[BRAND-NAME DRUG COMPANY SPECIAL ORDER]

OMB Control No. [insert]
Expires [insert][1]

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

FTC Matter No. P062105

ORDER TO FILE SPECIAL REPORT

Pursuant to a resolution of the Federal Trade Commission dated March 28, 2006, entitled "Resolution Directing The Use Of Compulsory Process," a copy of which is enclosed, Company A, hereinafter referred to as the "Company," is ordered to file a Special Report with the Commission containing the information specified herein. The enclosed Authorized Generic Drug Study Federal Register Notice describes the purpose and scope of the information collection.

Please supply the following information, data, and documents, consistent with the Definitions and Instructions contained in Appendix A:

Part I

1. State the full name of the Company and its official address, and its state of incorporation.

2. State whether the Company is a subsidiary company; whether the Company has subsidiary companies; and report the same information specified in Item 1 regarding each parent or subsidiary engaged in research and development, planning and design, production and manufacturing, distribution, or sales and marketing of any drug product.

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[1] Under the Paperwork Reduction Act, as amended, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

3. Submit one copy of each organization chart and personnel directory in effect on January 1 of each year since January 1, 2001, (a) for the Company as a whole and, (b) for each of the Company's subsidiaries or divisions involved in the AG drug business, if any.

4. For each drug on "List A" provided by the FTC, state whether any orally administered capsule or tablet form of the drug, at any strength, has been marketed in the United States as an AG drug product (either currently or previously), with a launch date after Jan. 1, 2001, under an NDA for which the Company holds rights or held rights at the time of launch or any time thereafter.

5. For each drug on "List B" provided by the FTC, state whether the specified dosage form and strength of the drug has been marketed in the United States as an AG drug product (either currently or previously), with a launch date after Jan. 1, 2001, under an NDA for which the Company holds rights or held rights at the time of launch or any time thereafter.

6. Submit a list of all of the Company's orally administered prescription AG drug products of any capsule or tablet form launched in the United States after Jan. 1, 2001 (either currently or previously marketed under a NDA for which the Company holds or held the rights), including but not limited to the drugs on the lists provided by the FTC, and provide the following information regarding marketing in the United States: (a) proprietary/trade name of the AG, if any; (b) proprietary/trade name of the brand-name drug for which the NDA authorizes the marketing of the AG; (c) active ingredient; (d) dosage form; (e) NDA number of the brand-name drug that authorizes the marketing of the AG (5 digits, no letter); (f) dosage strength; (g) date of approval of the NDA for each strength; (h) the AG's 9-digit National Drug Code (NDC) number for each strength (labeler and product code separated by a hyphen); (i) the date of launch for each NDC number; (j) the date of discontinuance for each NDC number, if any; (k) the name of the firm/business entity associated with each NDC labeler code; (l) the relationship (or former relationship) of each labeler code firm/entity to the Company, e.g., current or former division, subsidiary, affiliate, licensee, contractor; (m) the address and phone number of the firm/business entity associated with each NDC labeler code.

7. For each AG on the list provided by the Company in response to Item 6, state whether the marketing entity is part of the Company, so that the Company will coordinate with the marketing entity in providing complete answers to the requests in Part III, Items 10, 15, 18, 21, 24, 27, 28, and 30 below or whether the marketing entity is not part of the Company, so that the FTC will need to contact the AG marketing entity identified in Item 6(k).

Part II

8. Submit to the FTC by Jan. 31, 2008 a list of any additional AGs launched in the United States by Dec. 31, 2007 and the information requested in Item 6.

9. For changes in the information provided to the FTC in response to Item 6 that occur by Dec. 31, 2007, submit updated information to the FTC by Jan. 31, 2008.

Part III

10. For each AG drug on the list the Company provided to the FTC in response to Item 6, state the date of the first public announcement of the marketing or intended marketing of the AG in the United States.

11. For each AG drug on the list the Company provided to the FTC in response to Item 6, state whether marketing of the AG occurred pursuant to a litigation settlement agreement between the Company and an ANDA-generic company, or whether at any time the Company entered into a litigation settlement agreement not to market the AG or to market it after a specified date more than 30 days after execution of the agreement. If so, state the names of the parties, court, case number, date that the litigation was filed, and the date of the settlement agreement.

12. For each brand-name drug on the list the Company provided to the FTC in response to Item 6(b) (brand-name versions of AGs), provide the following information in regard to marketing in the United States: (a) proprietary/trade name of the brand-name drug; (b) active ingredient; (c) dosage form; (d) NDA number (5 digits, no letter); (e) dosage strength; (f) date of approval of the NDA for each strength; (g) the 9-digit National Drug Code (NDC) number for each strength (labeler and product code separated by a hyphen); (h) the name of the firm/business entity associated with each NDC labeler code; (i) the relationship (or former relationship) of each labeler code firm/entity to the Company, e.g., Company, predecessor company, current or former division, subsidiary, affiliate, licensee, contractor; (j) therapeutic category; (k) pharmacological class; (l) 14-digit GPI (Medi-Span's Generic Product Identifier); (m) date of entry by the first competing ANDA-generic drug; (n) whether the first ANDA-generic entry occurred pursuant to a 180-day exclusivity period, and if so, provide (o) the names of all ANDA-generic companies that entered during such exclusivity.

13. For all strengths of brand-name drugs on "List B" that were not covered in the response to Item 12 (i.e., brand-name drugs for which no AG was marketed), provide the information requested in Item 12.

14. For all strengths of brand-name drugs on "List B" listed in the response to Item 13 (i.e., brand-name drugs for which no AG was marketed), state whether a litigation settlement agreement between the Company and an ANDA-generic company provided that an AG would not be marketed. If so, state the names of the parties, court, case number, date that the litigation was filed, and the date of the settlement agreement.

15. Sales of AG drugs, by NDC. For each AG drug in the list the Company provided to the FTC in response to Item 6, for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the AG's 11-digit NDC number (including labeler, product, and package size codes separated by hyphens); (d) package size; (e) package type; total monthly sales to all customers, net of discounts, rebates, promotions, returns and chargebacks, in (f) units (as represented by the NDC's package size code), and in (g) dollars.

16. Sales of brand-name drugs (AG version marketed), by NDC. For each brand-name drug on the list the Company provided to the FTC in response to Item 12 (brand-name versions of AGs), for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) 11-digit NDC number (including labeler, product, and package size codes separated by hyphens); (d) package size; (e) package type; total monthly sales to all customers, net of discounts, rebates, promotions, returns and chargebacks, in (f) units (as represented by the NDC's package size code), and in (g) dollars.

17. Sales of brand-name drugs (no AG version marketed), by NDC. For all brand-name drugs on "List B" that were not covered in the response to Item 16 (i.e., brand-name drugs listed in response to Item 13, for which no AG was marketed), provide the information requested in Item 16.

18. Total sales/revenues from AG drugs. For each AG drug in the list the Company provided to the FTC in response to Item 6, for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the Company's total monthly sales/revenues attributable to all strengths and package sizes of the dosage form under consideration, net of discounts, rebates, promotions, returns and chargebacks, in dollars; and (e) the total monthly sales in prescriptions.

19. Total sales: brand-name drugs (AG version marketed). For each brand-name drug on the list the Company provided to the FTC in response to Item 12 (brand-name versions of AGs), for sales in the United States from Jan. 1, 2001-March 31,

2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the Company's total monthly sales attributable to all strengths and package sizes of the dosage form of the brand-name drug under consideration, net of discounts, rebates, promotions, returns and chargebacks, in dollars; and (d) the total monthly sales in prescriptions.

20. Total sales: brand-name drugs (no AG marketed). For all brand-name drugs on "List B" that were not covered in the response to Item 19 (i.e., brand-name drugs listed in response to Item 13, for which no AG was marketed), provide the information requested in Item 19.

21. Prices of AG drugs: WAC and AWP. For each AG drug in the list the Company provided to the FTC in response to Item 6, for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the AG's 11-digit NDC number (including labeler, product, and package size codes separated by hyphens); (d) package size; (e) package type; (f) wholesale acquisition cost ("WAC," see 42 U.S.C. § 1395-3a(b)(6)(B)); and (g) the average wholesale price ("AWP").

22. Prices of brand-name drugs (AG version marketed): WAC and AWP. For each brand-name drug on the list the Company provided to the FTC in response to Item 12 (brand-name versions of AGs), for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) 11-digit NDC number (including labeler, product, and package size codes separated by hyphens); (d) package size; (e) package type; (f) WAC; and (g) the AWP.

23. Prices of brand-name drugs (no AG marketed): WAC and AWP. For all brand-name drugs listed in the response to Item 13 that have been subject to ANDA-generic competition (i.e., brand-name drugs for which a date of ANDA-generic entry was entered in Item 13(m)), provide the information requested in Item 22 (for the period from Jan. 1, 2001-March 31, 2007).

24. Prices of AG drugs: AMP. For each AG drug in the list the Company provided to the FTC in response to Item 6, for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable quarter and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the AG's 9-digit NDC number (including labeler and product codes separated by a hyphen); and (d) the average manufacturer price ("AMP") as defined by, and reported to, the Centers for Medicare and Medicaid Services (CMS).

25. Price of brand-name drugs (AG version marketed): AMP. For each brand-name drug on the list the Company provided to the FTC in response to Item 12 (brand-name versions of AGs), for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable quarter and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) 9-digit NDC number (including labeler and product codes separated by a hyphen); and (d) the AMP as defined by, and reported to, the CMS.

26. Prices of brand-name drugs (no AG marketed): AMP. For all brand-name drugs listed in the response to Item 13 that have been subject to ANDA-generic competition (i.e., brand-name drugs for which a date of ANDA-generic entry was entered in Item 13(m)), provide the information requested in Item 25 (for the period from Jan. 1, 2001-March 31, 2007).

27. Submit all documents that were prepared by or for any officer(s) or director(s) of the Company and/or, if applicable, the marketing entity, or that are in the files of any current or prior Company (and/or marketing entity) senior vice president (or equivalent position) with product line responsibility (during all or part of the period from January 1, 2003-April 3, 2006) for an AG and/or a brand-name drug in the list the Company provided to the FTC in response to Item 6 (or, in the case of unincorporated entities, individuals exercising similar functions), as follows. (a) For each AG/brand-name pair identified in the list the Company provided to the FTC in response to Item 6, submit planning, decisional, or strategy documents prepared from Jan. 1, 2002 to April 3, 2006, including studies, surveys, analyses, and reports (both internal and external), that evaluated, considered, or analyzed (but did not merely refer to) the marketing or possible marketing of an AG or AGs (as a response to current or future generic competition or for other reasons), including but not limited to whether or not to license or otherwise market a brand-name drug product as an AG drug product; reasons for marketing an AG and/or refraining from marketing an AG; the timing of AG launch relative to a 180-day exclusivity period; the marketing of an AG during 180-day exclusivity; the marketing of an AG in the context of paragraph IV certifications and settlements of litigation; the marketing of AGs upon expiration of patents or marketing exclusivities claiming a brand-name drug product or its use; and the profitability or other benefits of marketing an AG drug. (b) With respect to AGs in general, submit documents as described in (a) of this Item.

28. For each AG drug identified in the list the Company provided to the FTC in response to Item 6, submit copies of any public announcements, e.g., press release(s) of the planned marketing or launch of the AG in the United States.

29. If the Company licensed or otherwise authorized the marketing by another entity of an AG drug product in the list the Company provided to the FTC in response to Item 6, submit the agreement that authorized marketing (including agreements

between the Company and any business entity acquired after the agreement was executed).

30. Submit planning, decisional, or strategy documents dated Jan. 1, 2006-April 29, 2007 that discuss the effect(s) or possible effect(s) of the enactment of Section 6003 of the Deficit Reduction Act of 2005, P.L. 109-171,[2] on the marketing of AGs after Jan. 1, 2007.

By direction of the Commission.

Deborah Platt Majoras
Chairman

SEAL

Date of Order:

[2] Section 6003 of the Deficit Reduction Act of 2005, P.L. 109-171, which became effective on Jan. 1, 2007, amends Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. § 1396r–8(b)(3)(A)) to include all drugs approved pursuant to 21 U.S.C. § 355(c), including AGs, in Medicaid best price calculations.

APPENDIX A

GENERAL INSTRUCTIONS

A. Organization of Responses and Due Dates of Parts

The Special Report consists of three parts, a Preliminary Report as specified in Part I, which must be filed by [date], or within 30 days of receipt of this Special Order, whichever is later; an Updated Preliminary Report as set forth in Part II, which must be filed by Jan. 31, 2008; and a Detailed Report as set forth in Part III, which must be filed by [date-90 days of receipt].

B. Responses to Questions

The Special Report should be entered into the Excel spreadsheets provided with this Order whenever possible. The FTC has entered the question numbers and the information that must be provided in the header row of each column. To efficiently enter the requested information, companies may wish to electronically "copy and paste" drug identifying or other information that must be entered on more than one row or worksheet. When it is not possible to enter the required answer or information into the applicable worksheet, or no worksheet has been provided, restate the Item and provide the required answer or information. If any question cannot be answered fully, give the information that is available and explain in detail in what respects and why the answer is incomplete.

All responses to Items 1-2 and 4-13 should be submitted to the FTC in both paper and in electronic form (as Excel, Word, or WordPerfect documents) on machine-readable CDs or DVDs.

C. DEFINITIONS

The following definitions apply to all Items:

(1) "Active ingredient" means a drug's nonproprietary established name, including the established names for all active ingredients, as defined at 21 C.F.R. § 299.4 and used in the Orange Book.[3]

(2) "ANDA" means Abbreviated New Drug Application, as set forth in 21 U.S.C. § 355(j).

(3) "ANDA-generic drug" means a drug marketed or sought to be marketed pursuant an approved ANDA and usually sold under the established name of the active ingredient(s).

[3] *See* FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS v, 2-2 (27th ed. 2007) [hereinafter Orange Book].

(4) "Authorized generic ("AG") drug" means any drug sold, licensed or marketed under an NDA approved by the FDA under 21 U.S.C. § 355(c); and marketed, sold or distributed (directly or indirectly) without using the listed drug's brand-name and with a different NDC product number or labeler number (or both).[4]

(5) "Brand-name" drug means an innovator drug product marketed pursuant to an approved NDA under a proprietary, trademark-protected name.

(6) "Capsule" means all dosage forms of capsules as set forth in Appendix C of the Orange Book, including capsule; capsule, delayed release (DR); capsule, delayed release pellets (DRP); and capsule, extended release (XR).

(7) "Company" means Company A, its domestic and foreign parents, predecessors, divisions, subsidiaries, affiliates, partnerships and joint ventures, and all directors, officers, employees, agents and representatives of the foregoing. The terms "subsidiary", "affiliate" and "joint venture" refer to any person in which there is partial (50 percent or more) or total ownership or control between the company and any other person. As used in this definition, the term "person" includes the company and means any natural person, corporate entity, partnership, association, joint venture, government entity, or trust.

(8) "Documents" means all computer files and written, recorded, and graphic materials of every kind in the possession, custody or control of the Company.

(9) "NDA" means a New Drug Application, as set forth in 21 U.S.C. § 355(b) and approved under 21 U.S.C. § 355(c).

(10) "Tablet" means all dosage forms of tablets as set forth in Appendix C of the Orange Book, including tablet; tablet, chewable (C); tablet, coated particles (CP); tablet, delayed release (DR); tablet, delayed release, orally disintegrating (DR OD); tablet, extended release (XR); tablet, orally disintegrating (OD).

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[4] Generally, AGs are marketed under a different product code, labeler code, trade name, trademark, and/or packaging (other than repackaging the listed drug for use in institutions) than the listed drug. *See* Medicaid Program; Prescription Drugs, 71 Fed. Reg. 77,174, 77,183-84, 77,198 (Dec. 22, 2006). Typically, the name of an AG is the nonproprietary established name of its active ingredients, but in some cases a trade name different from the brand-name of the listed drug is used. Also, AGs are usually marketed by a subsidiary or division of the brand-name manufacturer or a third party in a manner equivalent to the marketing practices of holders of an approved ANDA for a drug. *See* Letter from William K. Hubbard, FDA, to Stuart A. Williams, Mylan Pharmaceuticals, Inc., and James N. Czaban, Heller Ehrman White & McAuliffe 2 n.2 (July 2, 2004) (responding to the citizen petitions of Mylan and Teva regarding AG drugs and 180-day exclusivity).

D. Data Submissions

Unless modified by agreement in writing with the staff of the Federal Trade Commission, all numerical data submitted in response to Items 15-26 must be submitted in a spreadsheet format both on paper and on machine-readable CDs or DVDs. The Commission will accept database and spreadsheet data in the following formats: MS Excel, MS Access, tab-delimited or fixed width text files. All financial information required to be submitted by this Order should be in whole dollar amounts. For Items 15-26, the applicable month (quarter) and year requested refers to each month and year for which the Company provides the information called for by the given Item. If the information is not kept in the form requested, the Company is encouraged to contact the Commission representative to discuss alternative formats in which the information may be provided.

To identify the drug for which data is being provided, for those Items requesting data on AGs (Items 15, 18, 21, and 24) state on the applicable row or page the (b)(1) proprietary/trade name of the AG, if any; (b)(2) proprietary/trade name of the brand-name drug; (b)(3) active ingredient; (b)(4) dosage form; (b)(5) NDA number (5 digits, no letter); and the (b)(6) dosage strength (except for Item 18). For Items requesting data on brand-name drugs (Items 16-17, 19-20, 22-23, and 25-26), state the previously listed identifying information (b)(1)-(6), omitting (6) for Items 19 and 20.

E. Document Submissions

This Special Order covers documents in the Company's possession, custody or control, wherever the documents are located. However, unless or until the Commission notifies Company otherwise in writing, the Commission will not seek to enforce the Special Order to compel the production of documents that were located outside the United States at the time Company received the Special Order. In order to expedite the receipt of documents reflecting the views of all recipients of Special Orders, the Commission requests your cooperation in producing any such documents on a voluntary basis by the date specified in this Special Order.

Provide two paper copies of each document. All documentary responses should be Bates-stamped.

F. Responsibilities of Company and AG-Marketing Entity Officials

1. Companies that market AGs via entities that are part of the Company as defined in definition (7) are required to coordinate with those marketing entities in the submission of certain information on AGs in Part III, as described in the instructions to individual Items. If the marketing entity identified in Item 6(k) is not part of the Company, the FTC will also contact the marketing entity, and require it to submit certain information on the AGs it markets. The Company's response to Item 7 merely notifies the FTC, on a drug-by-drug, entity-by-entity basis, whether the Company will contact the marketing entity and

coordinate with it, because it is part of the Company or whether the FTC will contact the marketing entity, because the marketing entity is not part of the Company. For most Items, however, the Company and any independent marketing entity (which the FTC will contact separately) will be required to respond. The Company's response to Item 7 does NOT eliminate the Company's requirement to respond to each Item, unless expressly stated in the instructions for an Item.

2. The Special Report is required to be subscribed and sworn to by an official of the Company who has prepared or supervised the preparation of the Special Report from books, records, documents, correspondence, and other data and material in the Company's possession. In addition, if the Company indicates in response to Item 7 that it will coordinate with its AG marketing entity, then Items 10, 15, 18, 21, 24, 27-28, and 30 must be subscribed and sworn to by an official of the subsidiary, or other entity of the Company that markets AGs. Each subscriber to the Special Report is to give his or her full name, title, and contact information in a notarized certification at the end of the Special Report, as set forth in Appendix B.

G. Questions

Any questions you have relating to the scope or meaning of this Order, or suggestions for possible modifications thereto, should be directed to Karen A. Goldman, Federal Trade Commission, Office of General Counsel, 600 Pennsylvania Ave., N.W., Washington, DC 20580, (202) 326-2574, kgoldman@ftc.gov.

H. Submission of Report

The Special Report must be Bates-stamped.

You are advised that penalties may be imposed under applicable provisions of federal law for failure to file Special Reports or for filing false reports.

Two copies of the Special Report shall be filed with the Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Ave., NW, Washington, DC 20580 by 5:00 PM on the dates specified herein.

INSTRUCTIONS FOR SPECIFIC ITEMS

Part I

1-3. Self-explanatory.

4. To facilitate the Company's response, the FTC has provided two lists of drugs marketed by the Company in the United States during the relevant time frame. "List A" is a list of drugs for which the available information indicates that an AG was launched by the Company, or with its authorization, after Jan. 1, 2001 (a blank list will be provided if the FTC is not aware of any AGs). Using the Excel spreadsheet containing List A, confirm that at least one orally administered capsule or tablet form of each drug has been marketed as an AG by entering "yes" in the applicable column. If the Company believes that no orally administered capsule or tablet form of the drug has been marketed as an AG, enter "no."

5. "List B" is a list of the Company's orally administered capsule and tablet dosage forms of drugs for which at least one ANDA with a paragraph IV certification was filed and generic competition began after Jan. 1, 2001, or for which generic competition has not yet begun and at least one ANDA with a paragraph IV certification was filed after Jan. 1, 2001. The list contains only those strengths for which a paragraph IV certification has been made. Some of the drugs on List B may also appear on List A. Using the Excel spreadsheet containing List B, enter "yes" if a particular strength of a drug has been marketed as an AG in the United States, or "no" if it has not.

6. The Company's response to this Item must include all orally administered AGs of any capsule or tablet dosage form launched in the United States after Jan. 1, 2001, for which the Company holds rights to the NDA under which the AG is marketed, or held rights to the NDA when the AG was launched or any time thereafter, regardless of whether the AG is currently marketed by the Company. The response must address, but is not limited to, the drugs on the lists provided by the FTC. Thus, the Company's response must include all orally administered capsule or tablet dosage forms of its AGs, regardless of whether the drug was on either List A or List B, or whether the corresponding brand-name drug was subject only to paragraph I, II, or III certifications.

   Enter the list of the Company's AG drugs and the required information for each on the spreadsheet provided by the FTC. Enter the specific dosage form, e.g., capsule DR, capsule XR, tablet DR, or tablet XR. Enter each strength for each dosage form on a different row. If more than one entity marketed a particular drug, use different rows to enter the information for each entity.

   Item 6(h), (k), (m). The response to Item 6(h) should include all 9-digit NDC numbers used in the direct or indirect marketing, sale, or distribution of the AG in the United States, whether by the Company or by other entities, e.g., licensees under the Company's NDA. Thus, Item 6(k) should provide a complete list of entities that market the AG, whether the marketing entity is part of the Company or independent of it. Do not, however, include NDC numbers that cover repackaged or relabeled drug products (such as those for use in institutions) that were previously sold under one of the aforementioned NDCs. If the NDCs associated with the AG have changed, e.g., due to marketing by

different business entities, provide all NDC numbers that have been used. If there are multiple NDC numbers for a given strength, each should be entered on a different row.

The address and phone number of the firm/business entity that markets the AG (requested in Item 6(m)) need only be entered the first time that the name of the entity is provided in response to Item 6(k).

7. If an AG is marketed via an entity that is part of the Company as defined in definition (7), the Company must enter "yes" on the applicable spreadsheet column, and it is required to coordinate with the marketing entity in the submission of information on that AG. If an AG is marketed by an entity that is not a part of the Company, such as a contractor or licensee, the Company must enter "no," and the marketing entity will be contacted by the FTC and asked to provide certain information. A Company's response of "no" to Item 7 does NOT eliminate the Company's requirement to respond to each Item below, unless expressly stated in the instructions for an Item.

Because some manufacturers of brand-name pharmaceuticals also manufacture ANDA-generic drugs, the FTC reserves the right to request additional information from the Company, and directly from marketing entities that are part of the Company, even if the Company has responded to this request or provided a coordinated response to an Item.

Part II

8. This Item requests the basic information in Item 6 on any AGs launched in the United States by Dec. 31, 2007 pursuant to a NDA for which the Company holds rights, that were not included in the Company's initial response to that Item. For the purposes of this study, the FTC will not require any information beyond that requested in Item 6 for these AGs.

9. This Item requests updated information on AGs identified by the Company in its initial response to Item 6, including but not limited to, whether the marketing of the AG has been discontinued or otherwise changed (e.g., dosage form or strength, marketing entity).

Part III

10. On the applicable spreadsheet and column, enter the date of the first public announcement by any entity, including but not limited to announcements made by the Company, of the intended marketing of each AG. Documentation of the first announcement is requested in Item 28.

11. On the applicable spreadsheet and column, enter "yes" if the marketing of the AG occurred pursuant to a settlement agreement, or if the Company entered into a settlement agreement not to market the AG or to market it after a specified date more than 30 days

after execution of the agreement; enter "no" if there were no such agreements. If "yes," restate Item 11 on a separate document, identify the AG, and provide the required information about the litigation.

12. For identification and informational purposes, Item 12(a)-(f) repeats information provided in Item 6(b)-(g). Each strength should be listed in a separate row, followed by the rest of the requested information. If there are multiple NDC numbers for a given strength, each should be entered in a different row.

Item 12(j), (k). State the therapeutic category and pharmacological class as set forth in the U.S. Pharmacopeial Convention, Inc., U.S.P. Medicare Model Guidelines, Version 2, Feb. 6, 2006.[5]

Item 12(l). When entering the 14-digit GPI, separate the two-digit fields with dashes.

Items 12(m), (n), (o). If the brand-name drug has not been subject to ANDA-generic competition, enter "none" in response to Item 12(m), and do not respond to Items 12(n) and (o).

13. Enter the required information for each brand-name drug on "List B" that was not covered in the response to Item 12 on the spreadsheet provided by the FTC. Enter the specific dosage form, e.g., capsule DR, capsule XR, tablet DR, or tablet XR. Enter each strength, and each 9-digit NDC number related to a particular strength, in a different row. If the NDCs associated with the drug have changed, provide all NDC numbers that have been used. With respect to therapeutic category and pharmacological class, follow the instructions in Item 12. If the brand-name drug has not been subject to ANDA-generic competition, enter "none" in response to Item 13(m), and do not respond to Items 13(n) and (o).

14. On the applicable spreadsheet and column, enter "yes" if a litigation settlement agreement between the Company and an ANDA-generic company provided that an AG would not be marketed, and if not, enter "no." If "yes," restate Item 14 on a separate document, identify the drug, and provide the required information about the litigation.

15. Item 15 requests monthly net sales data for AGs for all 11-digit NDCs arising from the 9-digit NDCs provided in response to Item 6(h), i.e., including all package size codes for those NDCs.

If the Company answered "yes" to Item 7 with respect to a particular drug, the Company must coordinate with its marketing entity in providing the information requested in Item 15. If the Company is not coordinating with its marketing entity with respect to a

[5] *See* http://www.usp.org/pdf/EN/mmg/modelGuidelinesV2.0-2006-02-06.pdf . *See also* Drug List Table, at http://www.usp.org/pdf/EN/mmg/drugListingV2.0-2006-02-06.pdf .

particular drug, i.e., it answered "no" in response to Item 7 for that drug, the Company should only submit data for Items 15(a)-(f). In such cases, the FTC will ask the marketing entity to provide the information requested in Items 15(g).

16. Include sales for each strength provided in response to Item 12(e). Thus, the response to Item 16 should include sales for all 11-digit NDC codes arising from the 9-digit codes provided in response to Item 12(g).

17. Include sales for all 11-digit NDC codes arising from the 9-digit codes provided in response to Item 13.

18. Responses to this Item represent the Company's combined sales or revenues from all strengths and NDC numbers.

    If the Company answered "yes" to Item 7 with respect to a particular drug, the Company must coordinate with its marketing entity and provide the net sales for the Company (including the marketing entity) with respect to that drug. However, the Company must respond to Item 18 even if the Company answered "no" to Item 7 and is not coordinating with the marketing entity. In such cases, the Company should provide its revenues (including royalties, license fees, and transfer payments) arising from sales in the United States, not the sales of the independent marketing entity. In calculating its net revenues, the Company should include its own discounts, rebates, promotions, returns and chargebacks (if any), not those of the independent marketing entity.

19, 20. Responses to these Items represent the Company's combined sales from all strengths and NDC numbers.

21. The referenced 11-digit NDCs should have been listed in response to Item 15(c).

22. The referenced 11-digit NDCs should have been listed in response to Item 16(c).

23. The 11-digit NDCs should be a subset of those listed in response to Item 17. Provide data for the entire requested period, regardless of whether the drug was subject to ANDA-generic competition for the entire time.

24. Item 24 requests the quarterly Average Manufacturer Price ("AMP," *see* 42 U.S.C. § 1396r-8(k)(1)), for each AG listed by the Company in response to Item 6, for all 9-digit NDCs provided in response to Item 6(h).

    If the Company answered "yes" to Item 7 with respect to a particular drug, the Company must coordinate with its marketing entity in providing the information requested in Item 24. If the Company is not coordinating with its marketing entity with respect to a particular drug, i.e., it answered "no" in response to Item 7 for that drug, the Company

should not respond to this Item. In such cases, the FTC will ask the independent marketing entity to provide the AMP.

25. The Company must provide the information requested in Item 25, regardless of its response to Item 7 and whether it is coordinating with the marketing entity.

26. The 11-digit NDCs should be those listed in response to Item 23. Provide data for the entire requested period, regardless of whether the drug was subject to ANDA-generic competition for the entire time.

27. When responding to Item 27(b), do not duplicate documents provided in response to Item 27(a).

If the Company answered "yes" to Item 7 with respect to a particular drug, the Company must coordinate with its marketing entity in responding to Item 27(a) with respect to that drug. In responding to Item 27(b) in regard to documents generally about AG drugs, the Company must coordinate with its marketing entity if it answered "yes" to Item 7 with respect to any drug. However, the Company must respond to Items 27(a) and 27(b) even if it answered "no" in response to Item 7 and is not coordinating with the marketing entity. In such cases, the marketing entity will be asked to respond to Items 27(a) and 27(b), in addition to the Company.

Group the documents by drug product, and if applicable, segregate the documents obtained from the Company from the documents obtained from the marketing entity. For each document, indicate the name of the person from whose files the document came and whether the document was generated within the Company or externally; if generated externally, provide the name of the source of the document.

28. If the Company answered "yes" to Item 7 with respect to a particular drug, the Company must coordinate with its marketing entity in responding to this Item with respect to that drug. Group the documents by drug product.

29. The Company must respond to Item 29 with respect to all AGs for which the Company answered "no" in response to Item 7, and is not coordinating with the marketing entity. Group the documents by drug product, and indicate the name of the person from whose files the document came.

If an agreement authorizing the marketing of an AG was previously submitted to the FTC pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[6] do not provide another copy of the agreement. Provide the names of the parties, the date of the agreement, and the date that the agreement was submitted to the FTC.

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[6] *See* P.L. 108-173, tit. XI, Subtit. B, § 1112, 117 Stat. 2066, 2461-2 (2003).

30. The Company must respond to this Item, and if the Company answered "yes" to Item 7 with respect to any drug, the Company must coordinate with its marketing entity in responding to this Item. For each document, indicate the name of the person from whose files the document came.

APPENDIX B

Certification

This Special Report, together with any and all appendices and attachments thereto, was prepared and assembled under my supervision in accordance with instructions issued by the Federal Trade Commission in its Special Orders for the Authorized Generic Drug Study. Subject to the recognition that, where so indicated, reasonable estimates have been made because books and records do not provide the required information, the information is, to the best of my knowledge, true, correct, and complete. Where copies rather than original documents have been submitted, the copies are true, correct, and complete.

_____

TYPE OR PRINT NAME AND TITLE

_____

TYPE OR PRINT COMPANY NAME AND ADDRESS

_____

TYPE OR PRINT PHONE NUMBER AND E-MAIL ADDRESS

_____

(Signature)

Subscribed and sworn to before me at the City of _____,

State of _____, *this* _____*day*

of _____, *20*____.

_____

(Notary Public)

My Commission Expires: _____