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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

In the Matter of	**)**	
	)	**Docket No. C- 4568**

1. Respondent Hikma i

C. “Acquirer(s)” means the following:

1.

e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture 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; and

f. to [illegible] notification(s) [illegible]

Respondent has a legal obligation to retain the original copies, the 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 Respondent shall provide that 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 Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

J. "cGMP" means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

K. "Clinical Trial(s)" means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.

L. "Closing Date" means, as to each Divestiture Product, the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.

M. "Confidential Business Information" means all information owned by, or in the possession or control of, the Respondent that is not-1.17 Td [t5t5tetce normr i aet, t dat i-2(,)]TJ 0.006

N. "Contract Manufacture" means the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;

2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent of, and in the identical dosage strength, formulation, and presentation as, a Contract Manufacture Product on behalf of an Acquirer; or

3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

O. "Contract Manufacture Product(s)" means:

1. Lithium Products;

2. Prednisone Products; and

3. any ingredient, material, or component used in the manufacture of the foregoing Products including the active pharmaceutical ingredient(s), excipient(s), or packaging materials (including, without limitation, drug vials);

provided, however, that with the consent of the Acquirer of the specified Product, the Respondent may substitute a Therapeutic Equivalent form of such Product in performance of that Respondent's agreement to Contract Manufacture.

P. "Development" means all preclinical and clinical drug development activities, 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 and registration; and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

Q. "Direct Cost" means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Acquirer for its use of any of the Respondent's employees' labor shall not exceed the average hourly wage rate for such employee;

provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Direct Cost" means such cost as is provided in such Remedial Agreement for that Divestiture Product.

R. “Divestiture Product(s)” means the following, individually and collectively:

1. Lithium Products;
2. Flecainide Products; and
3. Prednisone Products.

S. “Divestiture Product Assets” means the following, individually and collectively:

1. Lithium Product Assets;
2. Flecainide Product Assets; and
3. Prednisone Product Assets.

T. “Divestiture Product Core Employees” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Contract Manufacture Product.

U. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up, and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that wa(U.)Tj ”

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

X. "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.

Y. "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.

Z. "Geographic Territory" means the United States of America, including all of its territories and possessions, unless otherwise specified.

AA. "Flecainide Product(s)" means all Products in Development by Unimark that are orally administered tablets containing, as an active pharmaceutical ingredient, flecainide acetate, at the following strengths: 50mg, 100mg, and 150mg.

BB. "Flecainide Product Assets" means all rights to develop, manufacture, market, commercialize, sell, or distribute the Flecainide Products.

CC. "Flecainide Product Divestiture Agreements" means:

1. *Flecainide Agreement* between Unimark Remedies Limited and West-Ward Pharmaceuticals Corp., dated as of December 13, 2015;
2. *Termination of Share Subscription and Shareholder's Agreement* from Hikma Pharmaceuticals LLC to Unimark Remedies Limited, dated as of March 10, 2016;
3. *Termination of Product Development, Manufacturing, Supply and Marketing Agreement* from West-Ward Pharmaceutical Corporation to Unimark Remedies, dated as of March 10, 2016;
4. *Share Purchase Agreement* amongst Royal Star Limited and Hikma Pharmaceuticals LLC and Unimark Remedies Limited, dated as of March 10, 2016; and
5. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted with the foregoing listed agreements.

The Flecainide Product Divestiture Agreements are contained in Non-Public Appendix II. The Flecainide Product 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.

DD. "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.

EE. "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

1. any voting or non-voting stock, share capital, equity, other interests, or beneficial ownership in a specified entity; or
2. any notes or options convertible into any voting or non-voting stock in a specified entity.

PP. "Patent(s)

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets

7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of Respondent;

8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to the Respondent;

9. pursuant to which a Third Party is licensed by the Respondent to use the Product Manufacturing Technology;

10. constituting confidentiality agreements involving the specified Divestiture Product;

11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;

12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to the Respondent including, but not limited to, consultation arrangements; and/or

13. pursuant to which any Third Party collaborates with the 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 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 Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

XX. "Product Copyrights" m

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 all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

YY. "Product Development Reports" means:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including reference listed drug information) related 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, and descriptions of material

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14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including, without limitation, identification and sources of impurities;

15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of the specified Divestiture Product;

16. analytical methods development records related to the specified Divestiture Product;

17.

3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

AAA. "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 the Respondent 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 violation of any of the foregoing;

provided, however, that "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Hikma" 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 Respondent or the related corporate logos thereof; or general registered images or symbols by which Hikma can be identified or defined.

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

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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.

FFF. "Product Research and Development Employees" means all salaried employees of the Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

GGG. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information.

HHH. "Product Trade Dress" means the current trade dress of a Product, including but not limited to, Product packaging and the lettering of the Product trade name or brand name.

III. "Product Trademrodem08 - 0.05(26.j 0.45 0 Td ( )T Td ( )TjTd [(m)8(e)-6(a)-6(ns)9(t(r)9(o)16(d)

3. any agreement between the 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 or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

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

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1. designating employees of the Respondent 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 processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
3.

UUU. "Unimark Supplementary Agreement" means the *Supplementary Agreement* between Unimark Remedies Limited and West-Ward Pharmaceutical Corporation, dated as of February 18, 2016. The Unimark Supplementary Agreement relates and refers to the Unimark Product Development Agreement. The Unimark Supplementary Agreement is contained in Non-Public Appendix II.

VVV. "Unimark Share Subscription and Shareholders' Agreement" means the *Share Subscription and Shareholders' Agreement* between Hikma Pharmaceuticals LLC and Unimark Remedies Limited and The Promoters of Unimark Remedies Limited, dated as of April 13, 2011. The Unimark Share Subscription and Shareholders' Agreement is contained in Non-Public Appendix II.

WWW. "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 the Respondent; *provided, however*, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Acquisition Date, Respondent shall divest the Prednisone Product Assets and the Lithium Product Assets and grant the related Divestiture Product Licenses, absolutely and in good faith, to Renaissance pursuant to, and in accordance with, the Prednisone/Lithium Product Divestiture Agreements (which

provided further, however, that if Respondent has divested the Prednisone Product Assets and the Lithium Product Assets to Renaissance

a. acquire any additional Ownership Interest in Unimark;

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6. not provide, disclose or otherwise make available, directly or indirectly, any

2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s) supplied by the Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the

5. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Monitor (if any has been appointed), make available to the Acquirer and the Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;

6. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);

7. in the event Respondent becomes (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer and (ii) that Product is the subject of an ANDA: provide Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondent uses or has used to source its own supply of the Product that is the Therapeutic Equivalent of the Contract Manufacture Product, where such facility(ies) is still suitable for use for such manufacturing;

8. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture; and

9. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products.

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H. Respondent shall require, as a condition of continued employment post-divestiture of the Divestiture Product Assets, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has 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 the Respondent (other than as necessary to comply with the requirements of this Order).

I. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the relevant Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer'e.

5. for a period of one (1) year after the Closing Date, not: (i) directly or indirectly

L. Respondent 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:

1. under any Patent owned by or licensed to the Respondent 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; or

2. under any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the Respondent 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: (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 Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America. The Respondent shall also covenant to that Acquirer that as a condition of any assignment or license from the Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the res9(u5a)]TJ -0.01 Tc 0.01 Twcw
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United States of America.

N. For any patent infringement suit filed prior to the Closing Date in which the Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that the 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 Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America, the Respondent shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from the 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 the 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 the Respondent's outside counsel related to that Divestiture Product.

O. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology (for the Contract Manufacture Products) and the related obligations imposed on the Respondent 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;

2. to create a viable and effective competitor that is independent of the Respondent in the Business of each Divestiture Product within the Geographic Territory; 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.

III.

IT IS FURTHER ORDERED that:

A. At any time after the Respondent signs the Consent Agreement in this matter, the

B. The Commission shall select the Monitor, subject to the consent of Respondent, 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. Not later than ten (10) days after the appointment of the Monitor, Respondent 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 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, Respondent shall consent to the following terms and conditions regarding the pa(a)-4(ntio)nnd i

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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, iss

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent 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 submititionsw [(s)tee er terpos.9(It46(s)1( )-1

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

8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

9. Respondent 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.

C. Respondent 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. For each Divestiture Product that is a Contract Manufacture Product, Respondent shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of the Respondent, all as soon as reasonably practicable.

E. 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.

F. 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.

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IT IS FURTHER ORDERED that this Order shall terminate on May 4, 2026.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED: May 4, 2016

NON-PUBLIC APPENDIX I
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE LITHIUM PRODUCTS AND THE PREDNISONE PRODUCTS

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

NON-PUBLIC APPENDIX II
AGREEMENTS RELATED TO THE DIVESTITURE
OF THE FLECAINIDE PRODUCTS

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