[GENERIC 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:

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.

3. Submit one copy of each organization chart and personnel directory in effect on

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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.

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 AG drug on the list of AG drugs provided by the FTC, state the (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) 14-digit GPI (Medi-Span's Generic Product Identifier); (h) the AG's 9-digit National Drug Code (NDC) number for each strength (labeler and product code separated by a hyphen); (i) name of the firm/business entity associated with each NDC labeler code; (j) date of launch for each NDC number; (k) date of discontinuance for each NDC number, if any; (l) date of the first public announcement of the marketing or intended marketing of the AG; and (m) whether at any time the Company marketed the drug as an ANDA-generic drug.

5. Submit a list of the Company's orally administered prescription AG drug products of any capsule or tablet form that were launched after Jan. 1, 2001, but are not on the FTC's list of AG drugs (if any), and provide the information requested in Item 4.

6. For each AG drug addressed in Items 4 and 5, state whether marketing of the AG occurred pursuant to a litigation settlement agreement between the Company and a brand-name company. If so, state the names of the parties, court, case number, date that the litigation was filed, and the date of the settlement agreement.

7. For each drug on the list of ANDA-generic drugs provided by the FTC and any ANDA-generic drugs identified in response to Item 4(m), state the (a) brand-name of the reference listed drug (RLD); (b) NDA number of the RLD; (c) active ingredient; (d) dosage form; (e) ANDA number (5 digits, no letter); (f) dosage strength; (g) the ANDA-generic's 9-digit National Drug Code (NDC) number for each strength (labeler and product code separated by a hyphen); (h) name of the firm/business entity associated with each NDC labeler code; (i) date of launch for each NDC number; (j) date of discontinuance for each NDC number, if any; (k) whether entry of the Company's ANDA-generic drug product occurred pursuant to a 180-day exclusivity period; and if entry occurred pursuant to 180-day exclusivity, the (l) date the exclusivity period began, the (m) date of expiration of the exclusivity period, and the (n) names of any other ANDA-generic companies that entered during the exclusivity period.

8. For each ANDA-generic drug addressed in Item 7, state the (a) active ingredient; (b) dosage form; (c) ANDA number (5 digits, no letter); (d) dosage strength; (e)

date of ANDA filing; (f) date of ANDA approval for each dosage strength; (g) 14-digit GPI (Medi-Span's Generic Product Identifier); (h) patent numbers of patents for which the Company made a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii); (i) paragraph number of the certification for each patent number; (j) date of each patent certification; (k) paragraph number of any amended patent certifications; and the (l) date of amendment of the patent certification.

9. Sales of AG drugs, by NDC. For each AG drug addressed in Items 4 and 5, 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 11-digit NDC number (including labeler, product, and package size codes separated by hyphens); (d) package size; (e) package type; total 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.

10. Sales and costs of ANDA-generic drugs, by NDC. For each ANDA-generic drug addressed in Item 7, for sales in the United States from Jan. 1, 2001-March 31, 2007, provide the information requested in Item 9, and (h) the cost to manufacture, including all direct and indirect labor, material, and overhead expenses. If the Company does not manufacture a drug, provide the cost of purchasing it in response to (h), and indicate that the stated amount is the cost of purchase.

11. Total sales of AG drugs. For each AG drug addressed in Items 4 and 5, for sales in the United States for the period 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 sales attributable to all strengths and package sizes of the dosage form under consideration, net of discounts, rebates, promotions, returns and chargebacks, in dollars; and (d) the total sales in prescriptions.

12. Total sales of ANDA-generic drugs. For each ANDA-generic drug addressed in Item 7, for sales in the United States from Jan. 1, 2001-March 31, 2007, provide the information requested in Item 11.

13. Prices of AG drugs: WAC and AWP. For each AG drug addressed in Items 4 and 5, 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 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").

14. Prices of ANDA-generic drugs: WAC and AWP. For each drug on the list of ANDA-generic drugs addressed in Item 7, for sales in the United States from Jan. 1, 2001-March 31, 2007, provide the information requested in Item 13.

15. Prices of AG drugs: AMP. For each AG drug addressed in Items 4 and 5, for the period 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 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).

16. Prices of ANDA-generic drugs: AMP. For each ANDA-generic drug addressed in Item 7, for the period from Jan. 1, 2001-March 31, 2007, provide the information requested in Item 15.

17. Cost data and documents. For each ANDA-generic drug addressed in Item 7, state the (a) active ingredient; (b) dosage form; (c) ANDA number (5 digits, no letter); (d) research and development costs; (e) the costs of filing the ANDA; (f) the costs for patent-related litigation (if any). Also, submit (g) any documents sufficient to show the identified product's research and development costs, costs to file the ANDA, patent-related litigation costs (if any), and any other sunk costs allocated to the drug. In those cases in which the Company is not the sole defendant, describe how litigation expenses have been distributed among the defendants.

18. Submit documents that were prepared from Jan. 1, 2003 to April 3, 2006, by or for any officer(s) or director(s) of the Company, or that are in the files of any current or prior Company (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 any specific ANDA-generic drug (or, in the case of unincorporated entities, individuals exercising similar functions) (a) that considered, evaluated, analyzed, or discussed AGs or the possibility of AGs with regard to whether to file an ANDA and/or make a paragraph III or IV certification with respect to any specific drug (regardless of whether the Company filed such ANDA); (b) that considered, evaluated, analyzed or discussed the impact that entry by an AG drug had or would have on the profitability (during 180-day exclusivity or otherwise) of any specific ANDA-generic drug product marketed by the Company, or for which submission of an ANDA was under consideration; or (c) that comprise planning, decisional, or

strategy documents that discuss AGs but not in regard to a particular drug, including documents that discuss AGs in regard to filing ANDAs, making paragraph III or IV certifications, and/or the possible impact of AGs on the profitability of ANDA-generic drugs during 180-day exclusivity or otherwise.

19. For the AG drugs addressed in Items 4 and 5: Submit planning, decisional, or strategy documents, including studies, surveys, analyses, and reports (both internal and external), that were prepared from Jan. 1, 2003 to April 3, 2006, by or for any officer(s) or director(s) of the Company, or that are in the files of any current or prior Company (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 the specified AG drug (or, in the case of unincorporated entities, individuals exercising similar functions), that evaluated, considered, or analyzed the marketing or possible marketing of the AG*;* the timing of AG launch relative to any anticipated 180-day exclusivity period; the effect or potential effect of the AG on ANDA-generic competition; the marketing of the AG in the context of settlements of patent-related litigation; the profitability or other benefits of marketing the AG; and/or whether to market an ANDA-generic drug or an AG.

20. For the AG drugs addressed in Items 4 and 5: (a) If the Company and the brand-name company entered into an agreement that licensed or otherwise authorized the marketing of the identified drug product as an AG, submit the agreement. (b) Submit copies of any public announcements, e.g., press release(s), of the planned marketing or launch of each AG.

By direction of the Commission.

Deborah Platt Majoras
Chairman

SEAL

Date of Order:

APPENDIX A

GENERAL INSTRUCTIONS

A. Organization of Responses and Due Dates of Parts

The Company's Special Report 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 4-8 should be submitted to the FTC in both paper and 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.[2]

(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 to an approved ANDA and usually sold under the established name of the active ingredient(s).

(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

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

(directly or indirectly) without using the listed drug's brand-name and with a different NDC product number or labeler number (or both).[3]

(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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[3] 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 9-17 must be submitted in a spreadsheet format both on paper and on machine-readable CDs. 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 9-16, 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 9, 11, 13, and 15) 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 for which the NDA authorizes the marketing of the AG; (b)(3) active ingredient; (b)(4) dosage form; (b)(5) NDA number (5 digits, no letter) of the brand-name drug that authorizes the marketing of the AG; and the (b)(6) dosage strength (except for Item 11). For Items requesting data on ANDA-generic drugs (Items 10, 12, 14, and 16) state on the applicable row or page the (b)(1) active ingredient; (b)(2) dosage form; (b)(3) ANDA number (5 digits, no letter); and the (b)(4) dosage strength (except for Item 12).

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. Group the documents by drug product. 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. All documentary responses should be Bates-stamped.

F. Responsibilities of Company

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. 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

1-3. Self-explanatory.

4. The FTC has provided two lists of drugs marketed by the Company during the relevant time frame that must be addressed in the Company's Special Report. The first is a list of AG drugs that were first launched in the United States after Jan. 1, 2001 (a blank list will be provided if the FTC is not aware of any AGs)**.** Using the Excel spreadsheet containing this list, enter the information requested in Item 4 with regard to marketing in the United States. 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. When entering the 14-digit GPI, separate the two-digit fields with dashes.

   The response to Item 4(h) should include all of the Company's 9-digit NDC numbers used in the marketing, sale, or distribution of the AG in the United States. Do not 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, 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.

5. Add to the Excel spreadsheet containing the FTC's list of AGs any other AGs that fit the specified criteria but were not on FTC's list. Follow the instructions for Item 4 for entering the requested information on these AGs.

6. On the applicable spreadsheet and column, enter "yes"if the marketing of the AG occurred pursuant to a settlement agreement, "no" if it did not. If "yes," restate Item 6 in a separate document, identify the AG, and provide the required information about the litigation.

7. The second list provided by the FTC is a list of ANDA-generic drugs marketed by the Company (i) for which at least one ANDA with a paragraph IV certification was filed by any company and the first ANDA-generic launch in the United States by any company was after Jan. 1, 2001; and (ii) for which an AG version of the applicable brand-name drug was first launched in the United States by another company after Jan. 1, 2001. Using the Excel spreadsheet containing this list, enter the information requested in Item 7 with regard to in the United States. Add any ANDA-generic drugs identified in response to Item 4(m) to the FTC's list (if they are not already on the list), and enter the information requested in Item 7. 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; enter all strengths marketed by the Company, even if the Company is aware that no AG was marketed for a particular strength.

   The response to Item 7(g) should include all of the Company's 9-digit NDC numbers used in the marketing, sale, or distribution of the ANDA-generic drug in the United States. Do not 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 ANDA-generic drug have changed, 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.

8. Enter each patent number in a separate column, followed by columns with the information requested with respect to each patent. When entering the 14-digit GPI, separate the two-digit fields with dashes.

9. Item 9 requests monthly net sales data for AGs for all 11-digit NDCs arising from the 9-digit NDCs provided in response to Item 4(h) and Item 5, i.e., including all package size codes for those NDCs.

10. Item 10 requests monthly net sales and cost data for all 11-digit NDCs arising from the 9-digit NDCs provided in response to Item 7(g).

11, 12. Responses to Items 11 and 12 represent combined sales from all strengths and NDC numbers.

13, 14. Items 13 and 14 request monthly WAC and AWP for all 11-digit NDCs arising from the 9-digit NDCs provided in response to Items 4(h), 5, and Item 7(g), respectively.

15, 16. Items 15 and 16 request the quarterly AMP (*see* 42 U.S.C. § 1396r-8(k)(1)), for all 9-digit NDCs provided in response to Items 4(h), 5, and Item 7(g), respectively.

17. Self-explanatory.

18. The documents requested by this Item are not limited to those that consider drugs marketed or previously marketed by the Company, nor are they limited to those that discuss drugs identified in the lists provided by the FTC. For example, responsive documents might consider drugs for which the Company filed an ANDA that has not yet been approved; drugs for which the Company considered making a paragraph IV certification, but the ANDA that was filed did not contain a paragraph IV certification; or drugs for which the Company considered filing an ANDA, but ultimately did not.

    Do not duplicate documents when responding to Items 18(a), (b), and (c).

19. Do not duplicate documents submitted in response to Item 18.

20. For press releases, the source of the document need not be provided.

    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,[4] 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.

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

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.

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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: _____