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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	)	
TEVA PHARMACEUTICAL INDUSTRIES LTD., **a corporation;**	)	**Docket No. C-4589**
and	)	
ALLERGAN PLC, **a corporation.**	)	

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Teva Pharmaceutical Industries Ltd. ("Teva") of the voting securities of certain entities (defined herein as "Allergan Generic Pharmaceutical Entities") and related assets from their ultimate parent entity, Respondent Allergan plc ("Allergan") (Teva and Allergan hereinafter collectively referred to as "Respondents"), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

B. "Allergan" means: Allergan plc; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Allergan plc, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Commission" means the Federal Trade Commission.

D. "Respondents" means Teva and Allergan, individually and collectively.

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 approv each.l4 T

1. "Betamethasone Dipropionate Product(s)" means the Products manufactured, in Development, marketed, or sold, pursuant to each of the following Applications:

    a. NDA No. 019137, ANDA No. 070885, and any ANDA that relies on NDA No. 019137 as the Reference Listed Drug. These Products are topically administered creams containing, as an active pharmaceutical ingredient, betamethasone dipropionate, at the following strength: EQ 0.05% Base;

    b. ANDA No. 070275, ANDA No. 070281, and any ANDA that relies on ANDA No. 070275 as the Reference Listed Drug. These Products are topically administered lotions containing, as an active pharmaceutical ingredient, betamethasone dipropionate, at the following strength: EQ 0.05% Base;

    c. NDA No. 019141, ANDA No. 071012, and any ANDA that relies on NDA No. 019141 as the Reference Listed Drug. These Products are topically administered ointments containing, as an active pharmaceutical ingredient, betamethasone dipropionate, at the following strength: EQ 0.05% Base; and

    d. NDA No. 018741, ANDA No. 074304, and any ANDA that relies on NDA No. 018741 as the Reference Listed Drug. These Products are topically administered ointments (augmented) containing, as an active pharmaceutical ingredient, betamethasone dipropionate, at the following strength: EQ 0.05% Base.

2. "Betamethasone Valerate Product(s)" means the Products manufactured, in Development, marketed, sold pursuant to each of the following Applications:

    a. NDA No. 018865, ANDA No. 070051, and any ANDA that relies on NDA No. 018865 as the Reference Listed Drug. These Products are topically administered ointments containing, as an active pharmaceutical ingredient, betamethasone valerate, at the following strength: EQ 0.1% Base; and

    b. NDA No. 018861, ANDA No. 070050, and any ANDA that relies on NDA No. 018861 as the Reference Listed Drug. These Products are topically administered creams containing, as an active pharmaceutical ingredient, betamethasone valerate, at the following strength: EQ 0.1% Base.

3. "Clobetasol Product(s)" means the Products manufactured, in Development, marketed, or sold pursuant to each of the following Applications:

    a. NDA No. 021644, ANDA No. 078854 and any ANDA that relies on NDA No. 021644 as the Reference Listed Drug. These Products are topically administered shampoos that contain, as an active pharmaceutical ingredient, clobetasol propionate at the following strength: 0.05%; and

b. ANDA No. 074407, and any ANDA that relies on ANDA No. 074407 as the Reference Listed Drug. These Products are topically administered ointments that contain, as an active pharmaceutical ingredient, clobetasol propionate, at the following strength: 0.05%.

4. "Desonide Product(s)" means the Products manufactured, in Development, marketed, or sold pursuant to each of the following Applications: NDA No. 017010 and any ANDA that relies on NDA No. 017010 as the Reference Listed Drug. These Products are topically administered creams that contain, as an active pharmaceutical ingredient, desonide, at the following strength: 0.05%.

5. "Fluocinolone Product(s)" means the Fluocinolone Products as defined in Non-Public Appendix VI.

6. "Fluorouracil Product(s)" means the Fluorouracil Products as defined in Non-Public Appendix VI.

7. "Probenecid Product(s)" means the Products manufactured, in Development, marketed, or sold pursuant to each of the following Applications:

   a. ANDA No. 084211, and any ANDA that relies on ANDA No. 084211 as the Reference Listed Drug. These Products are orally administered tablets that contain, as an active pharmaceutical ingredient, probenecid, at the following strengths: 500 mg; and

   b. ANDA No. 084279, and any ANDA that relies on ANDA No. 084279 as the Reference Listed Drug. These Products are orally administered tablets that contain, as active pharmaceutical ingredients, colchicine and probenecid, at the following strengths: 0.5 mg colchicine and 500 mg probenecid.

8. "Triamcinolone Product(s)" means the Products manufactured, in Development, marketed, or sold pursuant to each of the following Applications:

   a. ANDA No. 062364 and any ANDA that relies on ANDA No. 062364 as the Reference Listed Drug. These Products are topically administered creams that contain, as active pharmaceutical ingredients, nystatin and triamcinolone acetonide, at the following strengths: 100,000 units/gm nystatin and 0.1% triamcinolone acetonide; and

   b. ANDA No. 063305 and any ANDA that relies on ANDA No. 063305 as the Reference Listed Drug. These Products are topically administered ointments that contain, as active pharmaceutical ingredients, nystatin and triamcinolone acetonide, at the following strengths: 100,000 units/gm nystatin and 0.1% triamcinolone acetonide.

O. “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

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

U. "Categorized Assets" means the following assets and rights of the specified Respondent (as that Respondent is identified in the definition of the Divestiture Product), as such assets and rights are in existence as of the date the specified Respondent signs the Agreement Containing Consent Orders in this matter and to be maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date for each Divestiture Product:

1. all rights to all of the Applications related to the specified Divestiture Product;
2. all rights to all of the Clinical Trials related to the specified Divestiture Product;
3. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
4. all Product Approvals related to the specified Divestiture Product;
5. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
6. all Product Marketing Materials related to the specified Divestiture Product;
7. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
8. all Website(s) related exclusively to the specified Divestiture Product;
9. the content related exclusively to the specified Divestiture Product that is displayed

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 specified 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 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 approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);

11. all Product Development Reports related to the specified Divestiture Product;

12. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;

13. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

14. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date:

a. a list of all customers for the specified Divestiture Product and a listing of

b. for each High Volume Account, a lis

18. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date incl

V. "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.

W. "Cipla" means Cipla Limited, a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of India with its principal executive offices located at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, India 400 013.

X. "Clinical Plan" means a written clinical plan setting forth the protocol for the conduct of a Clinical Trial, preparation and filing of each Regulatory Package related to such Clinical Trial, and the activities to be conducted by each Person that is a party to conducting such Clinical Trial in support of such Clinical Trial, including the timelines for such Clinical Trial.

Y. "Clinical Trial(s)" means a controlled study in humans of the safety, efficacy or bioequivalence of a Product, and includes, without limitation, such clinical trials as are designed to support expd incl.5 -ict, and includes, without 58under.

CC. "Contract Manufacture" means the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer (including, without limitation, for the purposes of Clinical Trials and/or commercial sales);
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.

DD. "Contract Manufacture Product(s)" means the following Divestiture Products, individually and collectively:

1. Alendronate Products;
2. Carbidopa/Levodopa Products;
3. Clozapine Products;
4. Clozapine II Products;
5. Desmopressin Products;
6. Diazepam Products;
7. Disopyramide Products;
8. Estradiol Products;
9. Ethinyl Estradiol/Etonogestrel Vaginal Ring Products;
10. Ezetimibe/Simvastatin Products;
11. Fentanyl Products;
12. Glyburide/Metformin Products;
13. Injectable Epirubicin Products;
14. Injectable Fludarabine Products;
15. Injectable Methotrexate Products;
16. Metoclopramide Products;
17. Modified Release Aspirin/Dipyridamole Product(s)
18. Modified Release Clarithromycin Products;
19. Modified Release Dextroamphetamine Products;
20. Modified Release Metformin/Saxagliptin Products;
21. Modified Release Mirtazapine Products;

22. Modified Release Phentermine/Topiramate Products;

23. Nabumetone Products;

24. Nitrofurantoin Products;

25. Nortriptyline Products;

26. OC Desogestrel/Ethinyl Estradiol Azurette Products;

27. OC Desogestrel/Ethinyl Estradiol Caziant Products;

28. OC Drospirenone/Ethinyl Estradiol Zarah Products;

29. OC Estradiol Valerate/Estradiol Valerate/Dienogest Products;

30. OC Ethinyl Estradiol/Ethynodiol Zovia Products;

31. OC Ethinyl Estradiol/Levonorgestrel Products;

32. OC Ethinyl Estradiol/Levonorgestrel Levora Products;

33. OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Products;

34. OC Ethinyl Estradiol/Norethindrone Microgestin 1.5/30 Products;

35. OC Ethinyl Estradiol/Norethindrone Necon Products;

36. OC Ethinyl Estradiol/Norethindrone Tilia Fe Products;

37. OC Norethindrone Camila Products;

38. OC Norethindrone Errin Products;

39. Propranolol Products;

40. Tamoxifen Products;

41. Trimethoprim Products; and

42. and 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, a Respondent may substitute a Therapeutic Equivalent form of such Product in performance of that Respondent's agreement to Contract Manufacture.

EE. "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.

FF. "Development Two Product Divestiture Agreements" means the "Development Two Product Divestiture Agreements" as defined in Non-Public Appendix IV.

GG. "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 a 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.

HH. "Divestiture Product(s)" means the following, individually and collectively:

1. "Acitretin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 202552, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, acitretin, at the following strengths: 10 mg; 17.5 mg; 22.5 mg; 25 mg.
2. "Alendronate Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 075710, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, alendronate sodium, at the following strengths: EQ 5 mg Base; EQ 10 mg Base; EQ 35 mg Base; EQ 40 mg Base; EQ 70 mg Base.
3. "Benzoyl Peroxide/Clindamycin Product(s)" means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 202440, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered gels and contain, as active pharmaceutical ingredients, benzoyl

a. ANDA No. 078404, and any supplements, amendments, or revisions to this ANDA. These Products are sterile suspensions administered by inhalation using a nebulizer containing as an active pharmaceutical ingredient, budesonide, at the following strengths: 0.25 mg/2ml; 0.5 mg/2ml; and

b. ANDA No. 202558, and any supplements, amendments, or revisions to this ANDA. These Products are sterile suspensions administered by inhalation using a nebulizer containing as an active pharmaceutical ingredient, budesonide, at the following strength: 1.0 mg/2ml.

5. "Buprenorphine/Naloxone Product(s)" the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 022410 (Suboxone) or the Therapeutic Equivalent of Suboxone as the Reference Listed Drug. These Products are films administered either to the buccal area or the sublingual area and contain, as active pharmaceutical ingredients, buprenorphine hydrochloride and naloxone hydrochloride, at the following strengths: EQ 2.0 mg Base buprenorphine hydrochloride and EQ 0.5 mg Base naloxone hydrochloride; EQ 4.0 mg Base buprenorphine hydrochloride and EQ 1.0 mg Base naloxone hydrochloride; EQ 8.0 mg Base buprenorphine hydrochloride and EQ 2 mg Base naloxone hydrochloride; EQ 12.0 mg Base buprenorphine hydrochloride and EQ 3 mg Base naloxone hydrochloride.

6. "Buspirone Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 074253, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, buspirone hydrochloride, at the following strengths: 5 mg; 10 mg; 15 mg.

7. "Carbidopa/Levodopa Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to each of the following Applications:

   a. ANDA No. 073589;

   b. ANDA No. 073607; and

   c. ANDA No. 073618;

   and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as active pharmaceutical ingredients, carbidopa and levodopa, at the following strengths: 10 mg carbidopa and 100 mg levodopa; 25 mg carbidopa and 100 mg levodopa; 25 mg carbidopa and 250 mg levodopa.

a. ANDA No. 071134;

b. ANDA No. 071135; and

c. ANDA No. 071136;

and any supplements, amendments, or revisions to these ANDAs. These Products

at the following strengths: 10 mg ezetimibe and 10 mg simvastatin; 10 mg ezetimibe and 20 mg simvastatin; 10 mg ezetimibe and 40 mg simvastatin; 10 mg ezetimibe and 80 mg simvastatin.

20. "Fentanyl Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 206329, and any supplements, amendments, or revisions to this ANDA. These Products are sublingually or buccally administered tablets containing, as an active pharmaceutical ingredient, fentanyl citrate, at the following strengths: EQ 0.1 mg Base; EQ 0.2 mg Base; EQ 0.4 mg Base; EQ 0.6 mg Base; EQ 0.8 mg Base.

21. "Fluocinonide Emulsified Product(s)" means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 074204, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered creams containing, as an active pharmaceutical ingredient, fluocinonide (emulsified base), at the following strength: 0.05%. The holder of this ANDA is G & W Laboratories.

22. "Fluocinonide Product(s)" means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 073085, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered creams containing, as an active pharmaceutical ingredient, fluocinonide, at the following strength: 0.05%. The holder of this ANDA is G & W Laboratories.

23. "Flutamide Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Ivax) pursuant to the following Application: ANDA No. 075780, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, flutamide, at the following strength: 125 mg.

24. "Glyburide/Metformin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Ivax) pursuant to the following Application: ANDA No. 076345, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, glyburide and metformin hydrochloride, at the following strengths: 1.25 mg glyburide and 250 mg metformin; 2.5 mg glyburide and 500 mg metformin hydrochloride; 5 mg glyburide and 500 mg metformin.

25. "Griseofulvin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Ivax) pursuant to the following Application: ANDA No. 065354, and any supplements, amendments, or

revisions to this ANDA. These Products are orally administered liquid suspensions suspensions containing, as an active pharmaceutical ingredient, griseofulvin (micro size), at the following strength: 125 mg/5ml.

26. "Hydroxyzine Pamoate Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 040156, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, hydroxyzine pamoate, at the following strengths: EQ 25 mg HCL; EQ 50 mg HCL.

27. "Imiquimod Product(s)" means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 206671, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered creams containing, as an active pharmaceutical ingredient, imiquimod, at the following strength: 3.75%. The holder of this ANDA is G & W Laboratories.

28. "Injectable Epirubicin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to each of

30. "Injectable Methotrexate Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 203407, and any supplements, amendments, or revisions to this ANDA. These Products are administered by injection and contain, as an active pharmaceutical ingredient, methotrexate, at the following strength: 50 mg/2 ml; 250 mg/10 ml; 500 mg/20 ml; 1000 mg/40 ml (25 mg/1 ml).

31. "Injectable Paclitaxel Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are administered by intravenous infusion and contain, as an active pharmaceutical ingredient, paclitaxel (lyophilized -for injectable suspension), at the following strength: 100 mg/vial.

32. "Injectable Propofol Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 075102, and any supplements, amendments, or revisions to this ANDA. These Products are administered by injection and contain, as an active pharmaceutical ingredient, propofol, at the following strength: 10 mg/ml.

33. "Levalbuterol Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 077756, and any supplements, amendments, or revisions to this ANDA. These Products are solutions administered by inhalation containing, as an active pharmaceutical ingredient, levalbuterol hydrochloride, at the following strengths: EQ 0.021% Base; EQ 0.042% Base; EQ 0.0103% Base.

34. "Metoclopramide Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to each of the following Applications:

    a. ANDA No. 072750; and

    b. ANDA No. 071250;

    and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, metoclopramide, at the following strength: EQ 5 mg Base; EQ 10 mg Base.

35. “Minocycline Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 063011, and any supplements, amendments, or revisions to this ANDA. These Products

active pharmaceutical ingredient, dexmethylphenidate hydrochloride, at the following strengths: 5 mg; 10 mg; 15 mg; 20 mg; 30 mg. The Modified Release Dexmethylphenidate Products also include the orally administered extended release

44. "Modified Release Mirtazapine Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 076901, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets (orally disintegrating) containing, as an active pharmaceutical ingredient, mirtazapine, at the following strengths: 15 mg; 30 mg; 45 mg.

45. "Modified Release Phentermine/Topiramate Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 022580 (Qsymia) or the Therapeutic Equivalent of Qsymia as the Reference Listed Drug. These Products are orally administered extended release capsules containing, as active pharmaceutical ingredients, phentermine hydrochloride and topiramate, at the following strengths: EQ 3.75 mg phentermine hydrochloride and 23 mg topiramate; EQ 7.5 mg phentermine hydrochloride and 46 mg topiramate; EQ 11.25 mg phentermine hydrochloride and 69 mg topiramate; EQ 15 mg phentermine hydrochloride and 92 mg topiramate.

46. "Nabumetone Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 075189, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, nabumetone, at the following strengths: 500 mg; 750 mg.

47. "Nitrofurantoin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to each of the following Applications:

    a. ANDA No. 073671;

    b. ANDA No. 073652;

    and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, nitrofurantoin macrocrystalline, at the following strengths: 50 mg; 100 mg.

48. "Nortriptyline Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to each of the following Applications:

    a. ANDA No. 073553;

    b. ANDA No. 073554;

    c. ANDA No. 073555; and

    d. ANDA No. 073556;

54. “OC Ethinyl Estradiol/Levonorgestrel Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 206201, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and levonorgestrel, at the following strengths: 0.02 mg ethinyl estradiol and 0.15 mg levonorgestrel; 0.025 mg ethinyl estradiol and 0.15 mg levonorgestrel; 0.03 mg ethinyl estradiol and 0.15 mg levonorgestrel; 0.01 mg ethinyl estradiol (with no levonorgestrel).

55. “OC Ethinyl Estradiol/Levonorgestrel Levora Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 073594, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and levonorgestrel, at the following strength: 0.03 mg ethinyl estradiol and 0.15 mg levonorgestrel.

56. “OC Ethinyl Estradiol/Levonorgestrel Sronyx Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 077681, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and levonorgestrel, at the following strength: 0.02 mg ethinyl estradiol and 0.1 mg levonorgestrel.

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nyl estradiol and 0.1 mg levonorgestrel.

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l estradiovonorgestrelonorgestrel, at the following strength: 0.02 mg

[illegible] (following Applicatio

59. “OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Product(s)” means the following: the Products manufactured, in Dev.6ol/Norethindrone Mi crogestin 1/20 P following: the Products manufactured, in Dev.6ol/Noreth

64. “OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson La

d. ANDA No. 071975; and

e. ANDA No. 071976;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, propranolol hydrochloride, at the following strengths: 10 mg; 20 mg; 40 mg; 60 mg; 80 mg.

70. "Ramelteon Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 091693, and any supplements, amendments, or revisions to this ANDA. These Products ar

75. "Trimipramine Product(s)" means the following: the Products manufactured, in Development, marketed, or sold, pursuant to the following Application: ANDA No. 077361, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, trimipramine maleate, at the following strengths: EQ 25 mg Base; EQ 50 mg Base; EQ 100 mg Base. The holder of this ANDA is Mikah Pharma.

76. "Development Divestiture Product(s)" means each of the Development Divestiture Products as defined in Non-Public Appendix IV.

II. "Divestiture Product Assets" means the following, individually and collectively:

1. "Acitretin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Acitretin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Acitretin Products.

2. "Alendronate Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Alendronate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Alendronate Products.

3. "Benzoyl Peroxide/Clindamycin Product Assets" means all rights, title, and interest in and to all assets related to the Business related to the Benzoyl Peroxide/Clindamycin Products to the extent that such rights are owned, controlled, or held by Teva under the Development, Manufacturing and Commercialization Agreement between Perrigo Netherlands BV and Barr Laboratories, Inc., dated as of September 7, 2007, and all amendments, exhibits, attachments to the Development, Manufacturing and Commercialization Agreement executed prior to the termination of this agreement. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.G.

4. "Budesonide INH Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Budesonide INH Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Budesonide INH Products.

5. "Buprenorphine/Naloxone Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Buprenophine/Naloxone Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Buprenophine/Naloxone Products.

6. "Buspirone Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Buspirone Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Buspirone Products.

14. "Diazepam Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Diazepam Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Diazepam Products.

15. "Disopyramide Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Disopyramide Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Disopyramide Products.

16. "Estazolam Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Estazolam Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Estazolam Products.

17. "Estradiol Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Estradiol Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Estradiol Products.

18. "Ethinyl Estradiol/Etonogestrel Vaginal Ring Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Ethinyl Estradiol/Etonogestrel Vaginal Ring Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Ethinyl Estradiol/Etonogestrel Vaginal Ring Products.

19. "Ezetimibe/Simvastatin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Ezetimibe/Simvastatin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Ezetimibe/Simvastatin Products

20. "Fentanyl Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Fentanyl Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Fentanyl Products; provided, however, "Fentanyl Product Assets" excludes Patents that are owned, controlled or held by Teva on or before the Closing Date related to the Retained Product Fentora®(NDA No. 021947), and such Patents are not included in the Product Licensed Intellectual Property related to the Fentanyl Product(s).

21. "Fluocinonide Emulsified Product Assets" means all rights, title, and interest in and to all assets related to the Business related to the Fluocinonide Emulsified Products to the extent that such rights are owned, controlled, or held by Allergan under the Amended and Restated Supply Agreement by and between Actavis Pharma Inc., Actavis Mid Atlantic LLC, and G&W Laboratories, Inc., dated as of December 19,

2014, as amended February 5, 2015. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.B.

22. "Fluocinonide Product Assets" means all rights, title, and interest in and to all assets

related to each of the Injectable Epirubicin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Injectable Epirubicin Products.

29. "Injectable Fludarabine Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Injectable Fludarabine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Injectable Fludarabine Products.

30. "Injectable Methotrexate Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Methotrexate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Methotrexate Products.

31. "Injectable Paclitaxel Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Injectable Paclitaxel Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Injectable Paclitaxel Products.

32. "Injectable Propofol Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Injectable Propofol Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Injectable Propofol Products.

33. "Levalbuterol Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Levalbuterol Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Levalbuterol Products.

34. "Metoclopramide Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Metoclopramide Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Metoclopramide Products.

35. "Minocycline Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Minocycline Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Minocycline Products.

36. "Modified Release Amphetamine Sulfate Product Assets" means all rights, title and interest in and to all assets related to the Business related to the Amphetamine Sulfate Products to the extent that such rights are owned, controlled, or held by Teva under the Adderall XR Distribution and Supply Agreement by and between Shire LLC and Teva Pharmaceuticals USA, Inc., dated as of November 8, 2013 and all amendments, exhibits, attachments to the Adderall XR Distribution and Supply Agreement executed prior to the termination of this agreement by Teva and its re-execution by an Acquirer. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.J.

37. "Modified Release Aspirin/Dipyridamole Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Modified Release Aspirin/Dipyridamole Product Assets, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Aspirin/Dipyridamole Products.

38. "Modified Release Clarithromycin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Modified Release Clarithromycin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Clarithromycin Products.

39. "Modified Release Dexmethylphenidate Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Modified Release Dexmethylphenidate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Dexmethylphenidate Products.

40. "Modified Release Dextroamphetamine Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Modified Release Dextroamphetamine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Dextroamphetamine Products.

41. "Modified Release Metformin/Saxagliptin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Modified Release Metformin/Saxagliptin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Metformin/Saxagliptin Products.

42. "Modified Release Methylphenidate CAP Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Modified Release Methylphenidate CAP Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Methylphenidate CAP Products.

43. “Modified Release Methylphenidate TAB Product Assets” means all rights, title and interest in and to all assets related to the Business related to the Modified Release Methylphenidate TAB Products to the extent that such rights are owned, controlled, or held by Teva pursuant to the

States of America related to each of the OC Desogestrel/Ethinyl Estradiol Caziant Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Desogestrel/Ethinyl Estradiol Caziant Products, which include all rights to the Caziant® Product Trademark.

51. "OC Drospirenone/Ethinyl Estradiol Zarah Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Drospirenone/Ethinyl Estradiol Zarah Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Drospirenone/Ethinyl Estradiol Zarah Products which include all rights to the Zarah® Product Trademark.

52. "OC Estradiol Valerate/Estradiol Valerate/Dienogest Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the OC Estradiol Valerate/Estradiol Valerate/Dienogest Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Estradiol Valerate/Estradiol Valerate/Dienogest Products.

53. "OC Ethinyl Estradiol/Ethynodiol Zovia Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Ethynodiol Zovia Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Ethynodiol Zovia Products which include all rights to the Zovia® Product Trademark.

54. "OC Ethinyl Estradiol/Levonorgestrel Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Levonorgestrel Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Levonorgestrel Products; ; provided, however, "OC Ethinyl Estradiol/Levonorgestrel Product Assets" excludes Patents that are owned, controlled or held by Teva on or before the Closing Date related to the Retained Product Quartette®(NDA No. 204061), and such Patents are not included in the Product Licensed Intellectual Property related to the OC Ethinyl Estradiol/Levonorgestrel Product(s).

55. "OC Ethinyl Estradiol/Levonorgestrel Levora Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Levonorgestrel Levora Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Levonorgestrel Levora Products which include all rights to the Levora® Product Trademark.

56. “OC Ethinyl Estradiol/Levonorgestrel Sronyx Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Levonorgestrel Sronyx Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Levonorgestrel Sronyx Products which include all rights to the Sronyx® Product Trademark.

57. “OC Ethinyl Estradiol/Levonorgestrel Trivora Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Levonorgestrel Trivora Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Levonorgestrel Trivora Products which include all rights to the Trivora® Product Trademark.

58. “OC Ethinyl Estradiol/Norethindrone Tri-Norinyl Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Norethindrone Tri-Norinyl Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norethindrone Tri-Norinyl Products which include all rights to the Tri-Norinyl® and Leena® Product Trademarks.

59. “OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allerg

62. “OC Ethinyl Estradiol/Norethindrone Tilia Fe Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Norethindrone Tilia Fe Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norethindrone Tilia Fe Products which include all rights to the Tilia® Product Trademark.

63. “OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Products which include all rights to the Low-Ogestrel® Product Trademark.

64. “OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Products which include all rights to the Amethia® Product Trademark.

65. “OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Lo Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Lo Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Lo Products.

66. “OC Levonorgestrel/Ethinyl Estradiol Lutera Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allerg002 uct
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68. "OC Norethindrone Errin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to OC Norethindrone Errin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Norethindrone Errin Products which include all rights to the Errin® Product Trademark.

69. "Propranolol Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Propranolol Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Propranolol Products.

70. "Ramelteon Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Ramelteon Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Ramelteon Products.

71. "Rotigotine Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Rotigotine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Rotigotine Products.

72. "Tamoxifen Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Tamoxifen Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Tamoxifen Products.

73. "Tobramycin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Tobramycin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Tobramycin Products.

74. "Trimethoprim Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Trimethoprim Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Trimethoprim Products.

75. "Trimipramine Product Assets" means all rights, title and interest in and to all assets related to the Business related to the Trimiprami0003 Tw(leie116.275eted toTJ-17.335 -1TJ

76.

OO. "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.

PP. "Dr. Reddy's" means Dr. Reddy's Laboratories S.A., a corporation organized, existing, and doing business under and by virtue of the laws of the Swiss Confederation with its principal executive offices located at Elisabethenanlage 11, 4051 Basel, Switzerland.

QQ. "G & W Laboratories" means G & W Laboratories, a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey with its principal executive offices located at 111 Coolidge Street, South Plainfield, New Jersey 07080-3895.

RR. "Good Clinical Practices" means then-current standards, practices and promulgated or

8. Disopyramide Product Assets;
9. Estazolam Product Assets;
10. Estradiol Product Assets;
11. Fentanyl Product Assets;
12. Fluocinonide Product Assets;
13. Modified Release Clarithromycin Product Assets;
14. Modified Release Dextroamphetamine Product Assets;
15. Modified Release Methylphenidate CAP Product Assets;
16. Nortriptyline Product Assets;
17. OC Desogestrel/Ethinyl Estradiol Azurette Product Assets;
18. OC Desogestrel/Ethinyl Estradiol Caziant Product Assets;
19. OC Drospirenone/Ethinyl Estradiol Zarah Product Assets;
20. OC Estradiol Valerate/Estradiol Valerate/Dienogest Product Assets;
21. OC Ethinyl Estradiol/Ethynodiol Zovia Product Assets;
22. OC Ethinyl Estradiol/Levonorgestrel Product Assets;
23. OC Ethinyl Estradiol/Levonorgestrel Levora Product Assets;
24. OC Ethinyl Estradiol/Levonorgestrel Sronyx Product Assets;
25. OC Ethinyl Estradiol/Levonorgestrel Trivora Product Assets;
26. OC Ethinyl Estradiol/Norethindrone Tri-Norinyl Product Assets;
27. OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Product Assets;
28. OC Ethinyl Estradiol/Norethindrone Microgestin 1.5/30 Product Assets;
29. OC Ethinyl Estradiol/Norethindrone Necon Product Assets;
30. OC Ethinyl Estradiol/Norethindrone Tilia Fe Product Assets;
31. OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Product Assets;
32. OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Product Assets;
33. OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Lo Product Assets;
34. OC Levonorgestrel/Ethinyl Estradiol Lutera Product Assets;
35. OC Norethindrone Camila Product Assets;
36. OC Norethindrone Errin Product Assets;
37. Tamoxifen Product Assets; and
38. Trimethoprim Product Assets.

13. Modified Release Aspirin/Dipyridamole Products;
14. Modified Release Dexmethylphenidate Products;
15. Modified Release Methylphenidate TAB Products;
16. Modified Release Mirtazapine Products;
17. Nabumetone Products;
18. Nitrofurantoin Products; and
19. Propranolol Products.

XX. "Group B Product Assets" means the following Divestiture Product Assets, individually and collectively:

1. Acitretin Product Assets;
2. Alendronate Product Assets;
3. Budesonide INH Product Assets;
4. Buspirone Product Assets;
5. Desmopressin Product Assets;
6. Development One Product Assets;
7. Fluocinonide Emulsified Product Assets;
8. Glyburide/Metformin Product Assets;
9. Hydroxine Pamoate Product Assets;
10. Injectable Epirubicin Product Assets;
11. Levalbuterol Product Assets;
12. Metoclopramide Product Assets;
13. Modified Release Aspirin/Dipyridamole Product Assets;
14. Modified Release Dexmethylphenidate Product Assets;
15. Modified Release Methylphenidate TAB Product Assets;
16. Modified Release Mirtazapine Product Assets;
17. Nabumetone Product Assets;
18. Nitrofurantoin Product Assets; and
19. Propranolol Product Assets.

YY. “Group B Product Divestiture Agreements” means the following:

1. Asset Purchase Agreement between Teva Pharmaceutical Industries Ltd. and Impax

BBB. "Group C Product Divestiture Agreements" means

"G between Teva Pharmaceutical In

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

RRR. "Modified Release Amphetamine Sulfate Product Divestiture Agreements" means the following:

1. Asset Purchase Agreement by and between Teva Pharmaceuticals USA, Inc. and Prasco, LLC and dated as of June 16, 2016; and
2. Termination of Distribution and Supply Agreement by Teva Pharmaceuticals USA, Inc., accepted and agreed to by Shire LLC, dated as of June 16, 2016, that makes reference to the Adderall XR Distribution and Supply Agreement by and between Shire LLC and Teva Pharmaceuticals USA, Inc., dated as of November 8, 2013, (and which is necessary to effect the divestiture to Prasco, LLC).

The Modified Release Amphetamine Sulfate Product Divestiture Agreements are contained in Non-Public Appendix II.J. The Modified Release Amphetamine Sulfate 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.

SSS. "Monitor" means any monitor appointed pursuant to Paragraph V of this Order or Paragraph III of the related Order to Maintain Assets.

TTT. "NDC Number(s)" means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.

UUU. "Orders" means this Decision and Order and the related Order to Maintain Assets.

VVV. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.

WWW. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.

XXX. "Patent(s)" means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in

AAAA. "Pipeline External Manufacture Products" means, the following Divestiture Products, individually and collectively:

1. Budesonide INH Products (ANDA Number 202558);
2. Buprenorphine/Naloxone Products;
3. Cyclosporine Liquid Products;
4. Development Two Products;
5. Injectable Paclitaxel Products;
6. Fluocinonide Products;
7. Imiquimod Products;
8. Modified Release Dexmethylphenidate Products;
9. Ramelteon Products;
10. Rotigotine Products; and
11. Tobramycin Products.

BBBB. "Pipeline Internal Manufacture Products" means, the following Divestiture Products, individually and collectively:

1. Clozapine II Products;
2. Ethinyl Estradiol/Etonogestrel Vaginal Ring Products;
3. Ezetimibe/Simvastatin Products;
4. Fentanyl Products;
5. Injectable Methotrexate Products;
6. Modified Release Aspirin/Dipyridamole Products;
7. Modified Release Metformin/Saxagliptin Products;
8. Modified Release Phentermine/Topiramate Products;
9. OC Ethinyl Estradiol/Levonorgestrel Products; and
10. OC Estradiol Valerate/Estradiol Valerate/Dienogest Products.

CCCC. "Prasco" means Prasco LLC, a corporation organized, existing and doing business under and by virtue of the laws of the State of Ohio with its principal executive offices located at 6125 Commerce Court, Mason, Ohio 45040.

DDDD. "Product(s)" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.

EEEE. “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, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any Application related to that Product.

FFFF. “Product Contracts” means all contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent unless such contract applies generally to a Respondent’s sales of Products to that Third Party;
2. pursuant to which a Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party, for use in connection with the manufacture of the specified Divestiture Product;
3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the specific marketing roduct; had specifs.750.0014 TTt 0 TD.16(t)nufac10.725ive prty;

HHHH. “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.

16. analytical methods development records related to the specified Divestiture Product;
17. manufacturing batch records related to the specified Divestiture Product;
18. stability testing records related to the specified Divestiture Product;
19.

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 "Teva", "Allergan", or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by a Respondent or the related corporate logos thereof; or general registered images or symbols by which Teva or Allergan can be identified or defined.

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

1. all of the following intellectual property related to a Divestiture Product that is owned, licensed, held, or controlled by a Respondent as of the Closing Date, as follows:
    a. Patents that are related to a Divestiture Product that a Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued or withdrawn)

LLLL. “Product Manufacturing Employees” means all salaried employees of a Respondent who have directly participated in any of the following: (i) defining the commercial manufacturing process, (ii) confirming that the manufacturing process is capable of reproducible commercial manufacturing, (iii) formulating the manufacturing process performance qualification protocol, (iv) controlling the manufacturing process to assure performance Product quality, (iv) assuring that during routine manufacturing the process remains in a state of control, (v) collecting and evaluating data for the purposes of providing scientific evidence that the manufacturing process is capable of consistently

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

1. any agreement between a 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, 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 and a Third Party to effect the assignment of assets or rights of that 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 and effective;
3. any agreement between a 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 a Respondent and a Third Party to effect the assignment of assets or rights of that 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.

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

XXXX. "Right of Reference or Use" means the authority to rely upon, and otherwise use all of the following:

1. 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);
2. Product Development Reports; or

3. 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.

YYYY. "Sagent" means Sagent Pharmaceuticals, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 1901 N. Roselle Road, Suite 700, Schaumburg, Illinois 60195.

ZZZZ. "Shire" means Shire PLC, a corporation organized, existing, and doing business under and by virtue of the laws of Jersey (Channel Islands) with its principal executive offices located at 5 Riverwalk, Citywest Business Campus, Dublin 24, Republic of Ireland.

AAAAA. "SKU" means stock keeping unit.

BBBBB. "Supply Cost" means a cost not to exceed any of the following: (i) a Respondent's average direct cost per SKU or NDC Number in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date, or (ii) a Respondent's lowest net price (i.e., the final price per SKU or NDC Number charged by a Respondent net of all discounts, rebates, or promotions) of the relevant Divestiture Product to any of a Respondent's top 5 High Volume Accounts (as measured in units of the Divestiture Product purchased by those customers) for the relevant Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit; provided, however, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) 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, but only if the "Supply Cost" specified in such Remedial Agreement during the first twelve (12) month period of a Respondent supplying the Contract Manufacture Product does not exceed a Respondent's lowest net price (i.e., the final price per SKU or NDC Number charged by a Respondent net of all discounts, rebates, or promotions) of the relevant Divestiture Product to any of a Respondent's top 5 High Volume Accounts (as measured in units of the Divestiture Product purchased by those customers) for the relevant Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date.

CCCCC. "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 a 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. preparing and implementing a detailed technological transfer plan that contains, inter alia, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee;
4.

related to the marketing, distribution, or sale of these Products in the United States of America; and (iii) to use a

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group A Product Assets and grant the Divestiture Product Licenses related to the Group A Products, absolutely and in good faith, to Mayne pursuant to, and in accordance with, the Group A Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Mayne or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group A Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Group A Product Assets to

provided, however, that if Respondents have divested the Group B Product Assets to Impax prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Impax is not an acceptable purchaser of any of the Group B Product Assets, then Respondents shall immediately rescind the transaction with Impax, in whole or in part, as directed by the Commission, and shall divest the relevant Group B Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Group B Product Assets to Impax prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group B Product Assets to Impax (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.

C. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group C Product Assets and grant the Divestiture Product Licenses related to the Group C Products, absolutely and in good faith, to Sagent pursuant to, and in accordance with, the Group C Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Sagent or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group C Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Group C Product Assets to Sagent prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Sagent is not an acceptable purchaser of any of the Group C Product Assets, then Respondents shall immediately rescind the transaction with Sagent, in whole or in part, as directed by the Commission, and shall divest the relevant Group C Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Group C Product Assets to Sagent prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct

Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group C Product Assets to Sagent (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.

D. Not later than ten (10) days after the Acquisition Date,

provided, however, that if Respondents have divested the Group E Product Assets to Zydus prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Zydus is not an acceptable purchaser of any of the Group E Product Assets, then Respondents shall immediately rescind the transaction with Zydus, in whole or in part, as directed by the Commission, and shall divest the relevant Group E Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Group E Product Assets to Zydus prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group E Product Assets to Zydus (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.

F. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group F Product Assets and grant the Divestiture Product Licenses related to the Group F Products, absolutely and in good faith, to Dr. Reddy's pursuant to, and in accordance with, the Group F Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Dr. Reddy's or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group F Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Group F Product Assets to Dr.

may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group F Product Assets to Dr. Reddy's (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.

G. Not later than ten (10) days after the Acquisition Date, Respondent Teva shall divest the Benzoyl Peroxide/Clindamycin Product Assets, absolutely and in good faith, to Perrigo pursuant to, and in accordance with, the Benzoyl Peroxide/Clindamycin Product Divestiture Agreements (which agreements sh

I. Not later than ten (10) days after the Acquisition Date, Respondent Allergan shall divest the Trimipramine Product Assets, absolutely and in good faith, to Mikah Pharma pursuant to, and in accordance with, the Trimipramine Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Mikah Pharma or to reduce any obligations of Respondent Allergan under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Trimipramine Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent Allergan has divested the Trimipramine Product Assets to Mikah Pharma prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Allergan that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Allergan, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Trimipramine Product Assets to Mikah Pharma (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.

J. Not later than ten (10) days after the Acquisition Date, Respondent Teva shall divest the Modified Release Amphetamine Sulfate Product Assets, absolutely and in good faith, to Prasco pursuant to, and in accordance with, the Modified Release Amphetamine Sulfate Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Prasco or to reduce any obligations of Respondent Teva under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Modified Release Amphetamine Sulfate Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent Teva has divested the Modified Release Amphetamine Sulfate Product Assets to Prasco prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Teva that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Teva, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Modified Release Amphetamine Sulfate Product Assets to Prasco (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.

K. Prior to the Closing Date for each respective Divestiture Product, Respondent shall provide each Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by that Acquirer for the purposes of the Acquirer's determination whether to assume such contracts or agreements.

L.

4. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondent Teva's own use or sale;

5. agree to hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner unless (i) Respondent Teva can demonstrate that the failure was beyond the control of Respondent Teva and in no part the result of negligence or willful misconduct by Respondent Teva, and (ii) Respondent Teva is able to cure the supply failure not later than thirty (30) days after the receipt of notice from the relevant Acquirer of a supply failure; provided, however, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondent Teva's aggregate liability for any penalty incurred by an Acquirer from a customer directly related to that Acquirer's inability to supply the Divestiture Product to that customer that was the result of Respondent Teva's failure to supply the Divestiture Product to the Acquirer;

6. 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;

7. for each Contract Manufacturer Product for which Teva purchases the active pharmaceutical ingredient(s), components(s), or excipient(s) from a Third Party, provide that Acquirer with the actual price paid by Respondent Teva for each active pharmaceutical ingredient(s), component(s), and excipient(s), respectively, used to manufacture that Contract Manufacture Product;

8. for each Contract Manufacturer Product for which Teva is the source of the active pharmaceutical ingredient(s), component(s), or excipient(s), not charge the Acquirer any intracompany transfer profit for such active pharmaceutical ingredient(s), component(s) or excipient(s) in calculating the total price for the final finished Contract Manufacture Product to the Acquirer, but such charges shall only reflect Respondent Teva's actual cost;

9. 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);

10. in the event Respondent Teva becomes (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originallerence003 Tc-1uct;

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;

11. 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;

12. not be entitled to terminate any agreement to Contract Manufacture due to an Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency Law;

13. shall notify the Commission at least sixty (60) days prior to terminating any agreement with an Acquirer to Contract Manufacture for any reason, and shall submit at the same time a copy of such notice to the Monitor; and

14. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of Respondent Teva 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, a Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent Teva 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.

The foregoing requirements to Contract Manufacture shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer (or the Manufacturing Designee(s) of that Acquirer) is approved by the FDA to manufacture such Contract Manufacture Product for sale in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Teva; (ii) the date the Acquirer notifies the Commission and Respondent Teva of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or (iv) five (5) years after the Closing Date.

Q. For each Divestiture Product for which Teva is listed in the Application as a qualified source of any of the active pharmaceutical ingredient(s), at the option of the Acquirer of that Divestiture Product, Respondent Teva shall:

1. supply to that Acquirer the active pharmaceutical ingredient(s) for which Teva is

R. For each Acquirer, Respondent Teva shall designate employees of Respondent Teva knowledgeable about the marketing, distribution, warehousing, and sale (including administrative logistics of sales to the respective High Volume Accounts) related to each of the Divestiture Products to assist the Acqui

ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by a Respondent until the Closing Date(s) for the divestiture of the Divestiture Product Assets has occurred, including regularly

e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and

2. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to that Divestiture Product.

W. Respondents shall not, in the United States of America:

1. use any of the Product Trademarks related to Divestiture Products or any mark confusingly similar to the Product Trademarks as a trademark, tradename, or service mark except as may be necessary to sell stocks of Divestiture Products in existence as of the Acquisition Date;

2. attempt to register the Product Trademarks;

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

4. challenge or interfere with an Acquirer's use and registration of the Product Trademarks acquired by that Acquirer; or

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

X. For each Acquirer of a Pipeline External Manufacture Product or Pipeline Internal Manufacture Product that requires a Clinical Trial(s) prior to receiving final FDA approval of the Application related to that Pipeline External Manufacture Product or Pipeline Internal Manufacture Product, as applicable, Respondents shall:

1. designate employees of the Respondents th who will be respon directly with the Acquirer and/or its nx W a and the Interim Monitor (if one has be en appointed), and Respondents, for uurposes of ensuring the continued prosecuti manner;

2. coordinate with the Acquirer to prepare any protocols ne nx Acquirer'rke8pls n Designee(s);

3. assist the Acquirer to prepare and implement any nx

0nW aother event as the Respondent and Agreement related to the Divestiture Produc

4. prepare and implement a detailed transfer plan that contains, inter alia, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such information related to such Clinical Trial(s) to the Acquirer and/or its Clinical Research Organization Designee(s); and

5. provide, in a timely manner, assistance and advice to enable the Acquirer and/or its Clinical Research Organization Designee(s) to commence or continue such Clinical Trial in the same quality, scope, and pace as was planned or being achieved by the specified Respondent (as that Respondent is identified in the definition of the Divestiture Product) and in a manner consistent with Good Clinical Practices.

Y. Respondents 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 a 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 a 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. Respondents shall also covenant to that Acquirer that as a

provided, however, with respect to the Fentanyl Product(s), this provision shall take effect on October 1, 2017;

provided further, however, with respect to the OC Ethinyl Estradiol/Levonorgestrel Product, this provision shall take effect on the later of the following dates: (i) the date of the expiration of the first-to-file exclusivity period for a generic version of Quartette® (NDA No. 204061) as granted by the FDA to the first-to-file ANDA holder(s) of a Therapeutic Equivalent of Quartette, or April 1, 2017.

Z. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to 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.

AA. For any patent infringement suit filed prior to the Closing Date in which a Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that a 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

Supply Agreement and shall execute an agreement to supply the Armodafinil Products within ninety (90) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of

6. hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondent Teva to deliver the Armodafinil Products in a timely manner as required by the Remedial Agreement(s) unless (i) Respondent Teva can demonstrate that the failure was beyond the control of Respondent Teva and in no part the result of negligence or willful misconduct by Respondent Teva, and (ii) Respondent Teva is able to cure the supply failure not later than thirty (30) days after the receipt of notice from the Acquirer of a supply failure; provided, however, that in each instance where: (i) an agreement to supply Armodafinil is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for the Armodafinil Products, that agreement may contain limits on Respondent Teva's aggregate liability for any penalty incurred by an Acquirer from a customer directly related to that Acquirer's inability to supply the Divestiture Product to that customer that was the result of Respondent Teva's failure to supply the Armodafinil Product to the Acquirer.

C. Respondent Teva shall maintain manufacturing facilities necessary to manufacture the Armodafinil Products to the Acquirer of the agreement to supply Armodafinil Products.

D. From the date of the execution of the agreement to supply Armodafinil Products with an Acquirer, Respondents shall not, directly or indirectly (i) enforce or seek to enforce against the FDA or that Acquirer, or (ii) seek to have the FDA enforce against that Acquirer, any rights that Respondents may have to market on an exclusive basis any Product that is the subject of an ANDA that references or is based on Nuvigil (i.e., NDA Number 021875) as the Reference Listed Drug at 200 mg dosage strength of armodafinil. Not later than ten (10) days after the Acquisition Date, Respondent Teva shall provide written notification to the FDA and the Commission that Respondents shall not enforce any such rights against the Acquirer of the agreement to supply the Armodafinil Products.

E. The purpose of requiring Respondent Teva to supply the Armodafinil Products and the related obligations imposed on Respondent Teva by this Order is to remedy the lessening of competition in the sales and marketing of the Armodafinil Products and their Therapeutic Equivalents resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

IV.

IT IS FURTHER ORDERED that:

A. During the three (3) year period immediately following the Order Date, upon the request of any API Customer, Respondent Teva shall, in good faith, offer that API Customer the option to enter into a contract(s) for Respondent Teva to supply the API Product(s) that that API Customer has previously purchased from Respondent Teva under the following terms and conditions:

1. the term of the contract to supply shall be renewable for a period of up to three (3) years after the Order Date;

2.

B. Not later than ten (10) days from the Order Date, Respondent Teva shall notify each of the API Customers of their right to enter into a contract to purchase the API Products with Respondent Teva under the terms described in this Order. Such notifications shall be sent by certified mail with return receipt requested to (i) the employee(s) of the API Customer that have submitted the most recent purchase orders for the API Product to Respondent Teva, and (ii) the Chief Executive Officer and the General Counsel of the API Customer.

C. Not later than ten (10) days after a request by any API Customer to negotiate a contract with Respondent Teva to supply the API Products to that API Customer under the terms described in this Order, Respondent Teva shall notify the Commission of the request.

D. Not later than ten (10) days after the date of the execution of a contract with Respondent Teva to supply the API Products to an API Customer under the terms described in this Order, Respondent Teva shall submit a copy of that contract to the Commission.

E. The obligations in this Paragraph IV shall only apply to the supply of API Products to be used in the manufacture of API Finished Dosage Form Product(s) that will be marketed or sold in the United States of America.

F. The purpose of the provisions of this Order related to the supply of the API Products is to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner and to ensure that none of the API Customers are subjected to an unfair method of competition due to the Acquisition because of their reliance upon Respondent Teva as a source for their API Products.

V.

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 Order to Maintain Assets, and the Remedial Agreements.

B. The Commission shall select the Monitor, subject to the consent of Respondent Teva, which consent shall not be unreasonably withheld. If Respondent Teva 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 Teva of the identity of any proposed Monitor, Respondents 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 Teva 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 each 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, each Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:

1. The Monitor shall have the power and authority to monitor each 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 Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

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

3. The Monitor shall serve until divestiture of all Divestiture Product Assets has been completed, and the transfer and delivery of the related Product Manufacturing Technology has been completed, in a manner that fully satisfies the requirements of this Order, and, with respect to each Divestiture Product that is Contract Manufacture Product, until the earliest of: (i) the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and is able to manufacture the finished dosage form Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Teva; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent Teva of its intention to abandon its efforts to manufacture that Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that the Monitor's service shall not extend more than five (5) years after the Order Date unless the Commission decides

G. Each Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the 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 Monitor.

H. Each Respondent shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by each Acquirer with respect to the performance of a Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by a Respondent of its obligations under the Order; provided, however, beginning ninety (90) days after Respondent Teva has filed its final report pursuant to Paragraph IX.C., and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee 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 Teva.

I. Each Respondent may require the Monitor and each of the 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 Monitor from providing any information to the Commission.

J. The Commission may, among other things, require the Monitor and each of the 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 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.

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VI.

IT IS FURTHER ORDERED that:

A. If the Respondents have not fully complied with the obligations to assign, grant, license, 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, 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, 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 a Respondent to comply with this Order.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, 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, Respondents 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, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers ne0 T.49 -1.17ej Divrig9ief avsJssropo795 -1.16

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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 the Commission believes that the divestiture(s) 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. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by a 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 Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) 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 Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; provided further, however, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the

a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents 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 Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

9. Respondents 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.

G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

VII.

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

provided further, however, that pursuant to this Paragraph VII, a 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.

VIII.

IT IS FURTHER ORDERED that:

A. Any Remedial Agreement shall be deemed incorporated into this Order.

B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.

C. Respondents 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, Respondents 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 Respondent Teva, 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

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by Respondent Teva to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and

2. a detailed description of the timing for the completion of such obligations.

D. 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, Respondents 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. In addition to the foregoing, Respondents shall include in these reports a list containing (i) all of the Retained Products that are the Therapeutic Equivalent of a Divestiture Product and (ii) total sales in units and dollars in the United States of each of these Retained Products by the Respondents for either the one-year period immediately preceding the report or the full calendar or fiscal year that immediately precedes the report.

X.

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

A. any proposed dissolution of a Respondent;

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

C. any other change in a 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.

XI.

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

A. access, during business office hours of that 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 that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and

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

XII.

IT IS FURTHER ORDERED that Respondent Allergan's obligations under this Decision and Order, other than the covenant not to sue an Acquirer under certain Patents contained in Paragraph II.Y of this Order, shall terminate on the date on which all of the following have occurred:

A. Respondent Teva has acquired over fifty percent of the voting securities of each of the Allergan Generic Pharmaceutical Entities;

B. with respect to any Divestiture Product that

XIV.

IT IS FURTHER ORDERED that this Order shall terminate on September 7, 2026.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: September 7, 2016

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