

**IN THE IOWA DISTRICT COURT FOR POLK COUNTY**

**STATE OF IOWA,** )  
)  
**Plaintiff,** )  
)  
**vs.** )  
**GLAXOSMITHKLINE LLC and SB PHARMCO** )  
**PUERTO RICO, INC.,** )  
  
**Defendants.** )

**FILED**  
**POLK COUNTY, IA**  
**11 JUN 23 PM 2:13**  
**WELM DISTRICT COURT**  
**NO. CE 68819**

**FINAL CONSENT JUDGMENT**

Plaintiff, State of Iowa has filed a Petition for a permanent injunction and other relief in this matter pursuant to Iowa Code section 714.16 (Act) alleging that Defendants GLAXOSMITHKLINE LLC (hereinafter “GlaxoSmithKline”) and SB PHARMCO PUERTO RICO, INC. (hereinafter “SB Pharmco”) committed violations of the aforementioned Act. Plaintiff, by its counsel, and GlaxoSmithKline and SB Pharmco, by their counsel, have agreed to the entry of this Final Consent Judgment (“Consent Judgment”) by the Court without trial or adjudication of any issue of fact or law, and without admission of wrongdoing or liability of any kind.

**I. DEFINITIONS**

The following definitions shall be used in construing this Consent Judgment:

- A. “GlaxoSmithKline LLC” or “GlaxoSmithKline” shall mean GlaxoSmithKline LLC, all of its past and present officers, directors, shareholders, employees, subsidiaries, divisions, predecessors, and successors.
- B. “SB Pharmco Puerto Rico, Inc.” or “SB Pharmco” shall mean SB Pharmco Puerto Rico, Inc., all of its past and present officers, directors, shareholders, employees, subsidiaries, divisions, and predecessors.
- C. “Covered Conduct” shall mean Defendants’ production, manufacturing, processing, packing, holding, distribution, and sale of Covered Products manufactured at SB Pharmco’s production facility at Cidra, Puerto Rico.
- D. “Covered Products” shall mean those products, set forth in Exhibit A.
- E. “Effective Date” shall mean the date on which a copy of this Consent Judgment, duly executed by Defendants and by the signatory Attorney General, is approved by, and becomes a Judgment, of the Court.
- F. “Multistate Working Group” shall mean the Attorneys General and their staff representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Hawaii<sup>1</sup>, Idaho, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nebraska, Nevada, New Jersey, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin.

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<sup>1</sup> Hawaii is being represented on this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General’s Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii. For simplicity, the entire group will be referred to as the “Attorneys General,” and such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection.

- G. “Multistate Executive Committee” shall mean the Attorneys General and their staff representing Arizona, Florida, Illinois, Maryland, Oregon, Pennsylvania, Tennessee, and Texas.
- H. “Defendants” shall mean GlaxoSmithKline LLC and SB Pharmco Puerto Rico, Inc.
- I. “Parties” shall mean the Iowa Attorney General and Defendants.
- J. “Attorneys General” shall mean the Attorneys General of the Multistate Working Group.

## II. PREAMBLE

A. The Attorneys General conducted an investigation regarding the Covered Conduct. The Parties have agreed to resolve the concerns related to the Covered Conduct under the State Consumer Protection Laws<sup>2</sup>, as cited in footnote 2, by entering into this Consent Judgment.

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<sup>2</sup> ALABAMA- Deceptive Trade Practices Act, AL ST 8-19-1, 13A-9-42, 8-19-8; ALASKA -*Alaska Unfair Trade Practices and Consumer Protection Act*, AS 45.50.471 *et seq.*; ARIZONA - *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; ARKANSAS – Deceptive Trade Practices Act, Ark. Code Ann. §4-88-101, *et seq.*; CALIFORNIA - Bus. & Prof Code §§ 17200 *et seq.* and 17500 *et seq.*; COLORADO- *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 *et seq.*; CONNECTICUT - *Connecticut Unfair Trade Practices Act*, Conn. Gen. Stat. §§ 42-110a *et seq.*; DELAWARE - *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, *District of Columbia Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*; FLORIDA - *Florida Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.201 *et seq.*; HAWAII - *Uniform Deceptive Trade Practice Act*, Haw. Rev. Stat. Chpt. 481A and Haw. 501.201 *et seq.*; IDAHO - Consumer Protection Act, Idaho Code Section 48-601 *et seq.*; ILLINOIS - *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq.*; IOWA - *Iowa Consumer Fraud Act*, Iowa Code Section 714.16; KANSAS - *Kansas Consumer Protection Act*, K.S.A. 50-623 *et seq.*; KENTUCKY- *The Kentucky Consumer Protection Act*, KRS 367.110 *et seq.*; MAINE - *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MARYLAND - *Maryland Consumer Protection Act*, Md. Code Ann., Com. Law §§ 13-101 *et seq.*; MASSACHUSETTS - Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN - *Michigan Consumer Protection Act*, MCL § 445.901 *et seq.*; MISSOURI - *Missouri Merchandising Practices Act*, Mo. Rev. Stat. §§ 407 *et seq.*; MONTANA– *Montana Unfair Trade Practices and Consumer Protection Act*, Mont. Code Ann. § 30-14-101 *et seq.*; NEBRASKA - *Uniform Deceptive Trade Practices Act*, NRS §§ 87-301 *et seq.*; NEVADA - *Deceptive Trade Practices Act*, Nevada Revised Statutes 598.0903 *et seq.*; NEW JERSEY - *New Jersey Consumer Fraud Act*, NJSA 56:8-1 *et seq.*; NORTH CAROLINA - North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1.1, *et seq.*; NORTH DAKOTA - *Unlawful Sales or Advertising Practices*, N.D. Cent. Code § 51-15-02 *et seq.*; OHIO - *Ohio Consumer Sales Practices Act*, R.C. 1345.01, *et seq.*; OREGON - Oregon Unlawful Trade Practices Act, ORS 646.605 *et seq.*; PENNSYLVANIA - Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. 201-1 *et seq.*; RHODE ISLAND -*Rhode Island Deceptive Trade Practices Act*, Rhode Island General Laws § 6-13.1-1, *et seq.*; SOUTH DAKOTA - *South Dakota Deceptive Trade Practices and Consumer Protection*, SDCL ch. 37-24; TENNESSEE - Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101 *et seq.*; TEXAS - *Texas Deceptive Trade Practices-Consumer Protection Act*, TEX. BUS. & COM. CODE § 17.41, *et seq.*; VERMONT -

B. This Consent Judgment reflects a negotiated agreement entered into by the Parties as their own free and voluntary act, and with full knowledge and understanding of the nature of the proceedings and the obligations and duties imposed by this Consent Judgment. Defendants are entering into this Consent Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Defendants expressly deny. Through this Consent Judgment, Defendants do not admit any violation of law, and do not admit any wrongdoing that was or could have been alleged by any of the signatory Attorneys General before the date of the Consent Judgment. No part of this Consent Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Defendants. This Consent Judgment does not constitute an admission by Defendants that the Covered Conduct violated or could violate the State Consumer Protection Laws. It is the intent of the Parties that this Consent Judgment shall not be admissible or binding in any other matter, including, but not limited to, any investigation or litigation, other than in connection with the enforcement of this Consent Judgment. No part of this Consent Judgment shall create a private cause of action or convert any right to any third party for violation of any federal or state statute or law, except that an Attorney General may file an action to enforce the terms of this Consent Judgment. Nothing contained herein prevents or prohibits the use of this Consent Judgment for purposes of enforcement by the Iowa Attorney General.

C. This Consent Judgment does not create a waiver or limit Defendants' legal rights, remedies, or defenses in any other action by the Iowa Attorney General, and does not waive or

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Consumer Fraud Act, 9 V.S.A. §§ 2451 *et seq.*; WASHINGTON - *Unfair Business Practices/Consumer Protection Act*, RCW §§ 19.86 *et seq.*; WEST VIRGINIA - *West Virginia Consumer Credit and Protection Act*, W.Va. Code § 46A-1101 *et seq.*; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations).

limit Defendants' right to defend themselves from, or make arguments in, any other matter, claim, or suit, including, but not limited to, any investigation or litigation relating to the existence, subject matter, or terms of this Consent Judgment. Nothing in this Consent Judgment shall waive, release, or otherwise affect any claims, defenses, or other positions Defendants may assert in connection with any investigations, claims, or other matters the Attorneys General are not releasing hereunder. Notwithstanding the foregoing, the Iowa Attorney General may file an action to enforce the terms of this Consent Judgment.

D. This Consent Judgment does not constitute an approval by the Attorneys General of Defendants' business practices, and Defendants shall make no representation or claim to the contrary.

E. This Consent Judgment sets forth the entire agreement between the Parties hereto and supersedes all prior agreements or understandings, whether written or oral, between the Parties and/or their respective counsel, with respect to the Covered Conduct.

F. This Court retains jurisdiction of this Consent Judgment and the Parties hereto for the purpose of enforcing and modifying this Consent Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

G. This Consent Judgment may be executed in counterparts, each of which shall be deemed to constitute an original counterpart hereof, and all of which shall together constitute one and the same Consent Judgment. One or more counterparts of this Consent Judgment may be delivered by facsimile or electronic transmission with the intent that it, or they, shall constitute an original counterpart hereof.

H. This Consent Judgment relates solely to the Covered Conduct.

### **III. COMPLIANCE PROVISIONS**

- A. Defendants shall not, as a result of the manner in which the Covered Products are manufactured, make any written or oral claim for the Covered Products that is false, misleading, or deceptive.
- B. Defendants shall not, as a result of the manner in which the Covered Products are manufactured, represent that the Covered Products have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have.
- C. Defendants shall not, as a result of the manner in which the Covered Products are manufactured, cause likelihood of confusion or of misunderstanding as to the Covered Products' source, sponsorship, approval, or certification.

**IV. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES**

- A. Within 30 days of the Effective Date of this Consent Judgment, Defendants shall pay \$40.75 million to be divided and paid by Defendants directly to each Attorney General of the Multistate Working Group in an amount designated by and in the sole discretion of the Multistate Executive Committee.<sup>3</sup> Said payment shall be used by the Attorneys General for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, consumer education or litigation or local consumer aid or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted by state law, at the sole discretion of each Attorney General. The Parties acknowledge that the payment described herein is not a fine or penalty, or payment in lieu thereof.

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<sup>3</sup> The State of Iowa's share is \$716,570.

V. **REPRESENTATIONS AND WARRANTIES**

A. GlaxoSmithKline acknowledges that it is a proper party to this Consent Judgment. GlaxoSmithKline further warrants and represents that the individual signing this Consent Judgment on behalf of GlaxoSmithKline is doing so in his or her official capacity and is fully authorized by GlaxoSmithKline to enter into this Consent Judgment and to legally bind GlaxoSmithKline to all of the terms and conditions of the Consent Judgment.

B. SB Pharmco acknowledges that it is a proper party to this Consent Judgment. SB Pharmco further warrants and represents that the individual signing this Consent Judgment on behalf of SB Pharmco is doing so in his or her official capacity and is fully authorized by SB Pharmco to enter into this Consent Judgment and to legally bind SB Pharmco to all of the terms and conditions of the Consent Judgment.

C. The Attorney General warrants and represents that he is signing this Consent Judgment in his or her official capacity, and that he is fully authorized by his State to enter into this Judgment, including, but not limited to, the authority to grant the release contained in Section VI of this Consent Judgment, and to legally bind his State to all of the terms and conditions of this Consent Judgment.

VI. **RELEASE**

A. By execution of this Consent Judgment, the State of Iowa releases and forever discharges Defendants and all of their past and present officers, directors, shareholders, employees, subsidiaries, divisions, parents, predecessors, successors, assigns, and transferees (collectively, the "Released Parties"), from the following: all civil claims, causes of action, parens patriae claims, damages, restitution, fines, costs, attorneys' fees, remedies and/or penalties that were or

could have been asserted against the Released Parties by the Attorney General under Iowa Code section 714.16 or any amendments thereto, or by common law claims concerning unfair, deceptive, or fraudulent trade practices resulting from the Covered Conduct, up to and including the Effective Date of this Consent Judgment (collectively, the “Released Claims”).

B. Notwithstanding any term of this Consent Judgment, specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties, are any and all of the following:

1. Any claims related to the marketing or promotion of rosiglitazone that do not relate to the manner in which the product was manufactured at the Cidra, Puerto Rico facility.
2. Any criminal liability that any person or entity, including Released Parties, has or may have to the State of Iowa;
3. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Iowa, under any statute, regulation, or rule not expressly covered by the release in Section VI.A. including, but not limited to, any and all of the following claims:
  - a. State or federal antitrust violations;
  - b. Medicaid violations, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to Iowa’s Medicaid program;
  - c. Claims involving “best price,” “average wholesale price,” or “wholesale acquisition cost;”



- d. State false claims violations; and
  - e. Claims to enforce the terms and conditions of this Consent Judgment.
- 4. Actions of state program payors of the State of Iowa arising from the Covered Conduct, except for the release of civil penalties under the state consumer protection laws cited in footnote 2.
  - 5. Any claims individual consumers have or may have under the State of Iowa's consumer protection laws against any person or entity, including Released Parties.

## **VII. CONFLICTS**

A. If, subsequent to the Effective Date of this Consent Judgment, the federal government or any state, or any federal or state agency, enacts or promulgates legislation or regulations with respect to matters governed by this Consent Judgment that creates a conflict with any provision of the Consent Judgment and Defendants intend to comply with the newly enacted legislation or regulation, Defendants shall notify the Attorneys General (or the Attorney General of the affected State) of the same. If the Attorney General agrees, he shall consent to a modification of such provision of the Consent Judgment to the extent necessary to eliminate such conflict. If the Attorney General disagrees and the Parties are not able to resolve the disagreement, Defendants shall seek a modification from an appropriate court of any provision of this Consent Judgment that presents a conflict with any such federal or state law or regulation. Changes in federal or state laws or regulations, with respect to the matters governed by this Consent Judgment, shall not be deemed to create a conflict with a provision of this Consent Judgment unless Defendants cannot reasonably comply with both such law or regulation and the applicable provision of this Consent Judgment.

## VIII. DISPUTE RESOLUTION

- A. For the purposes of resolving disputes with respect to compliance with this Consent Judgment, should any of the signatory Attorneys General believe that one or both Defendants have violated a provision of this Consent Judgment subsequent to the Effective Date, then such Attorney General shall notify that Defendant or those Defendants in writing of the specific objection, identify with particularity the provisions of this Consent Judgment that the practice appears to violate, and give Defendants 30 days to respond to the notification.
- B. Upon receipt of written notice from any of the Attorneys General, each Defendant receiving such notice shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why that Defendant believes it is in compliance with the Consent Judgment or a detailed explanation of how the alleged violation occurred and statement explaining how and when that Defendant intends to remedy the alleged violation.
- C. Except as set forth in Sections VIII.E and F below, the Attorney General may not take any action during the 30 day response period. Nothing shall prevent the Attorney General from agreeing in writing to provide Defendant with additional time beyond the 30 days to respond to the notice.
- D. The Attorney General may not take any action during which a modification request is pending before a court pursuant to Section VII.A, except as provided for in Sections VIII.E and F below.
- E. Nothing in this Consent Judgment shall be interpreted to limit the State's Civil Investigative Demand ("CID") or investigative subpoena authority.

F. The Attorney General may assert any claim that one or both Defendants have violated this Consent Judgment in a separate civil action to enforce compliance with this Consent Judgment, or may seek any other relief afforded by law, but only after providing Defendant or Defendants an opportunity to respond to the notification as described above; provided, however, that the Attorney General may take any action if the Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

#### **IX. COMPLIANCE WITH ALL LAWS**

A. Except as expressly provided in this Consent Judgment, nothing in this Consent Judgment shall be construed as:

1. Relieving Defendants of their obligation to comply with all applicable state laws, regulations, or rules, or granting permission to engage in any acts or practices prohibited by any law, regulation, or rule; or
2. Limiting or expanding in any way any right any state represented by the Multistate Working Group may otherwise have to enforce applicable state law or obtain information, documents, or testimony from Defendants pursuant to any applicable state law, regulation, or rule, or any right Defendants may otherwise have to oppose any subpoena, civil investigative demand, motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to any such state law, regulation, or rule.

#### **X. GENERAL PROVISIONS**

A. Nothing in this Consent Judgment is intended to modify the Settlement Agreement, effective December 15, 2010, between the State of Iowa and GlaxoSmithKline, LLC formerly

B. Nothing will prevent the Attorney General from agreeing in writing to provide Defendants with additional time to perform any act required by the Consent Judgment. The Attorney General shall not unreasonably withhold his consent to the request for additional time.

C. All notices under this Consent Judgment shall be sent by overnight United States mail.

The documents shall be sent to the following addresses:

For GlaxoSmithKline LLC: and SB Pharmco Puerto Rico, Inc.:

Matthew J. O'Connor  
Covington & Burling LLP  
1201 Pennsylvania Avenue, NW  
Washington, DC 20004-2401

Barry H. Boise  
Pepper Hamilton LLP  
3000 Two Logan Square  
Eighteenth and Arch Streets  
Philadelphia, PA 19103

For State of Iowa:

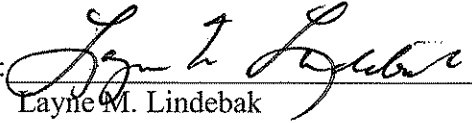
Layne M. Lindebak  
Assistant Attorney General  
Iowa Department of Justice  
Hoover Building—Second Floor  
1305 East Walnut Street  
Des Moines, IA 50319

IT IS SO ORDERED, this 23<sup>rd</sup> day of June, 2011

  
\_\_\_\_\_  
JUDGE, Fifth Judicial District

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FOR THE STATE OF IOWA

By: 

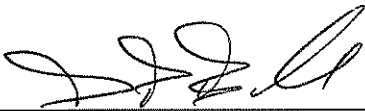
Date: 6-23-2011

Layne M. Lindebak  
Assistant Attorney General  
Iowa Department of Justice  
Hoover Office Building--Second Floor  
1305 East Walnut Street  
Des Moines, IA 50319  
Telephone: 515 281-7054  
Facsimile: 515 281-4902  
Email: Layne.Lindebak@iowa.gov

FOR GLAXOSMITHKLINE LLC

By: *S. Mark Werner* Date: *6.17.11*  
S. Mark Werner  
Senior Vice President  
GlaxoSmithKline LLC

FOR SB PHARMCO PUERTO RICO, INC.

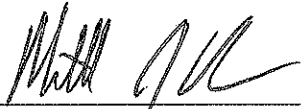
By:  \_\_\_\_\_

Desmond P. Burke  
Trustee  
SB Pharmco Puerto Rico, Inc.

Date: June 16<sup>th</sup> 2011



FOR DEFENDANTS GLAXOSMITHKLINE LLC & SB PHARMCO PUERTO RICO, INC.

By:  \_\_\_\_\_

Date: 6/20/11 \_\_\_\_\_

Geoffrey E. Hobart  
Matthew J. O'Connor  
Covington & Burling LLP  
1201 Pennsylvania Avenue, NW  
Washington, DC 20004-2401

FOR DEFENDANTS GLAXOSMITHKLINE LLC & SB PHARMCO PUERTO RICO, INC.

By: Barry H. Boise

Date: 6/15/11

Nina M. Gussack  
Barry H. Boise  
Pepper Hamilton LLP  
3000 Two Logan Square  
Eighteenth and Arch Streets  
Philadelphia, PA 19103

Approved as to form:

By:     *Kerrie M. Murphy*     Date:     6/16/11    

Kerrie M. Murphy AT0005576

GONZALEZ SAGGIO & HARLAN LLP

1501 42<sup>nd</sup> Street, Suite 465

West Des Moines, IA 50266-1090

Telephone: (515) 453-8509

Facsimile: (515) 267-1408

E-mail: kerrie\_murphy@gshllp.com

*Attorney for GlaxoSmithKline LLC and SB Pharmco Puerto Rico, Inc.*

Exhibit A - Product Produced at Cidra, Puerto Rico facility 2001 - 2009

PRODUCT NAME
Abreva <sup>®</sup> (Docosanol) Cream 10 %
Albenza <sup>®</sup> (albendazole, USP)
Avandamet <sup>®</sup> (Roglitazone maleate/Metformin HCL)
Avandia <sup>®</sup> (Rosiglitazone Maleate)
Bactroban <sup>®</sup> (Mupirocin) Ointment
Bactroban Cream <sup>®</sup> (Mupirocin Calcium)
Tagamet <sup>®</sup> / Cimetidine USP / Tagamet <sup>®</sup> HB
Compazine <sup>®</sup>
Coreg <sup>®</sup> (carvedilol)
Denavir Cream <sup>®</sup> (Penciclovir) <sup>1</sup>
Dibenzylidene <sup>®2</sup>
Dyazide <sup>®</sup>
Dyrenium <sup>®2</sup>
Ecotrin <sup>®</sup> Aqueous Film Coated
Factive <sup>®</sup> (gemifloxacin mesylate) <sup>3</sup>
Kytril <sup>®</sup> (Granisetron HCl) <sup>4</sup>
Paxil <sup>®</sup> (Paroxetine HCl) <sup>5</sup>
Paxil <sup>®</sup> Oral Suspension (Paroxetine HCL)
Paxil CR <sup>®</sup> (Paroxetine HCL)
Relafen <sup>®</sup> (Nabumetone)
Stelazine <sup>®</sup>
Thorazine <sup>®</sup>

<sup>1</sup> Divested as part of GlaxoSmithkline merger but manufactured at Cidra, until transferred to new owner (Novartis).

<sup>2</sup> Divested product: manufactured at Cidra, until transferred to new owner (Wellspring).

<sup>3</sup> Product manufactured under contract agreements with LG Life Sciences LTD (sold to Genesoft in 2002 before approved by the FDA in 2003).

<sup>4</sup> Divested as part of GlaxoSmithkline merger but manufactured at Cidra, until transferred to new owner (Roche).

<sup>5</sup> Generic version of product manufactured at Cidra but distributed by PAR Pharmaceutical.