UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Terrell McSweeny

	)
In the Matter of	)
	)
HIKMA PHARMACEUTICALS PLC,	)
a corporation;	)
	)
and	)
	)

The Commission having thereafter considered the matter and having 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, and having accepted the executed Consent Agreement and placed 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 the following Decision and Order ("Order"):

1. Respondent Hikma is a corporation organized, existing and doing business under and by virtue of the laws of England and Wales with its principle executive offices located at 13 Hanover Square, London W1S 1HW, United Kingdom and its United States address for service of process and the Complaint and Decision and Order, as follows: General Counsel, Hikma Pharmaceuticals PLC, c/o: West-Ward Pharmaceuticals, 401 Industrial Way West, Eatontown, NJ 07724.

2. Respondent C.H. Boehringer Sohn AG & Co. KG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany with its principle executive offices located at Binger Strasse 173, 55216 Ingelheim, Germany and its United States address for service of process and the Complaint and Decision and Order, as follows: Corporate Secretary, 900 Ridgebury Road, Ridgefield, Connecticut 06877.

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

ORDER

I.

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

A. "Hikma" means Hikma Pharmaceuticals, PLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Hikma Pharmaceuticals, PLC

D. "Commission" means the Federal Trade Commission.

E. "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

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.

F. "Acquisition" means Respondent Hikma's acquisition of certain assets of Respondent Boehringer pursuant to the Acquisition Agreement.

G. "Acquisition Agreement" means the Asset Purchase Agreement dated December 4, 2014, by and among Ben Venue Laboratories, LLC (as successor to Ben Venue Laboratories, Inc.), Boehringer Ingelheim Corporation, and Hikma Pharmaceuticals PLC, to effect the Acquisition among Hikma and Boehringer that was submitted to the Commission.

H. "Acquisition Date" means the date on which the Acquisition is consummated.

I. "Acyclovir Sodium Injection Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No. 074596, and any supplements, amendments, or revisions thereto.

J. "Acyclovir Sodium Injection Product Assets" means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Acyclovir Sodium Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Acyclovir Sodium Injection Products

Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. The term "Application" also includes an "Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

N. "Boehringer Transferred Assets" means the Transferred Assets that are included in the assets to be transferred by Ben Venue Laboratories, LLC to Respondent Hikma pursuant to the Acquisition Agreement.

O. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.

P. "Categorized Assets" means the following assets and rights of the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), as such assets and rights are in existence as of the date the Respondents sign15.37 0 Td ( )Tj -0.004 Tc 0.

sale or marketing of the specified Divestiture Product except for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and except as may be required by applicable Law and except as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;

b. to prohibit Respondents from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s) except for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and except as may be required by applicable Law;

c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondents of any such cross-referencing that is discovered by a Respondent);

d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;

e. to approve the timing of Respondents' discontinued use of those ND1 Numbers in the sale or -0.036 -1Tw 2.4 02.4 2(um)0Tw 29.6 -1Tw/or such Divestiture Pr

Intellectual Property;

provided further, 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 Divestiture Product and to Retained Products or Businesses of any Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, the specified Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the specified Respondent shall provide th

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Product(s); 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.

U. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval

The Divestiture Agreements are the means by which Hikma proposes to divest, transfer,

Respondent.

CC. "Divestiture Product Releasee(s)" means the following Persons:

1. the Acquirer for the assets related to a particular Divestiture Product;
2. any Person controlled by or under common control with that Acquirer; and
3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.

DD. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.

EE. "Domain Name" means the domain name(s) (universal 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.

FF. "Drug Master File(s)" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

GG. "Famotidine Injection Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No.'s 075825, 075684, 075622, and 075651, and any supplements, amendments, or revisions thereto.

HH. "Famotidine Injection Product Assets" means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Famotidine Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Famotidine Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.

II. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions.

JJ. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.

KK. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from the Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition

Date; (iii

VV. “Product 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 research, Development, manufacture,

and/or

13. pursuant to which any Third Party collaborates with a Respondent in the performance of research, Development, marketing, distribution or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), the Respondents 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 Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

XX. "Product Copyrights" means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product's sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and data contained in electronic databases (including

to the specified Divestiture Product;

4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;

5. annual and periodic reports related to the above-described Application(s), including any safety update reports;

6. FDA approved Product labeling related to the specified Divestiture Product;

7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;

8. FDA approved patient circulars and information related to the specified Divestiture Product;

9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;

10. summary of Product complaints from physicians related to the specified Divestiture Product;

11. summary of Product complaints from customers related to the specified Divestiture Product;

12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;

13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;

14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to .to2 t or 6(ge)4(d t)-2(o .,pi1(i)-6(cac)-20 a)4(n)-od /H3 <</MCID 11 >>B

ZZ. "Product Intellectual Property" means all of the following intellectual property related to a Divestiture Product (other than Product Licensed Intellectual Property) that is owned, licensed or controlled by Respondents as of the Closing Date:

1. Patents;
2. Product Copyrights;
3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

provided, however, that "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Hikma", or "Boehringer", or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondents or the related corporate logos thereof, or general registered images or symbols by which Hikma, or Boehringer can be identified or defined.

AAA. "Product Licensed Intellectual Property" means the following:

1. all of the following intellectual property related to a Divestiture Product that is owned, licensed or controlled by Respondents as of the Closing Date, as follows:
    a. Patents that are related to a Divestiture Product that the Respondents can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date;
    b. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that the Respondents can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and
2. in those instances in which Respondents (i) are the holder of an NDA for a Product that is the Therapeutic Equivalent of any Divestiture Product that is the subject of an ANDA, (ii) the NDA is not subject to an exclusive license to a Third Party, and (iii) the Product subject to such NDA is a Retained Product, a full, complete and unlimited Right of Reference or Use to the Drug Master File related to the NDA for this Retained Product to reference or use in any Application related to that

Divestiture Product.

BBB. "Product Manufacturing Technology" means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;

2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients or packaging materials; and

3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture that Product.

CCC. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (e.g, detailing reports, vendor lists, sales data), marketing information (e.g., competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.

Product.

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

1. any agreement between a Respondent(s) 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, 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(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture Product 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(s) 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(s) to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

4. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture Product 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.

HHH. "Retained Product" means any Product(s) other than a Divestiture Product.

III. "Right of Reference or Use" means the authority to rely upon, and otherwise use, (i) an investigation of the quality, safety or efficacy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, or *in silico* and any and all Clinical Trials), (ii) Product Development Reports, or (iii) Product Scientific and Regulatory Material for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.

JJJ. "Technology Transfer Standards" means requirements and standards sufficient to ensure

that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (i.e., ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, inter alia,

1. designating employees of the Respondent(s) knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the

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manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No. 076295, and any supplements, amendments, or revisions thereto.

OOO. "Valproate Sodium Injection Product Assets" means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Valproate Sodium Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Valproate Sodium Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.

PPP. "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 Divestiture Products.

II.

following:

a.

responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).

G. Not later than thirty (30) days after the Closing Date, Respondent

competitiveness of the Divestiture Product Assets.

J. Respondent Hikma shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer under the following:

1. any Patent owned by or licensed to Respondent Hikma as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to Respondent Hikma at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following(s)-TJ 0 Tc 0 Tw [(RTj -0.003 Tc 0.003 Tw [(o)-1i -0.004 Tc 0.004

United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.

L. For any patent infringement suit filed prior to the Closing Date in which any Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that any Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of such Divestiture Product(s), that Respondent shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;

2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and

3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of that Respondent's outside counsel related to that Divestiture Product.

M. The purpose of the divestiture of the Divestiture Product 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 Divestiture Product within the Geographic Territory; and

2. to create a viable and effective competitor, that is independent of Respondents

III.

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 Agreement Containing Consent Order, and the Remedial Agreements.

B. The Commission shall select the Monitor, subject to the consent of Respondent Hikma, which consent shall not be unreasonably withheld. If Respondent has 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 Respondent of the identity of any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.

C.

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.

IV.

IT IS FURTHER ORDERED that:

A. If Respondents have not fully complied with the obligations to assign, grant, license, maintain, divest, transfer, deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, remediate, 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, remediate, 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 Respondents to comply with this Order.

Divestiture Trus

orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

V.

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 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 V pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, however, that pursuant to this Paragraph V, the 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 relevant 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.

VI.

IT IS FURTHER ORDERED that:

A. Any Remedial Agreement shall be

D. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products 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.

VII.

IT IS FURTHER ORDERED that:

A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II.A., II.B., II.C., II.D., II.G., II.H., and II.I, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondents shall submit at the same time a copy of its report concerning compliance with this Order to the Monitor, if any Monitor has been appointed. 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 Order, 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 the Respondents to the relevant Acquirer, and
2. a detailed description of the timing for the completion of such obligations.

C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent Hikma 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.

VIII.

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

A. any proposed dissolution of Respondent;

B. any proposed acquisition, merger or consolidation of Respondent; or

C. any other change in 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.

IX.

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 Respondent Hikma made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent related to compliance with this Order, which copying services shall be provided by Respondent at the request of the authorized representative(s) of the Commission and at the expense of Respondent; and

B.

NON-PUBLIC APPENDIX I

Asset Purchase Agreement by and between Hikma Pharmaceuticals PLC and Amphastar Pharmaceuticals, Inc. dated December 31, 2015.

NON-PUBLIC APPENDIX II

Asset Purchase Agreement among Ben Venue Laboratories, Inc., Boehringer Ingelheim Corporation, and Hikma Pharmaceuticals, dated December 4, 2014.