the Decision and Order, In the Matter of Schering-Plough Corporation and Merck & Co., Inc. (Oct. 29, 2009).

³ Specifically, the Order incorporated the Merck Supply Agreement dated May 23, 1997 through Amendment No. 8.

PUBLIC VERSION

manufacture, marketing, and sale of the Animal Health Products.”⁴ The Transaction will sever the supply relationship between two animal health competitors, allow Merial to obtain certainty and control over its own supply of the Heartgard® Products, and achieve the Commission’s objective that Merial be completely independent of Merck. The Transaction will include all physical assets, contracts, permits (to the extent transferrable) and other government approvals, employees and personnel files, know-how, inventory and maintenance stores, and ancillary support necessary to ensure that Merial will be an independent, viable, and effective competitor for the sale of Animal Health Products.

For the reasons set forth above, and as explained in greater detail below, Merck respectfully requests that the Commission approve the proposed sale of the Barceloneta Manufacturing Facility to Merial.

II. RELEVANT BACKGROUND

A. The Order

On March 6, 2009, Schering-Plough Corporation (“**Schering-Plough**”) and Merck (together, the “**Respondents**”) entered into an Agreement and Plan of Merger whereby Schering-Plough proposed to acquire Merck and to maintain the surviving entity under the Merck name (the “**Acquisition**”). The FTC filed a complaint on October 29, 2009 alleging that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended,⁵ and Section 5 of the Federal Trade Commission Act, as amended,⁶ “by lessening competition in the market for the manufacture and sale of NK1 receptor antagonists for CINV and PONV in

⁴ Order, Paragraph II.D.3.

⁵ 15 U.S.C. § 18.

⁶ 15 U.S.C. § 45.

PUBLIC VERSION

humans and the manufacture and sale of numerous animal health products in the United States, including live poultry vaccines, killed poultry vaccines and cattle gonadotropins.”⁷ The Heartgard® Products, which are Ivermectin-based products used to treat heartworms in companion animals, were not among the Animal Health Products identified as raising any competitive concerns by the Acquisition.

On October 29, 2009, Respondents and the Commission entered into an Agreement Containing Consent Order that included the Order to settle the Commission’s allegations. To address the Commission’s concerns relating to Respondents’ animal health businesses, the Order required Merck to divest its interest in Merial Limited (a subsidiary of Merial Inc.), an animal health joint venture in which Merck was a 50% owner, to its joint venture partner, Sanofi-Aventis S.A. (“**Sanofi**”).

On September 18, 2009, prior to the entry of the Order and with the approval of the Commission, Merck sold its interest in Merial to Sanofi. The divestiture eliminated all animal health overlaps between Merck and Schering-Plough and thereby resolved all competition concerns relating to Animal Health Products raised by the Acquisition as alleged by the Commission. Merck and Schering-Plough consummated the Acquisition on November 3, 2009.

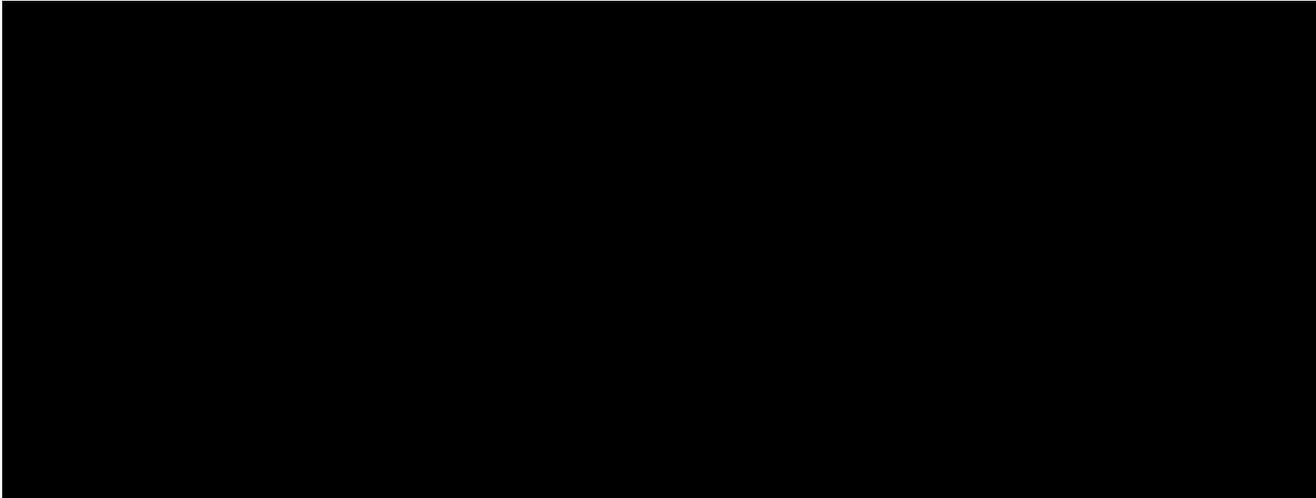
B. Merck’s Supply Relationship with Merial

Prior to the Acquisition, Merck manufactured and supplied the Heartgard® Products to Merial using the Barceloneta Manufacturing Facility. Notwithstanding the divestiture of Merck’s interest in Merial Limited, the Order required Merck to continue supplying the Heartgard® Products to Merial for a limited period to allow time for Merial to transition its

⁷ Analysis of Agreement Containing Consent Order to Aide Public Comment, *In the Matter of Schering-Plough Corporation and Merck & Co., Inc.*, File No. 091-0076 (Oct. 29, 2009).

PUBLIC VERSION

supply requirements to another provider. Merck’s temporary obligation to supply Merial with the Heartgard® Products after the Acquisition was memorialized in the Supply Agreement, which was incorporated into the Order as a Remedial Agreement.



C. The Barceloneta Manufacturing Facility

Merck has supplied Merial with the Heartgard® Products using the Barceloneta Manufacturing Facility since 1989.⁹ At this time, Merck does not use the Barceloneta Manufacturing Facility to supply itself or any other entity with any other product, animal health-related or otherwise. The Heartgard® Products are the only products manufactured at the Barceloneta facility. All units of the Heartgard® Products manufactured at the Barceloneta Manufacturing Facility are sold directly to Merial. The Barceloneta Manufacturing Facility has never, and currently does not, manufacture any units of the Heartgard® Products for sale by Merck, in generic form or otherwise. The Transaction for which approval is sought would result

8



9



PUBLIC VERSION

in the transfer to Merial of the very assets that Merck currently uses to manufacture the Heartgard® Products on behalf of Merial.

III. THE PROPOSED TRANSACTION SATISFIES THE PURPOSE AND OBJECTIVES OF THE ORDER AND RAISES NO COMPETITIVE ISSUES

A. The Transaction Raises No Competition Concerns

The Animal Health Products raising competition concerns that were identified in the Complaint and subject to remedial action set forth in the Order related to poultry vaccines and cattle gonadotropins. The Acquisition did not raise any competition concerns relating to Animal Health Products that are used to treat heartworms in companion animals, such as the Heartgard® Products. This Transaction, for which prior approval is sought, likewise does not raise any competition concerns relating to the Heartgard® Products (or any other Animal Health Products). The Transaction is a sale of manufacturing and related assets; it does not involve any competing products and it will not result in any change in market concentration for any putative relevant market in which the Heartgard® Products compete. Indeed, the result of the Transaction will be an improvement of the *status quo* as Merial will no longer rely on a competitor for its supply requirements for the Heartgard® Products.

B. The Transaction Will Grant Certainty and Control to Merial Over its Own Supply Requirements for the Heartgard® Products

The supply obligations for the Heartgard® Products set forth in the Supply Agreement, and incorporated into the Order, were imposed on Merck to ensure that Merial would remain a “viable and effective competitor that is independent of the Respondents in the research, development, manufacture, marketing and sale of the Animal Health Products.” Neither the Order nor the Supply Agreement, however, contemplated an indefinite supply relationship between Merck and Merial. Indeed, the FTC’s policy typically is to limit the entanglements between competitors in this situation. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The ideal long-term supplier of the Heartgard® Products to Merial is Merial itself, which is best positioned to know its own cost structure and output requirements. The Transaction will give Merial complete certainty of supply and total control over the cost and production of its own product.

C. The Agreement Provides Merial With All Necessary Assets and Ancillary Support to Be A Viable, Independent Competitor with Respect to the Heartgard® Products

1. Physical Assets

The Transaction will include all of the physical assets needed for Merial to become the manufacturer of the Heartgard® Products. The transaction will include all of the buildings, structures, fixtures, and other improvements to the property, except for certain structures unrelated to the manufacture of the Heartgard® Products that Merck has agreed to demolish at Merial's request.¹⁰ The demolition of these structures will not in any way impede Merial from immediately supplying itself with the Heartgard® Products. In addition, the sale will also transfer all tangible personal property needed for the manufacture of the Heartgard® Products, including vehicles, forklifts, equipment, machinery, tools, furnishing, computers, and other tangible property at the Barceloneta Manufacturing Facility.

¹⁰ At the request of Merial, Merck has agreed to demolish certain physical assets at the Barceloneta Manufacturing Facility unrelated to the production of the Heartgard® Products.

PUBLIC VERSION

2. Contracts

The Transaction will include the contracts relating exclusively to the manufacture of the Heartgard® Products or the Barceloneta Manufacturing Facility, to the extent that such contracts are immediately assignable. Contracts that are not immediately assignable are not critical to the operation of the Barceloneta Manufacturing Facility, and the parties have agreed to work cooperatively to transfer those contracts as expeditiously as possible. No contract that is not immediately assignable will impede Merial's ability to immediately commence supplying itself with the Heartgard® Products.

3. Permits and Other Government Approvals

The Transaction will include all permits, authorizations, licenses, franchises, plans, approvals, and any other similar documents issued or granted by a Governmental Authority, as defined in the Agreement (“Permits”), to the extent that such Permits are assignable. For those Permits that are non-assignable and require new applications, and to account for any time required to transfer assignable Permits, [REDACTED]

[REDACTED] The inability of the parties to immediately transfer all existing Permits will not impede Merial's ability to immediately commence supplying itself with the Heartgard® Products.

4. Employees and Personnel Files

Merial has determined the specific employees necessary for its continued, uninterrupted operations at Barceloneta. These employees are listed in Schedule C of the Agreement and will transfer to Merial with the sale of the Barceloneta Manufacturing Facility.

PUBLIC VERSION

5. Know-How

To ensure that Merial will be able to seamlessly continue the production of the Heartgard® Products, the Agreement confers to Merial all necessary Know-How. Know-How is defined to include Merck’s owned trade secrets, know-how, technology, improvements, and inventions used exclusively in the manufacture of the Heartgard® Products. These assets are intended to ensure that Merial is equipped to continue production post-sale without interruption.

6. All Inventory and Maintenance Stores

The Agreement provides for the transfer of all current Inventory and “M&M Stores.” Inventory is defined to include all raw materials, finished goods, stored fuel, and consumables used in the production of the Heartgard® Products and located at the Barceloneta Manufacturing Facility at the time of Closing. M&M Stores is defined to include all mechanical stores and maintenance, repair, and operating parts and materials located at the Barceloneta Manufacturing Facility at the time of Closing.

7. Transition Services Agreement (“TSA”)

To ensure that operations are smoothly transitioned, Merck also has agreed to provide transition services to Merial for a period of up to [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The parties believe that the Transition Services Agreement provides Merial with the necessary support to ensure that it will be successful in manufacturing the Heartgard® Products at the outset of its ownership.

PUBLIC VERSION

IV. REQUEST FOR EXPEDITIOUS APPROVAL

For the reasons discussed herein, Merck respectfully requests that the Commission approve the proposed sale of the Barceloneta Manufacturing Facility to Merial, as described in the attached Agreement, as soon as practicable after expiration of the public comment period.

V. REQUEST FOR CONFIDENTIAL TREATMENT

This application, including the attached Agreement and related documents, contains certain confidential and competitively-sensitive business information relating to the sale of the Barceloneta Manufacturing Facility. Disclosure of such confidential information may prejudice Merck and Merial, and cause harm to the ongoing competitiveness of both companies. Pursuant to Sections 2.41(f)(4) and 4.9(c) of the FTC's Rules of Practice and Procedure,¹¹ Merck has redacted such information from the public version of this application, and requests confidential treatment for such information under Section 4.10(a)(2) of the FTC's Rules of Practice and Procedure¹² and Sections 552(b)(4) and (b)(7) of the Freedom of Information Act.¹³ In the event that a determination is made that any material marked as confidential is not subject to confidential treatment, Merck requests that the FTC provide immediate notice of that determination and adequate opportunity to appeal such a decision.

¹¹ 16 C.F.R. §§ 2.41(f)(4) and 4.9(c).

¹² 16 C.F.R. § 4.10(a)(2).

¹³ 5 U.S.C. §§ 552(b)(4) and 552(b)(7).

PUBLIC VERSION

Respectfully submitted,



Richard C. Park
Maria R. Cirincione
Fried, Frank, Harris, Shriver, & Jacobson, LLP
801 17th Street, N.W.
Washington, DC. 20006

Counsel for Merck & Co., Inc.

Dated: December 12, 2014

PUBLIC VERSION

ANNEX A

The Asset Purchase Agreement

[Redacted from Public Version]