0710193

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **William E. Kovacic, Chairman**
Pamela Jones Harbour
Jon Leibowitz
J. Thomas Rosch

)

D. "Acquirer" means the following:

1. an entity specified by name in this Order to acquire particular assets or rights that 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; or

2. an entity approved by the Commission to acquire particular assets or rights that Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

E. "Acquisition" means Respondent Sun's acquisition of shares representing fifty percent (50%) or more of the voting rights in Taro.

F. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").

G. "Application(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug 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, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent and the FDA related thereto. The term "Application" also includes an "Investigational New Drug Application" ("IND") for a Product 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, drafts and data necessary for the preparation thereof, and all correspondence between Respondent and the FDA related thereto.

H. "Carbamazepine Products" means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Sun pursuant to the following of Respondent Sun's ANDAs:

1. Carbamazepine 100 mg chewable tablet, pursuant to ANDA No. 75-712;

2. Carbamazepine 200 mg IR tablet, pursuant to ANDA No. 77-272;

3. Carbamazepine 100 mg ER tablet, pursuant to ANDA No. 78-268;

4. Carbamazepine 200 mg ER tablet, pursuant to ANDA No. 78-268;

5. Carbamazepine 400 mg ER tablet, pursuant to ANDA No. 78-268; and

6. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term "Carbamazepine Products" shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by Sun or Taro for sale within the United States that contain the active pharmaceutical ingredient carbamazepine in the dosages strengths and presentations specified above.

I. "Carbamazepine Product Assets" means all of Respondent Sun's rights, title and interest in and to all assets related to Respondent Sun's business within the Geographic Territory related to the Carbamazepine Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Carbamazepine Products, including, without limitation, the Categorized Assets related to the Carbamazepine Products.

J. "Categorized Assets" means the following assets related to the specified Divestiture Product(s):

1. all Product Intellectual Property related to such Divestiture Product(s);

2. perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property to use, make, distribute, offer for sale, promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported the Divestiture .7(st i)9.7(n)]TJ1.15 o

7. a list of all of the NDC Numbers related to such Divestiture Product(s), and rights, to the extent permitted by Law:

    a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Effective Date;

    b. to prohibit Respondent from seeking from any customer any type of cross-

identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to such Divestiture Product(s);

14. a list of all customers and/or targeted customers for such Divestiture Product(s) and the net sales (in either units or dollars) of such Divestiture Products to such customers on either an a-9mererrer ar a a0ge9b05(a)ed b anr aith ar a a a a0ge9to b1ge9ated3.0006,.5(a)1. se3.0006

Respondent shall provide such Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent provides the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

K. "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.

L. "Closing Date" means, as to each Divestiture Product, the date on which 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, Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of the Divestiture Product(s); *provided however*, that the restrictions contained in this Order regarding the use, conveyance, provision, or disclosure of "Confidential Business Information" shall not apply to the following:

1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondent;

2. information related to the Carbamazepine Products that Taro can demonstrate it obtained without the assistance of Respondent Sun prior to the Acquisition;

3. information that is required by Law to be publicly disclosed;

4. information that does not directly relate to the Divestiture Products;

5. information relating to Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of generic pharmaceutical Products that does not discuss with particularity the Divestiture Products; or

6. information specifically excluded from the Categorized Assets.

N. "Contract Manufacture" means the manufacture of a Divestiture Product to be supplied by Respondent, Taro, or a Designee to an Acquirer.

O. "Designee" means any entity other than Respondent or Taro that will manufacture a Divestiture Product for an Acquirer.

P. "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 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 Respondent's employees' labor shall not exceed the average hourly wage rate for such employee; *provided, however*, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) 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 Products: the Carbamazepine Products.

S. "Divestiture Product Core Employees" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.

T. "Divestiture Product Releasee(s)" means the Acquirer for the assets related to a particular Divestiture Product or any entity controlled by or under common control with such Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Acquirer, or of such Acquirer-affiliated entities.

U. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.

V. "Domain Name" means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any entity or authority that issues and maintains the domain name registration. "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.

W. "Drug Master Files" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

X. "Effective Date" means the date on which the Acquisition occurs.

Y. "Generic Divestiture Product Agreement(s)" means the following agreements:

1. "Asset Purchase Agreement" between Sun Pharmaceutical Industries, Ltd., Caraco Pharmaceutical Laboratories, Ltd., and Torrent Pharmaceutical Ltd., Torrent Pharma, Inc, dated as of July 11, 2008, and all amendments, exhibits, attachments, agreements, and schedules thereto;

2. "Supply Agreement" between Sun Pharmaceutical Industries, Ltd., Caraco Pharmaceutical Laboratories, Ltd., and Torrent Pharmaceutical Ltd., Torrent Pharma, Inc dated as of July 11, 2008, and all amendments, exhibits, attachments, agreements, and schedules thereto;

3. "Quality Agreement" between Sun Pharmaceutical Industries, Ltd., Caraco Pharmaceutical Laboratories, Ltd., and Torrent Pharmaceutical Ltd., Torrent Pharma, Inc dated as of July 11, 2008, and all amendments, exhibits, attachments, agreements, and schedules thereto; and

related to the Carbamazepine Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Generic Divestiture Product Agreements are attached to this Order and contained in non-public Appendix II.A.

Z. "Geographic Territory" shall mean the United States of America (including all of the territories within its jurisdiction or control) unless otherwise specified.

AA. "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.

DD. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

EE. “NDC Numbers” means the National Drug Code number(s), including both the labeler code assigned by the FDA and the additional numbers assigned by the Application holder as a product code for a specific Product.

FF. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.

GG. “Patents” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by Respondent as of the Closing Date (*except* where this Order specifies a different time).

HH. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or Government Entity,

2. pursuant to which Respondent purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) from any Third Party for use in connection with the manufacture of the Divestiture Product(s);

3. relating to any clinical trials involving the Divestiture Product(s);

4. with universities or other research institutions for the use of the Divestiture Product(s) in scientific research;

5. relating to the particularized marketing of the Divestiture Product(s) or educational matters relating solely to the Divestiture Product(s);

6. pursuant to which a Third Party manufactures or packages the Divestiture Product(s) on behalf of Respondent;

7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the Divestiture Product(s) to Respondent;

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

9. constituting confidentiality agreements involving the Divestiture Product(s);

10. involving any royalty, licensing, or similar arrangement involving the Divestiture Product(s);

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

12. pursuant to which any Third Party collaborates with Respondent in the performance of research, Development, marketing, distribution or selling of the Divestiture Product(s) or the Divestiture Product(s) business;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), Respondent shall assign the Acquirer all such rights under the contract or agreement as are related to the Divestiture Product(s), but concurrently may retain similar rights for the purposes of the Retained Product(s).

LL. "Product Copyrights" means rights to all original works of authorship of any kind directly related to the Divestiture Product(s) 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

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

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

9. adverse event/serious adverse event summaries related to the specified Divestiture Product(s);

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

11. summary of Product complaints from customers related to the specified Divestiture Product(s); and

12. Product recall reports filed with the FDA related to the specified Divestiture Product(s).

NN. "Product Employee Information" means the following, for each Divestiture Product Core Employee, as and to the extent permitted by the Law:

1. a complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondent within ninety (90) days of the execution date of any Remedial Agreement);

2. with respect to each such employee, the following information:

    a. the date of hire and effective service date;

    b. job title or position held;

    c. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, Respondent may provide the employee's most recent performance appraisal;

    d. the base salary or current wages;

    e. the most recent bonus paid, aggregate annual compensation for Respondent's last fiscal year and current target or guaranteed bonus, if any;

    f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and

    g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all

b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by

SS. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of a Divestiture Product(s) 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 purchases 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 Divestiture Product(s); provided however, “Product Marketing Materials” excludes the pricing of each of the Divestiture Products to customers.

TT. “Product Research and Development Employees” means all salaried employees of Respondent who directly have participated in the research, Development, or regulatory approval process, or clinical studies of the specified Divestiture Product(s) (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; *provided, however*, that in each instance where: (1) a Carbamazepine Product Divestiture Agreement is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for the Divestiture Products, “Product Research and Development Employees” means the employees as specified in such Remedial Agreement for the Divestiture Products.

UU. “Product Trade Dress” means the current trade dress of the Divestiture Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

VV. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and exl rxl7(us5(a) Tc-ti)oreketingwaeed2ats,

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

1. any agreement between Respondent 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, 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;

2. any agreement between Respondent and a Third Party to effect the assignment of assets or rights of Respondent 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;

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

4. any agreement between Respondent and a Third Party to effect the assignment of assets or rights of Respondent 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.

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

ZZ. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.

AAA. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost in United States dollars of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Divestiture Product.

BBB. “Third Party(ies)” means any private entity other than the following: Respondent, Taro, or the Acquirer for the affected assets, rights and Divestiture Product(s).

provided further that if Respondent has divested the Carbamazepine Product Assets to Torrent prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Carbamazepine Product Assets to Torrent (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

B. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third

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3. make representations and warranties to the Acquirer that Respondent shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondent to deliver the Products in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that its failure was entirely beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent; *provided, however*, that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondent's aggregate liability for such a breach;

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

5. during the term of the Contract Manufacture between Respondent and the Acquirer, maintain manufacturing facilities necessary to manufacture each of the Divestiture Products in finished form, *i.e.*, suitable for sale to the ultimate consumer/patient; and

6. during the term of the Contract Manufacture between Respondent and the Acquirer, provide consultation with knowledgeable employees of Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling the Acquirer (or the Designee of the Acquirer) to obtain all Product Approvals to manufacture the Divestiture Products in the same quality achieved by the Respondent and in commercial quantiated after cetwei,ated (ated aomm)10.6(e)8.6(c)16.6 mann6(n)-..

E. Respondent shall:

1. submit to the Acquirer, at Respondent's expense, all Confidential Business Information related to the Divestiture Products;

2. deliver such Confidential Business Information as follows:

    a. in good faith;

    b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and

    c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

3. pending complete delivery of all such Confidential Business Information to the Acquirer, provide the Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files

F. Respondent shall not enforce any agreement against a Third Party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Acquirer to acquire the Product Manufacturing Technology related to the Divestiture Products or related equipment from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosur(s.1(Dt a Tls2) C9(cl)-9.1(o)-n.1(s)f9(d)-9.1(o)d.1(h)-9.4(o).1(en)-9

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph II.H.3. shall not prohibit Respondent from continuing to employ any Divestiture Product Core Employee under the terms of such employee's employment with Respondent prior to the date of the written offer of employment from the Acquirer to such employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for such Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product(s) has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

   provided, however, that, subject to those conditions of continued employment prescribed in this Order, this Order does not require nor shall be construed to require Respondent to terminate the employment of any employee or to prevent Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the Closing Date, not:

   a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer; or

   b. hire any Divestiture Product Employee; *provided, however*, Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

   provided, however, Respondent may do the following: (1) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (2) hire a Divestiture Product Employee who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent.

I. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each Divestiture Product Core Employee retained by Respondent, the direct supervisor(s) of any such employee, and any other employee retained by Respondent and designated by the Interim Monitor (if applicable) sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).

J. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of Respondent's employees who:

1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of each of the Divestiture Products;

2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient as the Divestiture Products; and/or

3. may have Confidential Business Information related to the Divestiture Products.

Respondent shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondent shall provide a copy of such notification to the Acquirer. Respondent shall maintain complete records of all such agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondent shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

K. Until Respondent completes the divestitures required by Paragraph II.A. and fully transfers the related Product Manufacturing Technology to the Acquirer,

1. Respondent shall take such actions as are necessary to:

a. maintain the full economic viability and marketability of the businesses associated with each Divestiture Product;

b. minimize any risk of loss of competitive potential for such business;

to, or otherwise participate in any litigation related to the Product Intellectual Property related to any of the Divestiture Products, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Carbamazepine Products; or (2) the use, import, export, supply, distribution, or sale of the Carbamazepine Products within the Geographic Territory.

N. For any patent infringement suit in which the Respondent is alleged to have infringed a Patent of a Third Party prior to the Closing Date or for such suit as the Respondent has prepared or is preparing as of the Closing Date to defend against such infringement claim(s), and where such a suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of the Divestiture Products within the Geographic Territory, Respondent shall:

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

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

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

O. Respondent shall not, in the Geographic Territory:

1. use the Product Trademarks related to the Divestiture Products or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;

2. attempt to register such Product Trademarks;

3. attempt to register any mark confusingly similar to such Product Trademarks;

4. challenge or interfere with the Acquirer's use and registration of such Product Trademarks; or

5. challenge or interfere with the Acquirer's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

provided however, that this Order shall not preclude Respondent from continuing to use those trademarks, tradenames, or service marks related to the Retained Products as of the Effective Date.

P. Respondent shall not 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 and/or the remedial purposes thereof.

III.

IT IS FURTHER ORDERED that:

A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and perform all of its responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.

B. The Commission shall select the Interim 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 Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim 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 an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.

3. The Interim Monitor shall serve until the date of completion by Respondent of the divestiture of all Carbamazepine Product Assets and the transfer of the Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:

    (1) with respect to each Divestiture Product, the date the Acquirer (or the Designee(s) of such Acquirer) is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent and Taro;

    (2) with respect to each Divestiture Product, the date the Acquirer notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture such Divestiture Product; or

    (3) with respect to each Divestiture Product, the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture such Divestiture Product;

    provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders;

    provided, further, that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed five (5) years from the Closing Date on the Remedial Agreement(s) to Contract Manufacture such Divestiture Product.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in

6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations 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 Interim Monitor.

7. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order; *provided, however,* beginning one hundred twenty (120) days after Respondent has filed its final report pursuant to Paragraph VI.B., and every one hundred twenty (120) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent and Taro.

8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor'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 Interim Monitor's duties.

F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

H. The Interim 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 Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Carbamazepine Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, 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, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, 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 Respondent to comply with this Order.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.

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 submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; and, *provided further, however*

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

V.

IT IS FURTHER ORDERED that:

With respect to Confidential Business Information, Respondent shall assure that, in any instance wherein its counsel (including in-house counsel under appropriate confidentiality arrangements) either retains unredacted copies of documents or other materials provided to the Acquirer or accesses original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to the Acquirer, that Respondent's counsel does so only in order to do the following:

A. comply 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. 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 assets and businesses associated with those Products; *provided, however*, that Respondent may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

provided, however, that pursuant to this Paragraph V, Respondent shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if the Acquirer withholds such agreement unreasonably); and (2) use its best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

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

B. Within thirty (30) days after the date this Order becomes final, a

approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product and to have any such manufacture to be independent of Respondent and Taro, all as soon as reasonably practicable.

E. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

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 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 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 such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that the purpose of the divestiture of the Carbamazepine Product Assets and the transfer of the Product Manufacturing Technology related to the Carbamazepine Products and the related obligations imposed on the Respondent by this Order is:

A. to ensure the continued use of the Carbamazepine Product Assets in the research, Development, and manufacture of each of the Carbamazepine Products for the purposes of the business associated with each Divestiture Product within the Geographic Territory;

B. to provide for the future use of the Carbamazepine Product Assets for the distribution, sale and marketing of the Carbamazepine Products in the Geographic Territory;

C. to create a viable and effective competitor, who is independent of the Respondent and Taro:

1. in the research, Development, and manufacture of each of the Carbamazepine Products for the purposes of the business associated with each Carbamazepine Product within the Geographic Territory; and

2. the distribution, sale and marketing of the each of the Carbamazepine Products in the Geographic Territory; and,

D. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

XI.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date on which the Order becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED:

NON-PUBLIC APPENDIX II.A.
GENERIC DIVESTITURE PRODUCT AGREEMENTS

[Redacted From Public Record Version But Incorporated By Reference]